



Oncology Pipeline Monitor 2026

Pilot Approach of Using IHSI Data to Inform
Hospital Decision-Makers in Austria on
Emerging Medicinal Products

Appendix

Main Report

Appendix

AIHTA Project Report No.: 186

Vienna, October 2026

List of records constituting the Oncology Pipeline

377 records sorted alphabetically by active substance. Drug class (incl. subcategory)- own categorisation. Valid as of 08.07.2026.

Active Substance (Compound)	Drug Class (incl. sub-category)	Expected Indication (EI)	Phase of Development	Expected EC Approval	IHSI Record ID
abexinostat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Abexinostat in combination with pazopanib for first line or later treatment of locally advanced or metastatic unresectable clear cell Renal cell carcinoma in adults and elderly	Phase 3	01-04-2028	973871
acalabrutinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Acalabrutinib in combination with R-CHOP for first line treatment of stage ii to iv non-germinal center Diffuse large B-cell lymphoma in adults and elderly	Phase 3	01-12-2027	1088183
acalabrutinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Acalabrutinib in combination with venetoclax for first line treatment of Chronic lymphocytic leukaemia, Small cell lymphocytic lymphoma in adults and elderly	Phase 3	01-05-2028	1134643
actinium ac 225 dotatate	Radiopharmaceuticals	Actinium ac 225 dotatate monotherapy for second line treatment of advanced, inoperable, somatostatin receptor expressing (SSTR+), well-differentiated Gastroenteropancreatic neuroendocrine tumour disease in adults and elderly that have progressed following prior treatment with 177Lu-labelled somatostatin analogue therapy	Phase 3	01-04-2028	1160037
adagrasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Adagrasib in combination with cetuximab for second line treatment of advanced or metastatic KRAS G12C-mutated Colorectal cancer in adults who have received prior treatment with fluoropyrimidine- and oxaliplatin- or irinotecan-based chemotherapy	Phase 3	01-03-2027	985919
afamitresgene autoleucel	Cell & Gene Therapies	Afamitresgene autoleucel monotherapy for second line treatment of metastatic or inoperable HLA-A*02-positive, MAGE-A4-positive Synovial sarcoma in adolescents over 16 years of age, adults and elderly who previously received either an anthracycline or ifosfamide containing regimen	Phase 2	01-10-2027	1207484
afamitresgene autoleucel	Cell & Gene Therapies	Afamitresgene autoleucel monotherapy for second line treatment of advanced HLA-A*02 positive, MAGE-A4 positive neuroblastoma, osteosarcoma, malignant peripheral nerve sheath tumour or Synovial sarcoma in children, adolescents and adults up to 21 years of age	Phase 1/2	01-02-2028	1210461
aglatimagene besadenovec	Cell & Gene Therapies	Aglatimagene besadenovec in combination with valacyclovir, radiation therapy and optional androgen deprivation therapy for adjuvant treatment of intermediate-high risk localised Prostate cancer in adults and elderly	Phase 3	01-12-2027	1150603
alpelisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Alpelisib in combination with fulvestrant for second line or later treatment of advanced HR-positive, HER2-negative with PIK3CA mutation, Breast cancer in adults and elderly who progressed or relapsed on or after treatment with an Arotamse Inhibitor and a CDK4/6 inhibitor	Under CHMP evaluation	01-09-2026	1051950
amivantamab	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Amivantamab in combination with FOLFIRI for second line treatment of recurrent, unresectable or metastatic KRAS/NRAS and BRAF wild-type Colorectal cancer in adults and elderly	Phase 3	01-10-2028	1236864
amivantamab/hyaluronidase	Other Monoclonal Antibodies	Amivantamab/hyaluronidase in combination with pembrolizumab or paclitaxel or pembrolizumab and carboplatin or as monotherapy for second line or later treatment of recurrent/metastatic Squamous cell carcinoma of head and neck in adults and elderly after platinum-based chemotherapy and a PD-1 or PD-L1 inhibitor	Phase 1/2	01-03-2027	1260229
anitocabtagene autoleucel	Cell & Gene Therapies	Anitocabtagene autoleucel monotherapy for fourth line or later treatment of relapsed or refractory Multiple myeloma in adults and elderly who have received prior lines of therapy, including an immunomodulatory drug and an anti-CD38 monoclonal antibody	Phase 2	01-08-2027	1200983
anzutresgene autoleucel	Cell & Gene Therapies	Anzutresgene autoleucel in combination with adjuvant low dose interleukin (IL)-2 for second line or later treatment of unresectable or metastatic HLA-A*02:01-positive cutaneous Melanoma in adults and elderly with disease progression on or after at least one PD-1 inhibitor	Phase 3	01-04-2028	1219409
apalutamide	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Apalutamide in combination with androgen deprivation therapy for first line treatment of high-risk, localised or locally advanced Prostate cancer in adults and elderly who are candidates for radical prostatectomy	Phase 3	01-04-2027	1006421
apalutamide	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Apalutamide in combination with gonadotropin releasing hormone agonist for first line treatment of high-risk, localised or locally advanced Prostate cancer in adults and elderly receiving primary radiation therapy	Phase 3	01-04-2027	1008039
apalutamide	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Apalutamide in combination with intermittent androgen deprivation therapy for first line treatment of metastatic hormone-sensitive Prostate cancer in male adults and elderly including degenerated and transgender	Phase 3	01-08-2027	1217450
arlocabtagene autoleucel	Cell & Gene Therapies	Arlocabtagene autoleucel monotherapy for fourth line or later treatment of relapsed or refractory Multiple myeloma in adults and elderly who have received a proteasome inhibitor, an immunomodulatory imide, and an anti-CD38 monoclonal antibody	Phase 2	01-10-2027	1241404
arsenic trioxide	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Arsenic trioxide monotherapy for consolidation treatment of newly diagnosed, non-high risk, acute promyelocytic Leukaemia in adolescents, adults and elderly	Phase 3	01-10-2028	1035276
arsenic trioxide	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Arsenic trioxide in combination with all-trans-retinoic acid for consolidation treatment of newly diagnosed, low- or intermediate-risk Acute promyelocytic leukaemia in adults and elderly	Phase 3	01-07-2028	1160576
ateganosine	Other	Ateganosine in combination with cemiplimab for third line treatment of advanced/metastatic stage 3b or 4 Non-small cell lung cancer in adults, older adults and elderly who have progressed after two prior lines of systemic treatment including an ICI (anti-PD-1/PD-L1) and platinum-based chemotherapy	Phase 3	01-11-2028	1211716
atezolizumab	Immune Checkpoint Inhibitors	Atezolizumab monotherapy for adjuvant treatment of high-risk ctDNA-positive, muscle-invasive Bladder cancer in adults and elderly following cystectomy	Phase 3	01-02-2027	1173998
atezolizumab	Immune Checkpoint Inhibitors	Atezolizumab in combination with lenvatinib for second line treatment of locally advanced or metastatic and/or unresectable Hepatocellular carcinoma in adults and elderly who have progressed on prior systemic treatment with atezolizumab plus bevacizumab	Phase 3	01-04-2027	1218497
atezolizumab	Immune Checkpoint Inhibitors	Atezolizumab in combination with sorafenib for second line treatment of locally advanced or metastatic and/or unresectable Hepatocellular carcinoma in adults and elderly who have progressed on prior systemic treatment with atezolizumab plus bevacizumab	Phase 3	01-04-2027	1219411

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axicabtagene ciloleucel	Cell & Gene Therapies	Axicabtagene ciloleucel in combination with cyclophosphamide, fludarabine and dexamethasone for second line or later treatment of relapsed or refractory large B-cell lymphoma in adults and elderly in the outpatient setting	Phase 2	01-02-2027	1153459
azacitidine/cedazuridine	Small-Molecule Targeted Therapies (Epigenetic modulators)	Azacitidine/cedazuridine monotherapy for first line or later treatment of myeloid Neoplasm in adults and elderly	Phase 2/3	01-07-2028	1178679
azd0120	Cell & Gene Therapies	Azd0120 monotherapy for fourth line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly who have previously received a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 antibody	Phase 1/2	01-12-2028	1218254
azenosertib	Immune Checkpoint Inhibitors	Azenosertib monotherapy for second line or later treatment of platinum-resistant, high-grade serous, Cyclin E1 positive Fallopian tube cancer, Ovarian cancer, Primary peritoneal carcinosarcoma in adults and elderly	Phase 2	01-10-2027	984428
azercabtagene zapreleucel	Cell & Gene Therapies	Azercabtagene zapreleucel monotherapy for second line treatment of relapsed/refractory Diffuse large B-cell lymphoma in adults and elderly	Phase 1	01-08-2027	1009132
belzutifan	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Belzutifan in combination with pembrolizumab for adjuvant treatment of intermediate-high risk, high risk, or M1 NED clear cell Renal cell carcinoma in adults and elderly post nephrectomy	Under CHMP evaluation	01-09-2026	1142992
belzutifan	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Belzutifan monotherapy for first line or later treatment of locally advanced or metastatic Pheochromocytoma, Paraganglioma in adolescents, adults and elderly	Phase 2	01-02-2027	1182994
belzutifan	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Belzutifan in combination with lenvatinib for second line or later treatment of locally advanced or metastatic unresectable clear cell Renal cell carcinoma in adults and elderly who have progressed after prior anti-PD-1/L1 therapy	Under CHMP evaluation	01-09-2026	1200878
bezucastinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Bezucastinib in combination with sunitinib for second line or later treatment of locally advanced, metastatic, and/or unresectable PDGFR-negative Gastrointestinal stromal tumour in adults and elderly without succinate dehydrogenase deficiency and who had prior treatment with imatinib only	Phase 3	01-08-2027	1219125
bgb-16673	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Bgb-16673 monotherapy for second line treatment of relapsed or refractory Chronic lymphocytic leukaemia in adults and elderly previously exposed to both BTK inhibitors (BTKi) and BCL2 inhibitors (BCL2i)	Phase 3	01-10-2027	1152250
bgb-16673	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Bgb-16673 monotherapy for second line treatment of relapsed or refractory Mantle cell lymphoma in adults and elderly who have previously received a covalently-binding BTK inhibitor (BTKi) in any line of therapy	Phase 1/2	01-03-2028	1185248
blinatumomab	Other Monoclonal Antibodies	Blinatumomab in combination with low-intensity chemotherapy for first line treatment of newly diagnosed philadelphia-negative B-cell Acute lymphoblastic leukaemia in adults over 40 years of age and elderly	Phase 3	01-04-2028	1219588
bomedemstat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Bomedemstat monotherapy for fourth line treatment of Essential thrombocythaemia in adults and elderly who have an inadequate response to or are intolerant of hydroxyurea	Phase 3	01-11-2028	977621
bomedemstat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Bomedemstat monotherapy for first line treatment of Essential thrombocythaemia in adults and elderly who are cytoreductive therapy naive	Phase 3	01-01-2029	1193450
brenetafusp	Bispecific Antibody & T-Cell Engagers	Brenetafusp in combination with nivolumab for first line treatment of advanced, Stage IV or unresectable Stage III HLA-A*02:01-positive Melanoma in adults and elderly	Phase 3	01-02-2029	1223684
brentuximab vedotin	Other Monoclonal Antibodies	Brentuximab vedotin in combination with lenalidomide and rituximab for third line or later treatment of relapsed or refractory Diffuse large B-cell lymphoma in adults and elderly ineligible for haematopoietic stem cell transplantation or CAR-T therapy	Phase 3	01-04-2027	1135429
brexucabtagene autoleucel	Cell & Gene Therapies	Brexucabtagene autoleucel monotherapy for third line or later treatment of relapsed or refractory B-precursor Acute lymphoblastic leukaemia in children, adolescents and adults up to 21 years of age following conditioning chemotherapy regimen of fludarabine and cyclophosphamide	Phase 1/2	01-06-2027	1164040
brexucabtagene autoleucel	Cell & Gene Therapies	Brexucabtagene autoleucel in combination with fludarabine and cyclophosphamide for second line or later treatment of relapsed/refractory Mantle cell lymphoma in adults and elderly who are Bruton's Tyrosine Kinase inhibitors therapy naive	Phase 2	01-02-2027	1173736
brexucabtagene autoleucel	Cell & Gene Therapies	Brexucabtagene autoleucel monotherapy for second line or later treatment of relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma in children, adolescents and adults up to 21 years of age following conditioning chemotherapy regimen of fludarabine and cyclophosphamide	Phase 1/2	01-06-2027	1218502
camizestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Camizestrant monotherapy for adjuvant treatment of early stage, resected invasive ER-positive/HER2-negative Breast cancer in adults and elderly with an intermediate or high risk of recurrence after definitive locoregional therapy and standard adjuvant endocrine therapy for at least 2 years and up to 5 years	Phase 3	01-08-2028	1193557
camizestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Camizestrant in combination with palbociclib for first line treatment of advanced ER-positive, HER2-negative Breast cancer in adults and elderly	Phase 3	01-12-2027	1218610
camrelizumab	Immune Checkpoint Inhibitors	Camrelizumab in combination with rivoceranib for first line treatment of advanced Hepatocellular carcinoma in adults and elderly	Phase 3	01-08-2027	1129558
capivasertib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Capivasertib in combination with abiraterone and androgen deprivation therapy for first line treatment of metastatic PTEN-deficient, hormone-sensitive Prostate cancer in adults and elderly	Under CHMP evaluation	01-09-2026	1012012
capivasertib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Capivasertib in combination with CDK4/6 inhibitors and fulvestrant for first line treatment of locally advanced (inoperable) or metastatic HR-positive, HER2-negative Breast cancer in adults and elderly	Phase 3	01-09-2028	1218648
catequentinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Catequentinib monotherapy for second line or later treatment of recurrent, locally advanced or metastatic unresectable Synovial sarcoma in adults and elderly	Under CHMP evaluation	01-10-2026	1179161

