Mirvetuximab soravtansine (Elahere®) for the treatment of adults with folate receptor-alpha (FRα) positive epithelial ovarian, fallopian tube and primary peritoneal cancer

General information

Drug description [1]

Mirvetuximab soravtansine (Elahere®) is an antineoplastic monoclonal antibody-drug conjugate.

Indication [1]

Mirvetuximab soravtansine (Elahere®) is indicated for the treatment of adults with FRα positive epithelial ovarian, fallopian tube and primary peritoneal cancer.

Incidence [2]

In Austria, in 2022, a total of 718 women were newly diagnosed with ovarian cancer. The age standardised incidence rate[1] in Austria was in 2022 for females 14.1 per 100 000. As of 2022, prevalence in absolute numbers was 7197.

Current treatment [3]

The Onkopedia treatment recommendation for the treatment of ovarian cancer is displayed in Figure 1 of the Appendix.

Regulatory status

EMA [1]	FDA [4]
Approval status: On September 19 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending marketing authorisation for the medicinal product Elahere®. The indication is as follows: Elahere® as monotherapy is indicated for the treatment of adult patients with FRα positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens. Elahere® should be prescribed and supervised by physicians experienced in the use of cancer treatments. Detailed recommendations for the use of this product will be described in the summary of product characteristics, which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission. Other indications: None. ✓ **Orphan status**	**Approval status**: On March 22, 2024, the FDA approved mirvetuximab soravtansine-gynx (Elahere®) for adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Accelerated approval was granted for this drug on November 14, 2022. The indication is as follows: Elahere® is indicated for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test. Other indications: None.

Marketing authorisation holder in EU [1]

AbbVie Deutschland GmbH & Co. KG

Costs

Not yet determined.

[1] European Standard Population 2013.

Posology [5][2]

The recommended dose of Elahere® is 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity.

The total dose of Elahere® is calculated based on each patient's AIBW using the following formula:

AIBW = Ideal Body Weight (IBW [kg]) + 0.4*(Actual weight [kg] – IBW)

Female IBW (kg) = 0.9*height(cm) – 92

Premedicate with a corticosteroid, antihistamine, antipyretic, antiemetic, ophthalmic topical steroids, and lubricating eye drops.

Warnings and precautions [5][2]

Ocular Disorders

Elahere® can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis. Ocular adverse reactions occurred in 61% of patients with ovarian cancer treated with Elahere®. 9% of patients experienced Grade 3 ocular adverse reactions, including visual impairment, keratopathy/keratitis (corneal disorders), dry eye, photophobia, and eye pain; and one patient (0.2%) experienced Grade 4 keratopathy. The most common (≥5%) ocular adverse reactions were visual impairment (49%), keratopathy (36%), dry eye (26%), cataract (15%), photophobia (13%), and eye pain (12%).

The median time to onset for first ocular adverse reaction was 1.2 months (range: 0.03 to 12.9). Of the patients who experienced ocular events, 49% had complete resolution, and 39% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow-up. Ocular adverse reactions led to permanent discontinuation of Elahere® in 0.6% of patients. Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with Elahere® are recommended. Advise patients to avoid use of contact lenses during treatment with Elahere® unless directed by a healthcare provider. Refer patients to an eye care professional for an ophthalmic exam, including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms. Monitor for ocular toxicity and withhold, reduce, or permanently discontinue Elahere® based on the severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease, including pneumonitis, can occur in patients treated with Elahere®. Pneumonitis occurred in 10% of patients treated with Elahere®, including 0.8% with Grade 3 events, and 1 patient (0.2%) with a Grade 4 event. One patient (0.2%) died due to respiratory failure in the setting of pneumonitis and lung metastases. Pneumonitis resulted in Elahere® dose reduction in 1%, dose interruptions in 3%, and permanent discontinuation in 3% of patients. Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold Elahere® for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue Elahere® in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of Elahere® with close monitoring.

Peripheral Neuropathy

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with Elahere® across clinical trials; 2% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (19%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (2%), peripheral motor neuropathy (1%), neuralgia (0.4%), polyneuropathy (0.2%) and oral hypoesthesia (0.2%). The median time to onset of peripheral neuropathy was 1.3 months (range 0.03 to 29.1). Of the patients who experienced peripheral neuropathy, 28% had complete resolution and 13% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow-up. Peripheral neuropathy led to discontinuation of Elahere® in 0.4% of patients. Monitor patients for signs and symptoms of neuropathy, such as paraesthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening peripheral neuropathy, withhold dosage, dose reduce, or permanently discontinue Elahere® based on the severity of peripheral neuropathy.

Embryo-Fetal Toxicity

Based on its mechanism of action, Elahere® can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Elahere® and for 7 months after the last dose.

[2] Based on the FDA label

Study characteristics [6]									
Trial name/ NCT number	*n*	Intervention (I)	Comparator (C)	PE	Median follow-up	Characteristics	Biomarker	Funding	Publication(s)
NCT04209855 MIRASOL	453 (1:1)	Mirvetuximab soravtansine-gynx administered i.v. at a dose of 6 mg/kg of adjusted ideal body weight every 3 weeks.	Paclitaxel, pegylated liposomal doxorubicin or topotecan.[3]	PFS (investigator-assessed)	Not reported	open-label, multicentre, phase 3 trial	CA-125	ImmunoGen	MIRASOL [6]

Inclusion criteria[4]	Exclusion criteria	Patient characteristics at baseline I (n=227) vs. C (n=226)
❖ Female patients ≥ 18 years of age. ❖ Confirmed diagnosis of high-grade serous EOC, primary peritoneal cancer, or fallopian tube cancer. ❖ Platinum-resistant disease. ❖ Progressed radiographically on or after their most recent line of therapy. ❖ Willing to provide an archival tumour tissue block or slides or undergo a procedure to obtain a new biopsy using a low risk, medically routine procedure for immunohistochemistry confirmation of FRα positivity. ❖ Patient's tumor must be positive for FRα expression as defined by the Ventana FOLR1 CDx assay. ❖ At least one lesion that meets the definition of measurable disease by RECIST v1.1. ❖ Must have received at least 1 but no more than 3 prior systemic lines of anticancer therapy, and single-agent therapy is appropriate as the next line of treatment. ❖ Eastern Cooperative Oncology Group Performance Status of 0 or 1. ❖ Time from prior therapy: a. Systemic antineoplastic therapy (5 half-lives or 4 weeks). b. Focal radiation at least 2 weeks prior to first dose of study drug. ❖ Major surgery must be completed at least 4 weeks prior to first dose and have recovered or stabilised from the side effects of prior surgery. ❖ Adequate hematologic, liver, and kidney functions. ❖ Patients or their legally authorised representative must be willing and able to sign the informed consent form and to adhere to the protocol requirements.	❖ Endometrioid, clear