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catequentinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Catequentinib monotherapy for second line or later treatment of recurrent, locally advanced or metastatic unresectable Leiomyosarcoma in adults and elderly	Under CHMP evaluation	01-10-2026	1185207
cb-011	Cell & Gene Therapies	Cb-011 monotherapy for fourth line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly previously treated with a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody	Phase 1	01-06-2028	1222159
cemacabtagene ansegedleucl	Cell & Gene Therapies	Cemacabtagene ansegedleucl in combination with fludarabine and cyclophosphamide for first line, consolidation treatment of minimal residual disease-positive, large B-cell lymphoma in adults and elderly	Phase 2	01-12-2028	1231194
ciltacabtagene autoleucl	Cell & Gene Therapies	Ciltacabtagene autoleucl in combination with talquetamab consolidation post CAR-T therapy for fourth line or later treatment of relapsed and/or refractory Multiple myeloma in adults and elderly	Phase 2	01-02-2028	995545
cosibelimab	Immune Checkpoint Inhibitors	Cosibelimab monotherapy for first line treatment of advanced, recurrent or metastatic Cutaneous squamous cell carcinoma in adults and elderly who are not eligible for curative surgery or radiation	Under CHMP evaluation	01-06-2027	1173614
cretostimogene grenadenorepvec	Oncolytic Virus Therapies	Cretostimogene grenadenorepvec monotherapy for second line treatment of persistent or recurrent Bacillus Calmette-Guérin-unresponsive Non-muscle invasive bladder cancer in adults and elderly with carcinoma in-situ with or without Ta or T1 papillary tumours	Phase 3	01-08-2027	1131465
cretostimogene grenadenorepvec	Oncolytic Virus Therapies	Cretostimogene grenadenorepvec monotherapy for second line treatment of persistent or recurrent Bacillus Calmette-Guérin-unresponsive Non-muscle invasive bladder cancer in adults and elderly with high-grade Ta/T1 papillary disease without carcinoma in-situ	Phase 3	01-10-2027	1220285
daratumumab	Other Monoclonal Antibodies	Daratumumab in combination with lenalidomide for maintenance treatment of newly diagnosed Multiple myeloma in adults and elderly who are minimal residual disease positive after frontline autologous stem cell transplant	Phase 3	01-02-2027	1001349
daraxonrasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Daraxonrasib monotherapy for second line treatment of metastatic RAS-mutant or wild-type, pancreatic ductal Adenocarcinoma in adults and elderly who were previously treated with 5-fluorouracil based or gemcitabine-based regimen	Phase 3	01-08-2027	1233755
darolutamide	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Darolutamide in combination with androgen deprivation therapy for second line treatment of high risk biochemical recurrent PSMA-positive, hormone-sensitive Prostate cancer in adults and elderly	Phase 3	01-05-2028	1189764
darovasertib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Darovasertib in combination with crizotinib for first line treatment of metastatic HLA-A*02 negative Uveal melanoma in adults and elderly	Phase 2/3	01-10-2027	976684
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with durvalumab for first line treatment of locally recurrent inoperable or metastatic PD-L1 positive, triple-negative Breast cancer in adults and elderly	Phase 3	01-05-2028	1152717
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with durvalumab as neoadjuvant therapy followed by adjuvant durvalumab with or without chemotherapy for first line treatment of stage ii or iii primary invasive triple-negative or HR-low/HER2-negative Breast cancer in adults and elderly	Phase 3	01-01-2029	1159292
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with durvalumab for adjuvant treatment of stage I to III triple-negative Breast cancer in adults and elderly with germline BRCA1 or BRCA2 pathogenic mutation-negative who have residual invasive disease in the breast and/or axillary lymph nodes at surgical resection following neoadjuvant systemic therapy	Phase 3	01-07-2028	1218602
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with pembrolizumab for first line treatment of advanced or metastatic PD-L1 high (TPS ≥50%) non-squamous Non-small cell lung cancer in adults and elderly without actionable genomic alterations	Phase 3	01-04-2027	1218603
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with pembrolizumab and platinum chemotherapy for first line treatment of advanced or metastatic non-squamous Non-small cell lung cancer in adults and elderly who have tumour with PD-L1 TPS <50% and without actionable genomic alterations	Phase 3	01-04-2028	1218676
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with durvalumab and carboplatin for first line treatment of locally advanced or metastatic TROP-2 positive, actionable genomic alteration-negative Non-small cell lung cancer in adults and elderly	Phase 3	01-07-2027	1218693
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan monotherapy for adjuvant treatment of stage I to III triple-negative Breast cancer in adults and elderly with germline BRCA1 or BRCA2 pathogenic mutation-negative who have residual invasive disease in the breast and/or axillary lymph nodes at surgical resection following neoadjuvant systemic therapy	Phase 3	01-07-2028	1219285
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with pembrolizumab for first line treatment of advanced or metastatic non-squamous Non-small cell lung cancer in adults and elderly who have tumour with PD-L1 TPS <50% and without actionable genomic alterations	Phase 3	01-04-2028	1219289
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan monotherapy for second line treatment of locally advanced inoperable or metastatic HR-positive, HER2 IHC 0 Breast cancer in adults and elderly who are refractory to endocrine therapy	Phase 3	01-12-2028	1244002
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with osimertinib for first line treatment of locally advanced or metastatic or recurrent EGFR mutation-positive non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-01-2029	1224983
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan monotherapy for first line treatment of locally recurrent inoperable or metastatic PD-L1 positive, triple-negative Breast cancer in adults and elderly	Phase 3	01-05-2028	1229255
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan in combination with osimertinib for second line or later treatment of locally advanced or metastatic EGFR-mutated non-squamous Non-small cell lung cancer in adults and elderly whose disease has progressed on prior osimertinib treatment	Phase 3	01-07-2027	1229383
datopotamab deruxtecan	Antibody-Drug Conjugates	Datopotamab deruxtecan monotherapy for second line or later treatment of locally advanced or metastatic EGFR-mutated non-squamous Non-small cell lung cancer in adults and elderly whose disease has progressed on prior osimertinib treatment	Phase 3	01-07-2027	1230503

Active Substance (Compound)	Drug Class (incl. sub-category)	Expected Indication (EI)	Phase of Development	Expected EC Approval	IHSI Record ID
detalimogene voraplasamid	Cell & Gene Therapies	Detalimogene voraplasamid monotherapy for second line treatment of BCG-unresponsive Non-muscle invasive bladder cancer in adults and elderly with carcinoma in situ (CIS) with or without coexisting papillary Ta/T1 tumours	Phase 1/2	01-10-2027	1144747
disitamab vedotin	Other Monoclonal Antibodies	Disitamab vedotin in combination with pembrolizumab for first line treatment of locally advanced or metastatic HER2-expressing (IHC 1+ and greater) Urothelial carcinoma in adults and elderly	Phase 3	01-10-2027	1226601
divarasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Divarasib monotherapy for second line or later treatment of unresectable, locally advanced or metastatic KRAS G12C-mutated Non-small cell lung cancer in adults and elderly	Phase 3	01-11-2027	1076345
dordaviprone	Small-Molecule Targeted Therapies (Other targeted small molecules)	Dordaviprone monotherapy for treatment of newly diagnosed H3 K27M-mutant diffuse Glioma in children, adolescents, adults and elderly following completion of radiotherapy	Phase 3	01-12-2027	1070710
dorocubicel	Cell & Gene Therapies	Dorocubicel in combination with standard supportive care and GVHD prophylaxis for salvage treatment of high risk and very high risk Acute myeloid leukaemia in newborns, infants, toddlers, children, adolescents and adults up to 21 years of age	Phase 2	01-04-2027	1107589
dorocubicel	Cell & Gene Therapies	Dorocubicel in combination with standard supportive care and GVHD prophylaxis for second line treatment of high risk and very high risk Myelodysplastic syndrome in newborns, infants, toddlers, children, adolescents and adults up to 21 years of age	Phase 2	01-04-2027	1218996
dorocubicel	Cell & Gene Therapies	Dorocubicel in combination with standard supportive care and GVHD prophylaxis for second line treatment of high risk and very high risk Chronic myeloid leukaemia in newborns, infants, toddlers, children, adolescents and adults up to 21 years of age	Phase 2	01-04-2027	1218997
dostarlimab	Immune Checkpoint Inhibitors	Dostarlimab monotherapy for first line treatment of stage II/III, locally advanced mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H) Rectal cancer in adults and elderly	Phase 2	01-09-2027	1142555
dostarlimab	Immune Checkpoint Inhibitors	Dostarlimab in combination with carboplatin-paclitaxel followed by maintenance dostarlimab plus niraparib for treatment of recurrent or primary advanced Endometrial cancer in adults and elderly	Phase 3	01-09-2027	1219487
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with concurrent definitive chemoradiation therapy for first line treatment of locally advanced, unresectable Oesophageal squamous cell carcinoma in adults and elderly	Phase 3	01-04-2027	1023297
durvalumab	Immune Checkpoint Inhibitors	Durvalumab monotherapy for adjuvant treatment of newly diagnosed Hepatocellular carcinoma in adults and elderly who are at high risk of recurrence after curative hepatic resection or ablation	Phase 3	01-07-2027	1063267
durvalumab	Other Monoclonal Antibodies	Durvalumab in combination with tremelimumab and standard of care chemotherapy for first line treatment of locally advanced or metastatic Urothelial carcinoma in adults and elderly	Phase 3	01-05-2027	1109645
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with monalizumab for treatment of locally advanced (stage III), unresectable EGFR and ALK wild-type Non-small cell lung cancer in adults and elderly who have not progressed following definitive, platinum-based concurrent chemoradiation therapy	Phase 3	01-10-2027	1140687
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with tremelimumab and enfortumab vedotin for neoadjuvant, adjuvant treatment of stage T2-T4aN0/1M0 muscle-invasive Bladder cancer in adults and elderly who are cisplatin-ineligible or refused cisplatin and are undergoing radical cystectomy	Phase 3	01-03-2027	1144809
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with oleclumab for treatment of locally advanced (stage III), unresectable EGFR and ALK wild-type Non-small cell lung cancer in adults and elderly who have not progressed following definitive, platinum-based concurrent chemoradiation therapy	Phase 3	01-10-2027	1145451
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with bevacizumab and transarterial chemoembolization for first line treatment of unresectable locoregional Hepatocellular carcinoma in adults and elderly	Phase 3	01-02-2027	1161507
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with bacillus calmette-guerin for first line treatment of high-risk BCG-naïve Non-muscle invasive bladder cancer in adults and elderly	Under CHMP evaluation	01-10-2026	1173127
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with tremelimumab, lenvatinib and transarterial chemoembolization for treatment of locoregional Hepatocellular carcinoma in adults and elderly with disease that are not amenable to curative therapy	Phase 3	01-02-2027	1182215
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with bevacizumab for adjuvant treatment of newly diagnosed Hepatocellular carcinoma in adults and elderly who are at high risk of recurrence after curative hepatic resection or ablation	Phase 3	01-07-2027	1212214
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with enfortumab vedotin for neoadjuvant and durvalumab monotherapy for adjuvant treatment of stage T2-T4aN0/1M0 muscle-invasive Bladder cancer in adults and elderly who are cisplatin-ineligible or refused cisplatin and are undergoing radical cystectomy	Phase 3	01-03-2027	1218576
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with standard of care chemotherapy for first line treatment of locally advanced or metastatic unresectable Urothelial carcinoma in adults and elderly	Phase 3	01-05-2027	1220087
durvalumab	Immune Checkpoint Inhibitors	Durvalumab in combination with tremelimumab and transarterial chemoembolization for treatment of locoregional Hepatocellular carcinoma in adults and elderly with disease that are not amenable to curative therapy	Phase 3	01-05-2027	1220159
duvelisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Duvelisib monotherapy for second line or later treatment of relapsed or refractory nodal T follicular helper (TFH) cell Lymphoma in adults and elderly	Phase 3	08-12-2028	1231014
eftilagimod alfa	Other	Eftilagimod alfa in combination with paclitaxel for first line or later treatment of metastatic HR-positive/negative, HER2-negative/low and triple-negative Breast cancer in adults and elderly	Phase 2/3	01-02-2028	1186957
eg-007	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Eg-007 in combination with lenvatinib and pembrolizumab for second line treatment of advanced (stage iii or iv) or recurrent non-MSI-H or dMMR Endometrial cancer in adults and elderly who have disease progression on a platinum-containing therapy and who are not candidates for curative surgery or radiation	Phase 3	01-04-2028	1086979
elironrasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Elironrasib monotherapy for second line or later treatment of locally advanced or metastatic KRASG12C-mutated Non-small cell lung cancer in adults and elderly	Phase 1	01-02-2029	1171305

Active Substance (Compound)	Drug Class (incl. sub-category)	Expected Indication (EI)	Phase of Development	Expected EC Approval	IHSI Record ID
elranatamab	Bispecific Antibody & T-Cell Engagers	Elranatamab monotherapy for second line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly previously treated with lenalidomide and a proteasome inhibitor	Phase 3	01-02-2027	1219282
elranatamab	Bispecific Antibody & T-Cell Engagers	Elranatamab in combination with daratumumab for second line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly previously treated with lenalidomide and a proteasome inhibitor	Phase 3	01-05-2027	1199598
elranatamab	Bispecific Antibody & T-Cell Engagers	Elranatamab monotherapy for maintenance treatment of newly diagnosed Multiple myeloma in adults and elderly who are minimal residual disease-positive after undergoing autologous stem-cell transplantation	Phase 3	01-06-2028	1210810
elranatamab	Bispecific Antibody & T-Cell Engagers	Elranatamab monotherapy for second line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly who received prior anti-CD38 directed therapy and lenalidomide	Phase 3	01-06-2027	1222473
emactuzumab	Other Monoclonal Antibodies	Emactuzumab monotherapy for first line treatment of localised or diffuse Tenosynovial giant cell tumour in adolescents, adults and elderly where surgical removal of the tumour is not viewed as an option	Phase 3	01-12-2027	1145446
encorafenib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Encorafenib in combination with binimetinib for adjuvant treatment of stage IIB/C fully resected, BRAF V600E/K mutant Melanoma in adults and elderly	Phase 3	01-07-2028	1047388
encorafenib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Encorafenib in combination with binimetinib and pembrolizumab for first line treatment of metastatic or unresectable locally advanced BRAF V600E/K mutation-positive cutaneous Melanoma in adults and elderly	Phase 3	01-07-2027	1182198
enfortumab vedotin	Other Monoclonal Antibodies	Enfortumab vedotin in combination with pembrolizumab for neoadjuvant, adjuvant treatment of non-metastatic muscle invasive Bladder cancer in adults and elderly who are eligible for radical cystectomy plus pelvic lymph node dissection surgery	Under CHMP evaluation	01-10-2026	1140416
ensartinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Ensartinib monotherapy for second line treatment of advanced, recurrent or metastatic ALK-positive Non-small cell lung cancer in adults and elderly that have received up to 1 prior chemotherapy regimen and no prior ALK tyrosine kinase inhibitor	Under CHMP evaluation	01-01-2027	1052183
enzomenib	Small-Molecule Targeted Therapies (Epigenetic modulators)	Enzomenib monotherapy for treatment of relapsed or refractory Acute myeloid leukaemia in adults and elderly with a mixed lineage leukaemia rearrangement (MLLr) or nucleophosmin mutation (NPM1m)	Phase 1/2	01-08-2028	1158198
ep0031	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Ep0031 monotherapy for treatment of advanced RET fusion-positive Non-small cell lung cancer in adults and elderly	Phase 1/2	01-04-2028	1236387
epcoritamab	Bispecific Antibody & T-Cell Engagers	Epcoritamab in combination with R-CHOP for first line treatment of newly diagnosed CD20-positive Diffuse large B-cell lymphoma in adults and elderly	Phase 3	01-04-2027	1216746
epcoritamab	Bispecific Antibody & T-Cell Engagers	Epcoritamab monotherapy for second line or later treatment of relapsed or refractory CD20-positive Diffuse large B-cell lymphoma in adults and elderly previously treated with anti-CD20 mAb-containing combination chemotherapy who have failed or are ineligible for autologous stem cell transplant	Phase 3	01-07-2027	1242917
epcoritamab	Bispecific Antibody & T-Cell Engagers	Epcoritamab monotherapy for second line or later treatment of relapsed/refractory Diffuse large B-cell lymphoma in adults and elderly previously treated with anti-CD20 mAb-containing combination chemotherapy and failed previous HDT-ASCT or not eligible for HDT-ASCT	Phase 3	01-02-2027	1253982
epcoritamab	Bispecific Antibody & T-Cell Engagers	Epcoritamab in combination with lenalidomide for second line or later treatment of relapsed or refractory CD20-positive Diffuse large B-cell lymphoma in adults and elderly previously treated with anti-CD20 mAb-containing combination chemotherapy who have failed or are ineligible for autologous stem cell transplant	Phase 3	01-04-2027	1231414
etentamig	Bispecific Antibody & T-Cell Engagers	Etentamig monotherapy for third line or later treatment of relapsed or refractory Multiple myeloma in adults and elderly who have received a proteasome inhibitor, an immunomodulatory imide, and an anti-CD38 monoclonal antibody	Phase 3	01-04-2028	1153575
fianlimab	Immune Checkpoint Inhibitors	Fianlimab in combination with cemiplimab for first line treatment of unresectable locally advanced or metastatic Melanoma in adolescents, adults and elderly	Phase 3	01-09-2027	1160644
fianlimab/cemiplimab	Immune Checkpoint Inhibitors	Fianlimab/cemiplimab monotherapy for first line treatment of stage III and stage IV unresectable Melanoma in adults and elderly	Phase 3	01-07-2028	1223211
ficlatazumab	Other Monoclonal Antibodies	Ficlatazumab in combination with cetuximab for second line or later treatment of recurrent or metastatic HPV-negative Squamous cell carcinoma of head and neck in adults and elderly who have failed prior therapy with an anti-PD-1 or PD-L1 ICI and platinum-based chemotherapy	Phase 3	01-12-2028	1124114
firmonertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Firmonertinib monotherapy for first line treatment of locally advanced or metastatic EGFR exon 20 insertion mutation-positive, non-squamous Non-small cell lung cancer in adults and elderly not amenable to curative surgery or radiotherapy	Phase 3	01-11-2027	976518
fk-pc101	Cancer Vaccines	Fk-pc101 monotherapy for adjuvant treatment of localised high-risk or very high-risk Prostate cancer in children, adolescents, adults and elderly who have undergone radical prostatectomy	Phase 2	01-06-2028	1234132
fuzuloparib	Small-Molecule Targeted Therapies (PARP inhibitors)	Fuzuloparib in combination with abiraterone acetate and prednisone for first line treatment of metastatic castration-resistant Prostate cancer in adults and elderly	Phase 3	01-04-2028	1061830
galinpepimut-s	Cancer Vaccines	Galinpepimut-s monotherapy for third line, maintenance treatment of Acute myeloid leukaemia in adults and elderly	Phase 3	01-11-2027	1127935
gedatolisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Gedatolisib in combination with palbociclib and fulvestrant for second line or later treatment of locally advanced or metastatic PIK3CA wild-type, HR-positive, HER2-negative Breast cancer in adults and elderly previously treated with CDK4/6 and aromatase inhibitor therapy	Phase 3	01-03-2028	1028577
gedatolisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Gedatolisib in combination with fulvestrant for second line or later treatment of locally advanced or metastatic PIK3CA wild-type, HR-positive, HER2-negative Breast cancer in adults and elderly previously treated with CDK4/6 and aromatase inhibitor therapy	Phase 3	01-12-2027	1219373
gedatolisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Gedatolisib in combination with palbociclib and fulvestrant for second line or later treatment of locally advanced or metastatic PIK3CA mutated, HR-positive, HER2-negative Breast cancer in adults and elderly previously treated with CDK4/6 and aromatase inhibitor therapy	Phase 3	01-12-2027	1219374

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gemcitabine	Cytotoxic Chemotherapy	Gemcitabine monotherapy for first line treatment of locally advanced, unresectable Pancreatic cancer in adults and elderly	Phase 3	01-07-2028	1060671
gemtuzumab ozogamicin	Antibody-Drug Conjugates	Gemtuzumab ozogamicin in combination with mitoxantrone and cytarabine for first line treatment of CD33-positive Acute myeloid leukaemia in infants and toddlers, children and adolescents	Under CHMP evaluation	01-10-2026	1142015
giredestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Giredestrant in combination with everolimus for second line treatment of locally advanced unresectable or metastatic ER-positive HER2-negative Breast cancer in adults and elderly previously treated with a CDK4/6 inhibitor and endocrine therapy	Phase 3	01-08-2027	1218650
giredestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Giredestrant monotherapy for adjuvant treatment of medium- and high-risk stage I-III ER-positive, HER2-negative Breast cancer in adults and elderly	Phase 3	01-08-2027	1218664
giredestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Giredestrant in combination with CDK4/6 inhibitor for first line treatment of locally advanced or metastatic ER-positive HER2-negative Breast cancer in adults and elderly who are resistant to adjuvant endocrine therapy	Phase 3	01-06-2028	1226777
givastomig	Bispecific Antibody & T-Cell Engagers	Givastomig in combination with nivolumab and chemotherapy for treatment of unresectable, locally advanced, or metastatic HER2-negative, CLDN18.2 positive, PD-1L positive gastric, gastroesophageal junction, or oesophageal Adenocarcinoma in adults and elderly who are treatment-naïve	Phase 2	01-10-2028	1256378
givinostat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Givinostat monotherapy for treatment of high-risk JAK2V617F-positive Polycythaemia vera in adults and elderly	Phase 3	01-11-2027	1223706
glofitamab	Bispecific Antibody & T-Cell Engagers	Glofitamab in combination with polatuzumab vedotin plus rituximab, cyclophosphamide, doxorubicin, and prednisone (Pola-R-CHP) for first line treatment of CD20-positive Diffuse large B-cell lymphoma in adults and elderly	Phase 3	01-04-2028	1032788
glofitamab	Other Monoclonal Antibodies	Glofitamab monotherapy for second line or later treatment of relapsed/refractory Mantle cell lymphoma in adults and elderly who received prior treatment with a BTK inhibitor	Phase 3	01-06-2028	1203190
glsi-100	Cancer Vaccines	Glsi-100 monotherapy for preventive treatment of HLA-A*02 positive, HER2/neu positive Breast cancer in adults and elderly who are at high risk for disease recurrence and completed both neoadjuvant and adjuvant trastuzumab-based standard of care breast cancer therapy	Phase 3	01-04-2028	1165338
glsi-100	Cancer Vaccines	Glsi-100 monotherapy for preventive treatment of HLA-A*02-negative, HER2/neu-positive Breast cancer in adults and elderly who are at high risk for disease recurrence and completed both neoadjuvant and adjuvant trastuzumab-based standard of care breast cancer therapy	Phase 3	01-04-2028	1232954
glufosfamide	Cytotoxic Chemotherapy	Glufosfamide monotherapy for second line treatment of metastatic Pancreatic cancer in adults and elderly who have disease progression during or after treatment with gemcitabine	Phase 3	01-01-2028	979119
golodocitinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Golodocitinib monotherapy for second line or later treatment of relapsed/refractory peripheral T-cell lymphoma in adults and elderly	Phase 1/2	01-08-2027	1248237
gotistobart	Immune Checkpoint Inhibitors	Gotistobart monotherapy for second line treatment of metastatic unmutated or KRAS-positive squamous Non-small cell lung cancer in adults and elderly who progressed on PD-1/PD-L1 inhibitor	Phase 3	01-10-2027	1190237
gridegalutamide	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Gridegalutamide monotherapy for second line treatment of metastatic castration-resistant Prostate cancer in adults and elderly who have had previous treatment with an androgen receptor pathway inhibitor	Phase 3	01-01-2029	1237206
hafnium oxide	Radiopharmaceuticals	Hafnium oxide in combination with radiation therapy for first line treatment of locally advanced Squamous cell carcinoma of head and neck in adults over 60 years of age and elderly who are not eligible for platinum-based chemotherapy	Phase 3	01-07-2028	1188411
hafnium oxide	Radiopharmaceuticals	Hafnium oxide in combination with radiation therapy and cetuximab for first line treatment of locally advanced Squamous cell carcinoma of head and neck in adults over 60 years of age and elderly who are not eligible for platinum-based chemotherapy	Phase 3	01-07-2028	1219333
hlx22	Other Monoclonal Antibodies	Hlx22 in combination with trastuzumab and chemotherapy for first line treatment of locally advanced or metastatic unresectable HER2-positive, gastric or gastroesophageal junction Adenocarcinoma in adults and elderly	Phase 3	01-10-2028	1226012
iberdomide	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Iberdomide in combination with dexamethasone and daratumumab for second line or later treatment of relapsed or refractory Multiple myeloma in adults and elderly	Phase 3	01-08-2027	1063331
idroxioleic acid	Other	Idroxioleic acid in combination with radiotherapy and temozolomide for first line treatment of newly diagnosed primary Glioblastoma in adults and elderly	Phase 2/3	01-10-2028	1031127
ifinatamab deruxtecan	Antibody-Drug Conjugates	Ifinatamab deruxtecan monotherapy for second line or later treatment of extensive stage Small cell lung cancer in adults and elderly who have received prior platinum-based line therapy	Phase 2	01-08-2027	1235233
ifinatamab deruxtecan	Antibody-Drug Conjugates	Ifinatamab deruxtecan monotherapy for second line treatment of relapsed, extensive-stage Small cell lung cancer in adults and elderly who have received prior platinum-based line therapy	Phase 3	30-08-2028	1222942
ifx-hu2.0	Cancer Vaccines	Ifx-hu2.0 in combination with pembrolizumab for first line, adjunctive treatment of recurrent, Stage III or Stage IV unresectable Merkel cell carcinoma in adults and elderly	Phase 2/3	01-07-2028	1221554
igv-001	Cell & Gene Therapies	Igv-001 in combination with radiotherapy and temozolomide for first line treatment of newly diagnosed Grade III or Grade IV Glioblastoma in adults and elderly	Phase 2	01-08-2027	1070632
imlunestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Imlunestrant monotherapy for adjuvant treatment of early-stage, invasive, resected ER-positive, HER2-negative Breast cancer in adults and elderly who have previously received 2 to 5 years of adjuvant endocrine therapy and have an increased risk of disease recurrence	Phase 3	01-02-2029	1218609
inavolisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Inavolisib in combination with fulvestrant for second line or later treatment of locally advanced or metastatic HR-positive, HER2-negative, PIK3CA mutated Breast cancer in adults and elderly who progressed during or after CDK4/6 inhibitor and endocrine combination therapy	Phase 3	01-09-2027	975558
inavolisib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Inavolisib in combination with phesgo for maintenance treatment of locally advanced or metastatic PIK3CA-mutated HER2-positive Breast cancer in adults and elderly	Phase 3	01-10-2027	1217389

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intismeran autogene	Cancer Vaccines	Intismeran autogene in combination with pembrolizumab for neoadjuvant, adjuvant treatment of locally resectable advanced stage II-IV (M0) Cutaneous squamous cell carcinoma in adults and elderly	Phase 2/3	01-11-2027	1221024
intismeran autogene	Cancer Vaccines	Intismeran autogene in combination with pembrolizumab for adjuvant treatment of high-risk muscle-invasive Urothelial carcinoma in adults and elderly after radical resection	Phase 1/2	01-08-2028	1231115
intismeran autogene	Cancer Vaccines	Intismeran autogene in combination with pembrolizumab, and enfortumab vedotin for treatment of muscle-invasive Urothelial carcinoma in adults and elderly undergoing radical cystectomy and pelvic lymph node dissection	Phase 1/2	01-08-2028	1235269
iopofosine i 131	Radiopharmaceuticals	Iopofosine i 131 monotherapy for third line or later treatment of relapsed or refractory Waldenstrom's macroglobulinaemia in adults and elderly	Phase 2	01-09-2027	1000748
iopofosine i 131	Radiopharmaceuticals	Iopofosine i 131 monotherapy for third line or later treatment of Lymphoplasmacytic type lymphoma (Kiel Classification) in adults and elderly	Phase 2	01-09-2027	991278
ivonescimab	Immune Checkpoint Inhibitors	Ivonescimab in combination with pemetrexed and carboplatin for second line treatment of locally advanced or metastatic EGFR-mutant non-squamous Non-small cell lung cancer in adults and elderly who have progressed on or following EGFR-TKI treatment	Phase 3	01-10-2027	1152612
ivonescimab	Immune Checkpoint Inhibitors	Ivonescimab in combination with chemotherapy for first line treatment of metastatic without actionable genomic mutations, squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-01-2028	1218505
ivonescimab	Immune Checkpoint Inhibitors	Ivonescimab in combination with chemotherapy for first line treatment of metastatic without actionable genomic mutations, non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-07-2028	1248731
ivosidenib	Small-Molecule Targeted Therapies (Other targeted small molecules)	Ivosidenib monotherapy for first line or later treatment of locally advanced or metastatic IDH1 gene-mutated conventional Chondrosarcoma in adults and elderly who are not eligible for curative resection	Phase 3	01-12-2028	1073812
ivosidenib	Small-Molecule Targeted Therapies (Other targeted small molecules)	Ivosidenib monotherapy for first line treatment of Isocitrate Dehydrogenase-1 mutated Myelodysplastic syndrome in adults and elderly who have not received treatment with a hypomethylating agent	Phase 3	01-09-2028	1235040
ivospemin	Other	Ivospemin in combination with nab-paclitaxel and gemcitabine for first line or later treatment of metastatic BRCA-negative Pancreatic cancer in adults and elderly	Phase 2/3	01-12-2027	1079748
ixotatug vedotin	Antibody-Drug Conjugates	Ixotatug vedotin in combination with pegfilgrastim for second line or later treatment of advanced Claudin 6 expressing, platinum-resistant Ovarian cancer in adults and elderly	Phase 2	01-02-2029	1235377
lasofoxifene	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Lasofoxifene in combination with abemaciclib for second line treatment of locally advanced or metastatic ER+/HER2- with ESR1 mutation Breast cancer in adults and elderly who have previously received an aromatase inhibitor and ribociclib or palbociclib-based hormonal treatment	Phase 3	01-08-2028	1002075
lenvatinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Lenvatinib in combination with belzutifan for second line or later treatment of unresectable, locally advanced or metastatic clear cell Renal cell carcinoma in adults and elderly who have progressed after prior anti-PD-1/L1 therapy	Phase 3	01-02-2027	1141846
letetresgene autoleucel	Cell & Gene Therapies	Letetresgene autoleucel in combination with fludarabine and cyclophosphamide for second line or later treatment of advanced (metastatic or unresectable) HLA-A2-positive, NY-ESO1-positive and/or LAGE-1a-positive myxoid/round cell liposarcoma or Synovial sarcoma in children over 10 years of age, adolescents, adults and elderly who have disease progression following treatment with anthracycline based chemotherapy	Phase 2	01-08-2027	1173649
leuprolide acetate	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Leuprolide acetate in combination with standard endocrine therapy for treatment of stage i, ii, or iii HR-positive, HER2-negative Breast cancer in adults up to 49 years of age who are premenopause	Phase 3	01-11-2027	1170289
lifileucel	Cell & Gene Therapies	Lifileucel monotherapy for second line or later treatment of recurrent, metastatic, or persistent Cervical cancer in adults and elderly after a non-myeloablative lymphodepletion preparative regimen	Phase 2	01-01-2028	1219391
lifileucel	Cell & Gene Therapies	Lifileucel in combination with follow-on IL-2 for second line or later treatment of metastatic stage IIIC or stage IV unresectable Melanoma in adults and elderly progressed following prior therapy including a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor	Phase 2	01-10-2027	1163838
lifileucel	Cell & Gene Therapies	Lifileucel monotherapy for second line or later treatment of metastatic stage IV non-ALK, non-EGFR, non-ROS mutated Non-small cell lung cancer in adults and elderly who have progressed on or after chemotherapy and anti-PD-1 therapy	Phase 2	01-08-2027	1173651
lifileucel	Cell & Gene Therapies	Lifileucel monotherapy for second line or later treatment of recurrent, metastatic, or persistent Cervical cancer in adults and elderly after a non-myeloablative lymphodepletion preparative regimen who are previously treated with anti-PD-1 or anti-PD-L1 checkpoint inhibitor	Phase 2	01-01-2028	1219392
lirafugratinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Lirafugratinib monotherapy for second line treatment of unresectable or metastatic FGFR2 gene fusion, mutation, or amplification intrahepatic Cholangiocarcinoma in adults and elderly	Phase 1/2	01-09-2027	989812
lisocabtagene maraleucel	Cell & Gene Therapies	Lisocabtagene maraleucel monotherapy for third line or later treatment of relapsed or refractory Marginal zone lymphoma in adults and elderly previously treated with systemic therapies including anti-CD20 and alkylating agent or relapsed after haematopoietic stem cell transplant	Phase 2	01-04-2027	1219000
lisocabtagene maraleucel	Cell & Gene Therapies	Lisocabtagene maraleucel monotherapy for third line or later treatment of relapsed or refractory Chronic lymphocytic leukaemia, Small cell lymphocytic lymphoma in adults who have received Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor	Phase 1/2	01-02-2027	1219405
lisocabtagene maraleucel	Cell & Gene Therapies	Lisocabtagene maraleucel in combination with standard of care for first line treatment of transplant-ineligible Primary central nervous system lymphoma in adults and elderly	Phase 2	01-11-2028	1062112
loncastuximab tesirine	Antibody-Drug Conjugates	Loncastuximab tesirine in combination with rituximab for second line or later treatment of relapsed or refractory Diffuse large B-cell lymphoma in adults and elderly who are ineligible for stem cell transplantation	Phase 3	01-04-2027	1125191
lurbinededin	Cytotoxic Chemotherapy	Lurbinededin in combination with doxorubicin for first line treatment of metastatic Leiomyosarcoma in adults and elderly	Phase 3	01-07-2028	1007169

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lurbinectedin	Cytotoxic Chemotherapy	Lurbinectedin in combination with irinotecan for second line treatment of relapsed Small cell lung cancer in adults and elderly who failed one prior platinum-containing chemotherapy, with or without anti-PD-1 or anti-PD-L1 agents	Phase 3	01-04-2027	1054047
lurbinectedin	Cytotoxic Chemotherapy	Lurbinectedin monotherapy for second line treatment of relapsed Small cell lung cancer in adults and elderly who failed one prior platinum-containing chemotherapy, with or without anti-PD-1 or anti-PD-L1 agents	Phase 3	01-04-2027	1063112
luspatercept	Other	Luspatercept in combination with concomitant JAK2 inhibitor therapy for add-on treatment of anemia due to myeloproliferative neoplasm-associated Myelofibrosis in adults and elderly who require red blood cell transfusions	Phase 3	01-02-2027	1140715
lutetium (177Lu) vipivotide tetraxetan	Radiopharmaceuticals	Lutetium (177Lu) vipivotide tetraxetan monotherapy for second line treatment of stage IV PSMA-positive Prostate cancer in adults and elderly	Phase 3	01-10-2028	974936
lutetium (177Lu) vipivotide tetraxetan	Radiopharmaceuticals	Lutetium (177Lu) vipivotide tetraxetan in combination with standard of care (ARDT + ADT) for first line or later treatment of metastatic PSMA-positive, hormone-sensitive Prostate cancer in adults and elderly	Phase 3	01-02-2027	977169
lutetium Lu177 edotreotide	Radiopharmaceuticals	Lutetium Lu177 edotreotide monotherapy for first line treatment of inoperable, progressive grade 1 and 2, somatostatin receptor-positive Gastroenteropancreatic neuroendocrine tumour disease in adults and elderly	Phase 3	01-08-2027	1134801
lutetium Lu177 edotreotide	Radiopharmaceuticals	Lutetium Lu177 edotreotide monotherapy for first line or later treatment of unresectable well-differentiated aggressive grade 2 and grade 3, somatostatin receptor-positive Gastroenteropancreatic neuroendocrine tumour disease in adults and elderly	Phase 3	01-10-2028	1218632
methotrexate	Other	Methotrexate monotherapy for induction, consolidation, maintenance treatment of primary vitreoretinal Lymphoma in adults over 21 years of age and elderly	Phase 3	01-04-2028	980202
mevrometostat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Mevrometostat in combination with enzalutamide for second line treatment of progressive, metastatic castration-resistant Prostate cancer in adults and elderly after progression on prior abiraterone acetate treatment	Phase 3	01-11-2027	1226160
mevrometostat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Mevrometostat in combination with enzalutamide for first line treatment of metastatic castration-resistant Prostate cancer in adults and elderly who are ARSi or abiraterone naive	Phase 3	01-04-2028	1233796
mezigdomide	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Mezigdomide in combination with bortezomib and dexamethasone for second line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly who have had prior lenalidomide exposure	Phase 3	01-05-2028	982842
mezigdomide	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Mezigdomide in combination with carfilzomib and dexamethasone for second line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly who have received prior treatments with lenalidomide and an anti-CD38 monoclonal antibody	Phase 3	01-08-2027	1218848
mirvetuximab soravtansine	Other Monoclonal Antibodies	Mirvetuximab soravtansine in combination with bevacizumab for maintenance treatment of FRA-high, recurrent platinum-sensitive, high-grade serous Ovarian cancer in adults and elderly	Phase 3	01-02-2028	1077292
mitomycin (ugn-103)	Cytotoxic Chemotherapy	Mitomycin (ugn-103) monotherapy for first line treatment of intermediate-risk low-grade Non-muscle invasive bladder cancer in adults and elderly	Phase 3	01-10-2027	1178902
mitomycin (ugn-104)	Cytotoxic Chemotherapy	Mitomycin (ugn-104) monotherapy for treatment of low grade upper urinary tract Urothelial carcinoma in adults and elderly	Phase 3	01-07-2028	1063679
mocravimod	Small-Molecule Targeted Therapies (Other targeted small molecules)	Mocravimod monotherapy for adjunctive, maintenance treatment of Acute myeloid leukaemia in adults and elderly undergoing allogeneic haematopoietic cell transplantation	Phase 3	01-09-2028	970959
monalizumab	Other Monoclonal Antibodies	Monalizumab in combination with durvalumab for treatment of locally advanced (Stage III), unresectable EGFR and ALK wild-type Non-small cell lung cancer in adults and elderly who have not progressed following definitive, platinum-based concurrent chemoradiation therapy	Phase 3	01-10-2027	1201284
mosunetuzumab	Bispecific Antibody & T-Cell Engagers	Mosunetuzumab in combination with polatuzumab vedotin for second line or later treatment of relapsed or refractory Diffuse large B-cell lymphoma in adults and elderly who are ineligible for autologous stem cell transplant	Phase 3	01-02-2027	1153838
mosunetuzumab	Bispecific Antibody & T-Cell Engagers	Mosunetuzumab in combination with lenalidomide for second line or later treatment of relapsed or refractory CD20+, Grades 1-3A Follicular lymphoma in adults and elderly	Phase 3	01-05-2027	1114683
namodenoson	Small-Molecule Targeted Therapies (Other targeted small molecules)	Namodenoson monotherapy for second line or later treatment of advanced Hepatocellular carcinoma in adults and elderly with Child-Pugh Class B7 cirrhosis	Phase 3	01-03-2028	1011156
nanvuranlat	Small-Molecule Targeted Therapies (Other targeted small molecules)	Nanvuranlat monotherapy for second line treatment of advanced Biliary carcinoma in adults and elderly who have received 1 prior platinum-based therapy with or without a mAb targeting PD-1 or PD-L1	Phase 3	01-02-2029	1252359
navtemadlin	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Navtemadlin in combination with ruxolitinib for add-on treatment of intermediate or high risk primary, post essential thrombocythaemia, or post polycythaemia vera Myelofibrosis in adults and elderly who are JAK Inhibitor-naïve and have a suboptimal response to ruxolitinib	Phase 3	01-04-2028	1059807
naxitamab	Other Monoclonal Antibodies	Naxitamab in combination with granulocyte-macrophage colony-stimulating factor for second line treatment of high-risk Neuroblastoma in infants and toddlers, children, adolescents	Phase 2/3	01-10-2027	1142281
neladalkib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Neladalkib monotherapy for second line or later treatment of locally advanced or metastatic ALK-positive Non-small cell lung cancer in adults and elderly who have received prior ALK tyrosine kinase inhibitors	Phase 1/2	01-08-2027	1208185
nemtabrutinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Nemtabrutinib monotherapy for first line treatment of TP53-negative Chronic lymphocytic leukaemia, Small cell lymphocytic lymphoma in adults and elderly	Phase 3	01-09-2028	980150
nibrozetone	Small-Molecule Targeted Therapies (Other targeted small molecules)	Nibrozetone in combination with platinum chemotherapy for third line or later treatment of Small cell lung cancer in adults and elderly	Phase 3	01-10-2027	988434
nilotinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Nilotinib monotherapy for treatment of Chronic myeloid leukaemia in adults up to 55 years of age	Phase 1	01-08-2027	1245550

Active Substance (Compound)	Drug Class (incl. sub-category)	Expected Indication (EI)	Phase of Development	Expected EC Approval	IHSI Record ID
nivolumab	Immune Checkpoint Inhibitors	Nivolumab in combination with gemcitabine and cisplatin for neoadjuvant, first line treatment of stage T2-T4a, N0, M0 muscle-invasive Bladder cancer in adults and elderly prior to radial cystectomy	Phase 3	01-04-2027	1146038
nivolumab	Immune Checkpoint Inhibitors	Nivolumab monotherapy for adjuvant treatment of Hepatocellular carcinoma in adults and elderly who have high risk of recurrence after curative hepatic resection or ablation	Phase 3	01-06-2027	1151908
nogapendekin alfa inbakicept	Small-Molecule Targeted Therapies (Other targeted small molecules)	Nogapendekin alfa inbakicept in combination with bacillus calmette-guerin for second line treatment of BCG-unresponsive, high-grade Ta/T1 disease Non-muscle invasive bladder cancer in adults and elderly	Phase 2/3	01-02-2027	1252579
obixtamig	Bispecific Antibody & T-Cell Engagers	Obixtamig monotherapy for second line or later treatment of relapsed/refractory extra-pulmonary Neuroendocrine carcinoma in adults and elderly whose disease has progressed following at least one prior line of treatment including platinum-based chemotherapy	Phase 2	01-01-2029	1226631
octreotide	Small-Molecule Targeted Therapies (Other targeted small molecules)	Octreotide monotherapy for first line treatment of advanced well-differentiated Gastroenteropancreatic neuroendocrine tumour disease in adults and elderly	Phase 3	01-10-2027	1078678
odronextamab	Bispecific Antibody & T-Cell Engagers	Odronextamab monotherapy for first line treatment of stage II bulky or stage III / IV CD20-positive, grade 1-3a Follicular lymphoma in adults and elderly	Phase 3	01-12-2028	1143707
odronextamab	Bispecific Antibody & T-Cell Engagers	Odronextamab in combination with chemotherapy for first line treatment of Diffuse large B-cell lymphoma in adults and elderly	Phase 3	01-01-2029	1200575
olaparib	Small-Molecule Targeted Therapies (PARP inhibitors)	Olaparib monotherapy for maintenance treatment of advanced BRCA wild type high grade serous or endometrioid Ovarian cancer in adults and elderly following response to standard first-line platinum-based chemotherapy	Phase 3	01-05-2027	997854
olaparib	Small-Molecule Targeted Therapies (PARP inhibitors)	Olaparib in combination with pembrolizumab, platinum doublet, and chemoradiation for first line treatment of unresectable, locally advanced, stage III Non-small cell lung cancer in adults and elderly who are unable to undergo surgery with curative intent	Phase 3	01-05-2027	1001757
oleclumab	Other Monoclonal Antibodies	Oleclumab in combination with durvalumab for treatment of locally advanced (Stage III), unresectable EGFR and ALK wild-type Non-small cell lung cancer in adults and elderly who have not progressed following definitive, platinum-based concurrent chemoradiation therapy	Phase 3	01-10-2027	1197691
olomorasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Olomorasib in combination with pembrolizumab and chemotherapy for first line treatment of locally advanced or metastatic KRAS G12C-mutant non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-02-2028	1229304
olverembatinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Olverembatinib monotherapy for third line or later treatment of chronic phase T315I mutation-negative Chronic myeloid leukaemia in adults and elderly previously treated with at least two approved TKIs	Phase 3	01-10-2027	1052646
olverembatinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Olverembatinib monotherapy for treatment of chronic phase T315I mutation-positive Chronic myeloid leukaemia in adults and elderly	Phase 3	01-01-2028	1230605
olverembatinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Olverembatinib monotherapy for second line or later treatment of SDH-deficient Gastrointestinal stromal tumour in adolescents, adults and elderly	Phase 3	01-07-2028	1234117
olvimulogene nanivacirepvec	Oncolytic Virus Therapies	Olvimulogene nanivacirepvec in combination with platinum-doublet chemotherapy and bevacizumab for fourth line or later treatment of non-resectable, high-grade serous, platinum-resistant/refractory Ovarian cancer in adults and elderly	Phase 3	01-10-2027	1184847
orca-t	Cell & Gene Therapies	Orca-t in combination with tacrolimus for treatment of advanced Haematological malignancy in adults and elderly patients undergoing myeloablative allogeneic hematopoietic cell transplantation from an HLA-matched donor	Phase 3	01-08-2027	1159360
oregovomab	Other Monoclonal Antibodies	Oregovomab in combination with paclitaxel and carboplatin for first line treatment of newly diagnosed, advanced BRCA germline mutation-negative Fallopian tube cancer, Peritoneal carcinoma, Ovarian epithelial cancer in adults and elderly who have undergone optimal debulking surgery	Phase 3	01-04-2028	1136085
oregovomab	Other Monoclonal Antibodies	Oregovomab in combination with paclitaxel and carboplatin for first line treatment of newly diagnosed, advanced BRCA germline mutation-negative Fallopian tube cancer, Peritoneal carcinoma, Ovarian epithelial cancer in adults and elderly who have undergone optimal debulking surgery and neoadjuvant treatment with paclitaxel and carboplatin	Phase 3	01-04-2028	1219277
osimertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Osimertinib in combination with platinum-based chemotherapy for neoadjuvant treatment of completely resectable Stage II - IIIB N2 EGFR mutation-positive non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-02-2027	1075689
osimertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Osimertinib monotherapy for adjuvant treatment of stage IA2-IA3 EGFR mutation-positive non-squamous Non-small cell lung cancer in adults and elderly following complete tumour resection	Phase 3	01-06-2028	1088357
osimertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Osimertinib monotherapy for neoadjuvant treatment of completely resectable Stage II - IIIB N2 EGFR mutation-positive non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-02-2027	1218485
ost31-164	Cancer Vaccines	Ost31-164 monotherapy for maintenance treatment of resected, pulmonary recurrent Osteosarcoma in adolescents and adults up to 39 years of age	Phase 2	01-11-2027	1162891
ozekibart	Other Monoclonal Antibodies	Ozekibart monotherapy for treatment of unresectable or metastatic conventional Chondrosarcoma in adults and elderly	Phase 2	01-09-2027	1145716
paclitaxel	Cytotoxic Chemotherapy	Paclitaxel monotherapy for second line or later treatment of recurrent advanced platinum-resistant/refractory high grade serous Ovarian cancer in adults and elderly who have received at least one prior platinum-based chemotherapy regimen, including cisplatin, carboplatin or other organoplatinum compounds	Phase 3	01-10-2027	1011051
paclitaxel	Cytotoxic Chemotherapy	Paclitaxel monotherapy for first line treatment of recurrent or metastatic HER2-negative Breast cancer in adults over 19 years of age and elderly	Phase 3	01-08-2027	1029011
paclitaxel/hyaluronic acid	Cytotoxic Chemotherapy	Paclitaxel/hyaluronic acid monotherapy for second line treatment of persistent or recurrent BCG-unresponsive carcinoma in situ Non-muscle invasive bladder cancer in adults and elderly with or without Ta-T1 papillary disease	Phase 3	01-10-2027	1199623
pacritinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Pacritinib monotherapy for first line or later treatment of intermediate-1, intermediate-2 or high risk primary, post essential thrombocythaemia, or	Phase 3	01-04-2028	1030600

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		post polycythaemia vera Myelofibrosis in adults and elderly with severe thrombocytopaenia			
padeliporfin	Other	Padeliporfin monotherapy for first line treatment of low-grade non-invasive Transitional cell cancer of the renal pelvis and ureter localised in adults and elderly	Phase 3	01-02-2027	1148330
palazestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Palazestrant monotherapy for second line or later treatment of locally advanced or metastatic ER-positive, HER2-negative Breast cancer in adults and elderly whose disease has advanced on a endocrine therapy in combination with a CDK4/6 inhibitor	Phase 3	01-01-2028	1202411
palbociclib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Palbociclib in combination with anti-HER2 therapy and endocrine therapy for maintenance treatment of metastatic HR-positive HER2-positive Breast cancer in adults and elderly following induction treatment	Under CHMP evaluation	01-10-2026	1049326
pegargiminase	Other	Pegargiminase in combination with pemetrexed, cisplatin, and carboplatin for first line treatment of unresectable malignant Pleural mesothelioma in adults and elderly	Phase 2/3	01-08-2027	1155431
pelabresib	Small-Molecule Targeted Therapies (Epigenetic modulators)	Pelabresib in combination with ruxolitinib for first line treatment of Myelofibrosis in adults and elderly who are JAK inhibitor-naïve	Phase 3	01-10-2027	1057181
pelareorep	Oncolytic Virus Therapies	Pelareorep in combination with FOLFIRI and bevacizumab for second line treatment of metastatic RAS-mutated microsatellite-stable Colorectal cancer in adults and elderly	Phase 2	01-12-2028	1234809
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with Bacillus Calmette-Guerin for second line treatment of persistent or recurrent high risk Non-muscle invasive bladder cancer in adults and elderly following BCG induction	Phase 3	01-05-2027	1131276
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with concurrent chemoradiation therapy followed by pembrolizumab and olaparib for first line treatment of newly diagnosed limited-stage Small cell lung cancer in adults and elderly	Phase 3	01-08-2028	1133749
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with gemcitabine and cisplatin followed by surgery and postoperative pembrolizumab for neoadjuvant treatment of non-metastatic muscle-invasive Bladder cancer in adults and elderly who are eligible for radical cystectomy and pelvic lymph node dissection	Phase 3	01-07-2027	1137821
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with chemoradiotherapy for first line treatment of non-metastatic muscle-invasive Bladder cancer in adults and elderly	Phase 3	01-11-2027	1141570
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with standard of care chemotherapy for first line, adjuvant treatment of high-risk Endometrial cancer in adults and elderly who have undergone curative intent surgery	Under CHMP evaluation	01-11-2026	1141575
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with enfortumab vedotin for neoadjuvant, adjuvant treatment of non-metastatic muscle invasive Bladder cancer in adults and elderly who are eligible for radical cystectomy plus pelvic lymph node dissection surgery	Under CHMP evaluation	01-10-2026	1152281
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab monotherapy for first line treatment of inoperable, Stage III or IV or recurrent mismatch repair deficient (dMMR) Endometrial carcinoma in adults and elderly	Phase 3	01-03-2028	1161004
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with concurrent chemoradiation therapy followed by pembrolizumab for first line treatment of newly diagnosed limited-stage Small cell lung cancer in adults and elderly	Phase 3	01-08-2028	1219276
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with standard of care chemotherapy and radiotherapy for first line, adjuvant treatment of high-risk Endometrial cancer in adults and elderly who have undergone curative intent surgery	Under CHMP evaluation	01-11-2026	1219379
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with Bacillus Calmette-Guerin for adjuvant treatment of high risk Non-muscle invasive bladder cancer in adults and elderly who have undergone cystoscopy/TURBT and are BCG-naïve	Phase 3	01-05-2027	1220200
pembrolizumab	Immune Checkpoint Inhibitors	Pembrolizumab in combination with belzutifan for adjuvant treatment of intermediate-high risk, high risk, or M1 NED clear cell Renal cell carcinoma in adults and elderly post nephrectomy	Under CHMP evaluation	01-09-2026	1224102
penpulimab	Immune Checkpoint Inhibitors	Penpulimab in combination with cisplatin and gemcitabine for first line treatment of primary metastatic Nasopharyngeal carcinoma in adolescents, adults and elderly	Phase 3	01-08-2027	1106206
petosemtamab	Bispecific Antibody & T-Cell Engagers	Petosemtamab in combination with pembrolizumab for first line treatment of recurrent or metastatic PD-L1-positive Squamous cell carcinoma of head and neck in adults and elderly not amenable to local therapy with curative intent	Phase 3	01-01-2028	1222990
petosemtamab	Bispecific Antibody & T-Cell Engagers	Petosemtamab monotherapy for second line or later treatment of recurrent or metastatic incurable Squamous cell carcinoma of head and neck in adults and elderly whose disease progressed on or after anti-PD-1 therapy and platinum-containing therapy	Phase 3	01-01-2028	1231195
pimicotinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Pimicotinib monotherapy for treatment of unresectable Tenosynovial giant cell tumour in adults and elderly	Under CHMP evaluation	01-01-2027	1182066
pirtobrutinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Pirtobrutinib monotherapy for second line or later treatment of Mantle cell lymphoma in adults and elderly who are BTK inhibitor naïve	Phase 3	01-11-2027	1219520
pirtobrutinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Pirtobrutinib in combination with venetoclax and rituximab for second line or later treatment of Chronic lymphocytic leukaemia, Small cell lymphocytic lymphoma in adults and elderly not previously treated with a non-covalent BTK inhibitor and venetoclax	Phase 3	01-02-2027	1218639
pivekimab sunirine	Antibody-Drug Conjugates	Pivekimab sunirine monotherapy for first line treatment of CD123-positive Blastic plasmacytoid dendritic cell neoplasia in adults and elderly	Phase 1/2	01-08-2027	1144218
pivekimab sunirine	Antibody-Drug Conjugates	Pivekimab sunirine monotherapy for second line or later treatment of relapsed or refractory CD123-positive Blastic plasmacytoid dendritic cell neoplasia in adults and elderly	Phase 1/2	01-08-2027	1220115
plixorafenib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Plixorafenib in combination with cobicistat for salvage treatment of locally advanced or metastatic BRAF Class 1(V600) and Class 2 (including fusions)-harboring Cancer in children over 10 years of age, adolescents, adults and elderly	Phase 2	01-01-2028	1204856
polatuzumab vedotin	Other Monoclonal Antibodies	Polatuzumab vedotin in combination with rituximab, gemcitabine and oxaliplatin for second line or later treatment of relapsed or refractory Diffuse large B-cell lymphoma in adults and elderly	Phase 3	01-02-2027	1123228

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prexasertib	Immune Checkpoint Inhibitors	Prexasertib monotherapy for second line or later treatment of locally advanced or metastatic platinum-resistant high-grade, OncoSignature®-positive Endometrial cancer in adults and elderly	Phase 2	01-09-2028	1219122
prexasertib	Immune Checkpoint Inhibitors	Prexasertib in combination with ultra-low dose gemcitabine for second line or later treatment of high-grade, metastatic OncoSignature®-unselected serous Endometrial cancer in adults and elderly who have received prior platinum-based chemotherapy and anti-PD-(L)1 therapy	Phase 2	01-09-2028	1244168
prexasertib	Immune Checkpoint Inhibitors	Prexasertib monotherapy for second line or later treatment of high-grade, metastatic OncoSignature®-unselected serous Endometrial cancer in adults and elderly who have received prior platinum-based chemotherapy and anti-PD-(L)1 therapy	Phase 2	01-09-2028	1259294
prifetrastat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Prifetrastat in combination with fulvestrant for second line treatment of locally advanced or metastatic HR-positive, HER2-negative Breast cancer in adults and elderly whose disease progressed after prior CDK4/6 inhibitor-based therapy	Phase 3	01-11-2028	1165551
quaratusugene ozeplasmid	Cell & Gene Therapies	Quaratusugene ozeplasmid in combination with atezolizumab for maintenance treatment of extensive stage Small cell lung cancer in adults and elderly who did not develop tumour progression after receiving treatment with atezolizumab and chemotherapy as standard initial treatment	Phase 1/2	01-10-2027	1222474
relacorilant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Relacorilant in combination with nab-paclitaxel for second line or later treatment of advanced platinum-resistant, high-grade serous Fallopian tube cancer, Ovarian epithelial cancer, Primary peritoneal carcinosarcoma in adults and elderly	Under CHMP evaluation	01-11-2026	1024106
retifanlimab	Immune Checkpoint Inhibitors	Retifanlimab in combination with platinum-based chemotherapy for first line treatment of metastatic EGFR-negative, ALK-negative, BRAF-negative, and ROS1-negative, non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-02-2027	1146704
retifanlimab	Immune Checkpoint Inhibitors	Retifanlimab in combination with platinum-based chemotherapy for first line treatment of metastatic squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-02-2027	1219474
revumenib	Small-Molecule Targeted Therapies (Epigenetic modulators)	Revumenib monotherapy for second line treatment of relapsed or refractory KMT2A rearranged Acute leukaemia in infants and toddlers over 30 days of age, children, adolescents, adults and elderly	Phase 1/2	01-10-2027	979668
revumenib	Small-Molecule Targeted Therapies (Epigenetic modulators)	Revumenib monotherapy for treatment of relapsed or refractory NPM1-mutated Acute myeloid leukaemia in infants and toddlers over 30 days of age, children, adolescents, adults and elderly	Phase 1/2	01-08-2027	1196905
rezatapopt	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Rezatapopt monotherapy for second line or later treatment of locally advanced or metastatic TP53 Y220C-mutated Solid tumour in adolescents, adults and elderly	Phase 1/2	01-01-2028	1187091
rinabart sesutecan	Antibody-Drug Conjugates	Rinabart sesutecan monotherapy for second line or later treatment of high grade serous or endometrioid, platinum-resistant Fallopian tube cancer, Ovarian epithelial cancer, Primary peritoneal carcinosarcoma in adults and elderly who have received prior platinum-based therapy	Phase 3	01-01-2028	1166388
rinabart sesutecan	Antibody-Drug Conjugates	Rinabart sesutecan monotherapy for second line or later treatment of recurrent or progressive Endometrial cancer in adults and elderly after platinum-based chemotherapy and PD(L)-1 therapy	Phase 3	01-10-2028	1246372
ripretinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Ripretinib monotherapy for second line treatment of advanced KIT exon 11 and 17/18 mutated Gastrointestinal stromal tumour in adults and elderly who were previously treated with imatinib	Phase 3	01-10-2028	1083383
risvutatug rezetecan	Antibody-Drug Conjugates	Risvutatug rezetecan monotherapy for second line treatment of relapsed, extensive-stage Small cell lung cancer in adults and elderly	Phase 3	01-02-2029	1002418
rivoceranib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Rivoceranib in combination with camrelizumab for first line treatment of advanced Hepatocellular carcinoma in adults and elderly	Phase 3	01-10-2027	971208
rondecabtagene autoleucl	Cell & Gene Therapies	Rondecabtagene autoleucl monotherapy for third line or later treatment of relapsed or refractory aggressive B-cell non-Hodgkin's lymphoma in adults and elderly who are CAR-T naïve and previously treated with anti-CD20 monoclonal antibody and an anthracycline containing chemotherapy regimen	Phase 1/2	01-07-2028	1195685
ropeginterferon alfa-2b	Other	Ropeginterferon alfa-2b monotherapy for second line treatment of high risk Essential thrombocythaemia in adults and elderly with hydroxyurea resistance or intolerance	Phase 3	01-04-2027	1152975
ropeginterferon alfa-2b	Other	Ropeginterferon alfa-2b monotherapy for first line treatment of pre-fibrotic/early or overt low to intermediate-1 risk Myelofibrosis in adults and elderly	Phase 3	01-07-2028	1230238
ropeginterferon alfa-2b	Other	Ropeginterferon alfa-2b monotherapy for first line or later treatment of Essential thrombocythaemia in adults and elderly who are intolerant or refractory to or not eligible for other cytoreductive treatments	Phase 3	01-01-2029	1231393
rusfertide	Other	Rusfertide monotherapy for add-on treatment of Polycythaemia vera in adults and elderly with JAK2 V617F mutation or JAK2 exon 12 mutation	Phase 3	01-09-2027	987162
sacituzumab govitecan	Antibody-Drug Conjugates	Sacituzumab govitecan in combination with pembrolizumab for adjuvant treatment of triple-negative Breast cancer in adults and elderly who have residual invasive disease after surgery and neoadjuvant therapy	Phase 3	01-10-2028	1079061
sacituzumab govitecan	Antibody-Drug Conjugates	Sacituzumab govitecan in combination with pembrolizumab for first line treatment of locally advanced, inoperable, or metastatic PD-L1 positive, triple-negative Breast cancer in adults and elderly	Under CHMP evaluation	01-09-2026	1140932
sacituzumab tirumotecan	Cytotoxic Chemotherapy	Sacituzumab tirumotecan monotherapy for second line or later treatment of Endometrial cancer in adults and elderly who have received prior platinum-based chemotherapy and immunotherapy	Phase 3	01-09-2027	1002585
sacituzumab tirumotecan	Cytotoxic Chemotherapy	Sacituzumab tirumotecan in combination with pembrolizumab for second line or later treatment of unresectable locally advanced or metastatic HR-positive, HER2-negative Breast cancer in adults and elderly with radiographic disease progression after ≥1 line of endocrine therapy, including combination with a CDK4/6 inhibitor	Phase 3	01-11-2028	1226337
sacituzumab tirumotecan	Cytotoxic Chemotherapy	Sacituzumab tirumotecan monotherapy for third line or later treatment of advanced/metastatic unresectable gastric, gastroesophageal junction and oesophageal Adenocarcinoma in adults and elderly	Phase 3	01-05-2028	1227864
saruparib	Small-Molecule Targeted Therapies (PARP inhibitors)	Saruparib in combination with new hormonal agents for first line or later treatment of metastatic HRRm and non-HRRm, hormone-sensitive Prostate cancer in adults and elderly	Phase 3	01-01-2029	1002588

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satricabtagene autoleucl	Cell & Gene Therapies	Satricabtagene autoleucl monotherapy for second line treatment of advanced CLDN18.2 expression-positive Pancreatic cancer in adults and elderly	Phase 1/2	01-01-2028	1153185
satricabtagene autoleucl	Cell & Gene Therapies	Satricabtagene autoleucl monotherapy for third line or later treatment of advanced CLDN18.2 expression-positive gastric or gastroesophageal junction Adenocarcinoma in adults and elderly	Phase 1/2	01-01-2028	1200469
savolitinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Savolitinib in combination with osimertinib for second line or later treatment of locally advanced or metastatic EGFR-mutated, MET-overexpressed and/or amplified Non-small cell lung cancer in adults and elderly who have progressed on treatment with osimertinib	Phase 3	01-01-2028	1070875
selinexor	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Selinexor in combination with ruxolitinib for first line treatment of intermediate-1, or intermediate-2 or high-risk Myelofibrosis in adults and elderly	Phase 3	01-04-2027	1073561
selinexor	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Selinexor monotherapy for maintenance treatment of advanced or recurrent TP53 wild-type Endometrial cancer in adults and elderly who achieved confirmed partial or complete response to platinum-based therapy	Phase 3	01-04-2027	1075670
sepercatinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Selpercatinib monotherapy for adjuvant treatment of early stage (IB-IIIA) RET fusion-positive Non-small cell lung cancer in adults and elderly following definitive locoregional treatment with curative intent	Phase 3	01-02-2027	982632
senaparib	Small-Molecule Targeted Therapies (PARP inhibitors)	Senaparib monotherapy for first line, maintenance treatment of newly diagnosed III/IV BRCA mutation-positive Ovarian cancer in adults and elderly following first-line platinum-based chemotherapy	Under CHMP evaluation	01-09-2026	1071065
serplulimab	Immune Checkpoint Inhibitors	Serplulimab in combination with chemotherapy and concurrent radiotherapy for first line treatment of limited stage Small cell lung cancer in adults and elderly	Phase 3	01-01-2028	1142115
sevabertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Sevabertinib monotherapy for second line treatment of locally advanced EGFR and/or HER2 mutated Non-small cell lung cancer in adults and elderly	Phase 1/2	01-08-2027	1194751
sevabertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Sevabertinib monotherapy for first line treatment of locally advanced or metastatic activating HER2 mutation-positive non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-08-2028	1229769
sigvotatug vedotin	Antibody-Drug Conjugates	Sigvotatug vedotin monotherapy for second line or later treatment of locally advanced, unresectable (stage iiib, iiic), or metastatic non squamous Non-small cell lung cancer in adults and elderly previously treated with platinum-based chemotherapy and an anti-PD-(L)1 drug	Phase 3	01-10-2027	1222749
sintilimab	Immune Checkpoint Inhibitors	Sintilimab in combination with pemetrexed and platinum for first line treatment of advanced or metastatic non-squamous Non-small cell lung cancer in adults and elderly	Under CHMP evaluation	01-01-2027	1117917
snb-101	Cytotoxic Chemotherapy	Snb-101 monotherapy for second line or later treatment of extensive-stage Small cell lung cancer in adults and elderly	Phase 1/2	01-12-2028	1255307
soficabtagene geleucl	Cell & Gene Therapies	Soficabtagene geleucl monotherapy for second line treatment of relapsed or refractory T-cell Acute lymphoblastic leukaemia in infants and toddlers, children, adolescents, adults and elderly	Phase 2	01-04-2028	1167059
soficabtagene geleucl	Cell & Gene Therapies	Soficabtagene geleucl monotherapy for second line treatment of relapsed or refractory Lymphoblastic lymphoma in infants and toddlers, children, adolescents, adults and elderly	Phase 2	01-04-2028	1219131
sonesitatug vedotin	Antibody-Drug Conjugates	Sonesitatug vedotin monotherapy for second line or later treatment of unresectable, locally advanced or metastatic CLDN18.2-positive gastric or gastroesophageal junction Adenocarcinoma in adults and elderly	Phase 3	01-01-2028	1227105
sonrotoclax	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Sonrotoclax monotherapy for third line or later treatment of relapsed or refractory Mantle cell lymphoma in adults and elderly previously treated with a Bruton's tyrosine kinase inhibitor (BTKi) and anti-CD20 based immune or chemoimmunotherapy	Under CHMP evaluation	01-03-2027	1207495
sonrotoclax	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Sonrotoclax monotherapy for second line treatment of relapsed/refractory Waldenstrom's macroglobulinaemia in adults and elderly	Phase 2	01-04-2028	1226313
sotorasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Sotorasib in combination with carboplatin and pemetrexed for first line treatment of stage IV or advanced stage IIIB or IIIC KRAS p. G12C mutated, PD-L1 negative non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-04-2028	984164
sotorasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Sotorasib in combination with panitumumab for second line or later treatment of metastatic KRAS p.G12C mutated Colorectal cancer in adults and elderly	Phase 3	01-02-2027	1191507
sotorasib	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Sotorasib in combination with panitumumab and FOLFIRI for first line treatment of metastatic KRAS p.G12C mutated Colorectal cancer in adults and elderly	Phase 3	01-11-2028	1223003
sunvozertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Sunvozertinib monotherapy for first line treatment of locally advanced or metastatic EGFR exon 20 insertion mutated non-squamous Non-small cell lung cancer in adults and elderly not suitable to curative therapy	Phase 3	01-08-2027	985930
tabelecleucl	Cell & Gene Therapies	Tabelecleucl monotherapy for first line treatment of newly diagnosed Epstein-Barr virus associated lymphoproliferative disorder in infants and toddlers, children, adolescents, adults and elderly when standard first line therapy is inappropriate	Phase 2	01-04-2028	1147071
tacabrutideg	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Tacabrutideg monotherapy for second line or later treatment of Waldenstrom's macroglobulinaemia in adults and elderly	Phase 1/2	01-03-2028	1244737
tafasitamab	Other Monoclonal Antibodies	Tafasitamab in combination with lenalidomide and R-CHOP for first line treatment of newly diagnosed, high-intermediate and high risk CD20-positive Diffuse large B-cell lymphoma in adults and elderly	Under CHMP evaluation	01-11-2026	1130951
talazoparib	Small-Molecule Targeted Therapies (PARP inhibitors)	Talazoparib in combination with enzalutamide for second line treatment of metastatic DDR-gene mutated, castration-sensitive Prostate cancer in adults and elderly	Phase 3	01-02-2027	985093
taletrectinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Taletrectinib monotherapy for second line treatment of locally advanced or recurrent or metastatic ROS1-positive Non-small cell lung cancer in adults and elderly who are TKI-naïve	Under CHMP evaluation	01-04-2027	1232430
talquetamab	Bispecific Antibody & T-Cell Engagers	Talquetamab in combination with pomalidomide and dexamethasone for second line or later treatment of relapsed/refractory Multiple myeloma in adults and elderly who have received an anti-CD38 antibody and lenalidomide	Phase 3	01-05-2027	1225289
talquetamab	Bispecific Antibody & T-Cell Engagers	Talquetamab in combination with teclistamab and dexamethasone for second line or later treatment of relapsed/refractory Multiple myeloma in	Phase 3	01-05-2027	1229084

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		adults and elderly who have received an anti-CD38 antibody and lenalidomide			
talquetamab	Bispecific Antibody & T-Cell Engagers	Talquetamab in combination with daratumumab, pomalidomide and dexamethasone for second line or later treatment of relapsed or refractory Multiple myeloma in adults and elderly who received at least 1 prior line of antineoplastic therapy including a proteasome inhibitor and lenalidomide	Under CHMP evaluation	01-11-2026	1213462
talquetamab	Bispecific Antibody & T-Cell Engagers	Talquetamab in combination with daratumumab and dexamethasone for second line or later treatment of relapsed or refractory Multiple myeloma in adults and elderly who received at least 1 prior line of antineoplastic therapy including a proteasome inhibitor and lenalidomide	Under CHMP evaluation	01-11-2026	1219783
tambiciclib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Tambiciclib in combination with venetoclax and azacitidine for first line treatment of newly diagnosed Acute myeloid leukaemia in adolescents, adults and elderly with higher risk features by cytogenetic/morphology	Phase 1/2	01-04-2028	1258567
tambiciclib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Tambiciclib in combination with venetoclax and azacitidine for first line treatment of Acute myeloid leukaemia in adolescents, adults and elderly who failed to achieve a best response after 2 cycles of azacitidine/venetoclax	Phase 1/2	01-04-2028	1258568
tar-200	Other	Tar-200 monotherapy for second line treatment of high-risk BCG-unresponsive Non-muscle invasive bladder cancer in adults and elderly who are not candidates for or opted not to receive radical cystectomy	Phase 2	01-08-2027	1219385
tar-200	Other	Tar-200 monotherapy for second line treatment of high-risk BCG-unresponsive, high-grade Non-muscle invasive bladder cancer in adults and elderly with papillary disease who are ineligible for or elected not to undergo radical cystectomy	Phase 3	01-01-2028	1219386
tar-210 erdafitinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Tar-210 erdafitinib monotherapy for treatment of high-risk papillary-only Non-muscle invasive bladder cancer in adults and elderly who have susceptible FGFR alterations who had received intravesical Bacillus Calmette-Guérin (BCG)	Phase 3	01-12-2028	1240332
tara-002	Cell & Gene Therapies	Tara-002 monotherapy for treatment of high-grade BCG unresponsive Non-muscle invasive bladder cancer in adults and elderly	Phase 2	01-10-2028	1257777
tarlatamab	Bispecific Antibody & T-Cell Engagers	Tarlatamab monotherapy for third line or later treatment of relapsed/refractory Small cell lung cancer in adults and elderly who have progressed following one platinum-based regimen and at least one other prior line of therapy	Phase 2	01-10-2027	1219517
tarlatamab	Bispecific Antibody & T-Cell Engagers	Tarlatamab in combination with durvalumab for maintenance treatment of extensive stage Small cell lung cancer in adults and elderly following platinum-etoposide chemotherapy with concurrent durvalumab	Phase 3	01-11-2028	1222060
tebentafusp	Bispecific Antibody & T-Cell Engagers	Tebentafusp in combination with pembrolizumab for third line or later treatment of stage III or IV, unresectable HLA-A*02:01 positive non-ocular Melanoma in adults and elderly who have progressed on an anti-PD1, received prior ipilimumab and, if applicable, received a BRAF kinase inhibitor	Phase 3	01-10-2027	1142161
tebentafusp	Bispecific Antibody & T-Cell Engagers	Tebentafusp monotherapy for third line or later treatment of unresectable stage III or IV HLA-A*02:01 positive non-ocular Melanoma in adults and elderly who have progressed on an anti-PD1, received prior ipilimumab and, if applicable, received a BRAF kinase inhibitor	Phase 3	01-10-2027	1220096
teclistamab	Bispecific Antibody & T-Cell Engagers	Teclistamab monotherapy for second line or later treatment of progressive, relapsed or refractory Multiple myeloma in adults and elderly who have received an anti-CD38 monoclonal antibody and lenalidomide in any previous line	Under CHMP evaluation	01-10-2026	974453
telisotuzumab adizutecan	Antibody-Drug Conjugates	Telisotuzumab adizutecan monotherapy for treatment of refractory metastatic c-Met over-expressed Colorectal cancer in adults and elderly	Phase 3	01-12-2028	1225420
telisotuzumab vedotin	Antibody-Drug Conjugates	Telisotuzumab vedotin monotherapy for second line or later treatment of locally advanced or metastatic c-Met overexpressing, EGFR wild-type non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-10-2027	1141059
tinengotinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Tinengotinib monotherapy for second line or later treatment of refractory/relapsed, metastatic, unresectable FGFR-altered Cholangiocarcinoma in adults and elderly	Phase 3	01-04-2028	985905
tislelizumab	Immune Checkpoint Inhibitors	Tislelizumab in combination with chemotherapy for first line treatment of locally advanced unresectable or metastatic gastric or gastroesophageal junction Adenocarcinoma in adults and elderly	Phase 3	01-02-2029	1243008
tld-1433	Other	Tld-1433 monotherapy for first line treatment of BCG unresponsive or intolerant, with/without resected papillary disease (Ta, T1) (high grade) Non-muscle invasive bladder cancer in adults and elderly	Phase 2	01-10-2027	984511
tlx101-tx	Radiopharmaceuticals	Tlx101-tx in combination with standard of care for second line treatment of recurrent Glioblastoma in adults and elderly	Phase 3	01-11-2028	1244527
tovecimig	Bispecific Antibody & T-Cell Engagers	Tovecimig in combination with paclitaxel for second line treatment of advanced, metastatic or recurrent unresectable Cholangiocarcinoma in adults and elderly who have received prior systemic chemotherapy regimen and are not eligible to be treated with a molecularly targeted therapy	Phase 2/3	01-11-2027	1023822
tovorafenib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Tovorafenib monotherapy for first line treatment of RAF-altered low-grade Glioma in newborns, infants, toddlers, children, adolescents and adults up to 25 years of age	Phase 3	01-04-2028	1218659
trabedersen	Other	Trabedersen in combination with mFOLFIRINOX for treatment of advanced and unresectable or metastatic Pancreatic cancer in adults and elderly	Phase 2/3	01-10-2027	1220498
trastuzumab deruxtecan	Antibody-Drug Conjugates	Trastuzumab deruxtecan in combination with pertuzumab for first line or later treatment of advanced or metastatic HER2-positive Breast cancer in adults and elderly	Under CHMP evaluation	01-09-2026	975068
trastuzumab deruxtecan	Antibody-Drug Conjugates	Trastuzumab deruxtecan monotherapy for first line or later treatment of advanced or metastatic HER2-positive Breast cancer in adults and elderly with no more than 1 previous line of endocrine therapy in the metastatic setting	Phase 3	01-05-2027	1011558
trastuzumab deruxtecan	Antibody-Drug Conjugates	Trastuzumab deruxtecan monotherapy for first line treatment of unresectable, locally advanced or metastatic HER2 Exon 19 or 20-mutated, non-squamous Non-small cell lung cancer in adults and elderly who are treatment-naïve for palliative intent systemic therapy	Phase 3	01-03-2027	1159542
trastuzumab deruxtecan	Antibody-Drug Conjugates	Trastuzumab deruxtecan monotherapy for second line treatment of high-risk HER2 positive primary Breast cancer in adults and elderly with residual invasive breast cancer following neoadjuvant therapy	Under CHMP evaluation	01-09-2026	1217407

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trastuzumab deruxtecan	Cytotoxic Chemotherapy	Trastuzumab deruxtecan in combination with paclitaxel, trastuzumab and pertuzumab for neoadjuvant treatment of high risk early stage HER2-positive Breast cancer in adults and elderly	Phase 3	01-08-2027	1219334
trastuzumab pamirtecan	Cytotoxic Chemotherapy	Trastuzumab pamirtecan monotherapy for second line or later treatment of recurrent HER2-expressing Endometrial cancer in adults and elderly previously treated with platinum-based therapy and ICI treatment	Phase 1/2	01-10-2027	1139542
trastuzumab pamirtecan	Cytotoxic Chemotherapy	Trastuzumab pamirtecan monotherapy for third line or later treatment of advanced or metastatic HER2-low, HR-positive Breast cancer in adults and elderly whose disease has progressed on endocrine therapy and/or cyclin-dependent kinase 4/6 (CDK4/6) therapy and who are chemotherapy-naïve	Phase 3	01-12-2027	1226556
trilaciclib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Trilaciclib monotherapy for second line treatment of extensive stage chemotherapy-induced myelosuppression for Small cell lung cancer in adults and elderly when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen	Under CHMP evaluation	01-09-2026	1063365
trilaciclib	Small-Molecule Targeted Therapies (Serine/threonine & pathway kinase inhibitors)	Trilaciclib monotherapy for treatment of myelosuppression prevention associated with limited stage Small cell lung cancer in adults and elderly	Phase 3	01-10-2028	1257066
tub-040	Antibody-Drug Conjugates	Tub-040 monotherapy for salvage treatment of high-grade, platinum-resistant Ovarian cancer in adults and elderly	Phase 1/2	01-05-2028	1221982
tucatinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Tucatinib in combination with trastuzumab and pertuzumab for maintenance treatment of locally advanced or metastatic, unresectable HER2- positive Breast cancer in adults and elderly	Under CHMP evaluation	01-10-2026	1037495
tucatinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Tucatinib in combination with trastuzumab and mFOLFOX6 for first line treatment of locally advanced unresectable or metastatic HER2-positive, RAS wild-type Colorectal cancer in adults and elderly	Phase 3	01-05-2027	1080336
tucidinostat	Small-Molecule Targeted Therapies (Epigenetic modulators)	Tucidinostat in combination with nivolumab for first line or later treatment of unresectable or metastatic non-veal Melanoma in adolescents, adults and elderly who were not previously treated with PD-1 or PD-L1 inhibitors	Phase 3	01-11-2027	978878
varegacestat	Small-Molecule Targeted Therapies (Other targeted small molecules)	Varegacestat monotherapy for first line or later treatment of progressing Desmoid tumour in adolescents, adults and elderly	Phase 2/3	01-08-2027	1136271
vebreltinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Vebreltinib monotherapy for first line or later treatment of unresectable or metastatic c-Met Exon14 skip mutations, c-Met naïve/experienced Non-small cell lung cancer in adults and elderly	Phase 2	01-10-2027	1094577
vebreltinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Vebreltinib monotherapy for fourth line or later treatment of harboring MET amplification and wild-type epidermal growth factor receptor (EGFR), MET inhibitor naïve Non-small cell lung cancer in adults and elderly	Phase 2	01-10-2027	1246930
venetoclax	Small-Molecule Targeted Therapies (Apoptosis & protein homeostasis)	Venetoclax in combination with acalabrutinib for first line treatment of Chronic lymphocytic leukaemia in adults and elderly	Phase 3	01-01-2029	1231800
vepdegestrant	Small-Molecule Targeted Therapies (Hormone & endocrine therapies)	Vepdegestrant monotherapy for second line treatment of advanced metastatic ER-positive, HER2-negative Breast cancer in adults and elderly previously treated with endocrine-based therapy	Phase 3	01-10-2027	1217532
volrustomig	Bispecific Antibody & T-Cell Engagers	Volrustomig in combination with chemotherapy for first line treatment of metastatic EGFR-, ALK-, ROS1-negative Non-small cell lung cancer in adults and elderly with PD-L1 <50% who are not amenable to curative surgery or radiation	Phase 3	01-01-2029	1209930
vs-7375	Small-Molecule Targeted Therapies (RAS/KRAS pathway inhibitors)	Vs-7375 monotherapy for second line or later treatment of locally advanced or metastatic unresectable, KRAS G12D-mutated Ductal adenocarcinoma of pancreas in adults and elderly	Phase 2	01-10-2028	1242394
vusolimogene oderparepvec	Oncolytic Virus Therapies	Vusolimogene oderparepvec in combination with nivolumab for second line treatment of advanced cutaneous Melanoma in adolescents, adults and elderly who progressed on anti-PD-1 and anti-CTLA-4 containing treatment or are ineligible for anti-CTLA-4 treatment	Phase 2	01-10-2027	1226676
vusolimogene oderparepvec	Oncolytic Virus Therapies	Vusolimogene oderparepvec in combination with nivolumab for second line treatment of MSI-H or dMMR Solid tumour in adults and elderly who has progressed on prior anti-PD1/PD-L1 therapy	Phase 2	01-10-2027	1235473
zamtocabtagene autoleucl	Cell & Gene Therapies	Zamtocabtagene autoleucl monotherapy for second line treatment of relapsed/refractory Diffuse large B-cell lymphoma in adults and elderly who are not eligible for high-dose chemotherapy and autologous stem cell transplantation	Under CHMP evaluation	01-04-2027	1183560
zamtocabtagene autoleucl	Cell & Gene Therapies	Zamtocabtagene autoleucl monotherapy for third line or later treatment of relapsed/refractory Diffuse large B-cell lymphoma in adults and elderly who are not eligible for high-dose chemotherapy and autologous stem cell transplantation	Phase 2	29-04-2028	1193133
zanidatamab	Bispecific Antibody & T-Cell Engagers	Zanidatamab in combination with chemotherapy for first line treatment of unresectable locally advanced or metastatic HER2-positive gastric, gastro-oesophageal junction and oesophageal Adenocarcinoma in adults and elderly	Phase 3	01-02-2027	1142619
zanidatamab	Bispecific Antibody & T-Cell Engagers	Zanidatamab in combination with chemotherapy and tislelizumab for first line treatment of unresectable locally advanced, recurrent or metastatic HER2-positive gastric, gastro-oesophageal junction and oesophageal Adenocarcinoma in adults and elderly	Phase 3	01-04-2027	1219327
zanubrutinib	Small-Molecule Targeted Therapies (Non-receptor tyrosine kinase inhibitors)	Zanubrutinib in combination with rituximab for first line treatment of Mantle cell lymphoma in adults from 60 years of age and elderly who are not eligible for stem cell transplantation	Phase 3	01-04-2027	1124541
zanzalintinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zanzalintinib in combination with atezolizumab for third line treatment of metastatic microsatellite stable or microsatellite instability low Colorectal cancer in adults and elderly who have progressed after or are intolerant to standard of care therapy	Phase 3	01-10-2027	987693
zanzalintinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zanzalintinib in combination with nivolumab for first line treatment of unresectable, locally advanced or metastatic non-clear cell Renal cell carcinoma in adults and elderly	Phase 3	01-10-2027	1209223
zenocutuzumab	Bispecific Antibody & T-Cell Engagers	Zenocutuzumab monotherapy for second line treatment of locally advanced unresectable or metastatic NRG1 fusion-positive Pancreatic cancer in adults and elderly	Phase 2	01-09-2027	1141095
zenocutuzumab	Bispecific Antibody & T-Cell Engagers	Zenocutuzumab monotherapy for second line treatment of locally advanced unresectable or metastatic NRG1 fusion-positive Non-small cell lung cancer in adults and elderly	Phase 2	01-09-2027	1229097

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zenocutuzumab	Bispecific Antibody & T-Cell Engagers	Zenocutuzumab monotherapy for second line treatment of NRG1 fusion-positive Cholangiocarcinoma in adults and elderly	Phase 2	01-08-2027	1126858
zidesamtinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zidesamtinib monotherapy for third line or later treatment of locally advanced or metastatic ROS1-positive Non-small cell lung cancer in adults and elderly who have been previously treated with two or more ROS1 tyrosine kinase inhibitors	Phase 1/2	01-08-2027	1159334
zidesamtinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zidesamtinib monotherapy for first line or later treatment of locally advanced or metastatic ROS1-positive, tyrosine kinase inhibitor-naive Non-small cell lung cancer in adults and elderly	Phase 1/2	01-10-2027	1260576
ziftomenib	Small-Molecule Targeted Therapies (Epigenetic modulators)	Ziftomenib monotherapy for second line or later treatment of relapsed/refractory NPM1-mutant Acute myeloid leukaemia in adults and elderly who have failed or are ineligible for any approved standard of care therapies, including HSCT	Phase 1/2	01-10-2027	1200593
zilovertamab vedotin	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zilovertamab vedotin in combination with standard of care for second line or later treatment of relapsed or refractory Diffuse large B-cell lymphoma in adults and elderly who are ineligible for autologous stem cell transplant and/or CAR-T therapy	Phase 2/3	01-10-2028	1140850
zipalertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zipalertinib in combination with pemetrexed and carboplatin or cisplatin for first line treatment of locally advanced or metastatic EGFR exon 20 insertion mutation non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-02-2028	1222699
zipalertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zipalertinib monotherapy for second line treatment of locally advanced or metastatic EGFR exon 20 insertion mutation Non-small cell lung cancer in adults and elderly who have received prior platinum-based chemotherapy	Phase 1/2	01-08-2027	1229016
zocilurtatug pelitecan	Antibody-Drug Conjugates	Zocilurtatug pelitecan monotherapy for second line or later treatment of relapsed Small cell lung cancer in adults and elderly with disease progression during or after the most recent systemic therapy	Phase 3	01-01-2029	1225460
zongertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zongertinib monotherapy for second line or later treatment of advanced, unresectable and/or metastatic HER2 tyrosine kinase domain mutated Non-small cell lung cancer in adults and elderly	Phase 1	01-11-2027	1168299
zongertinib	Small-Molecule Targeted Therapies (Receptor tyrosine kinase inhibitors)	Zongertinib monotherapy for first line treatment of unresectable, locally advanced or metastatic HER2 tyrosine kinase domain mutations-positive non-squamous Non-small cell lung cancer in adults and elderly	Phase 3	01-03-2028	1222973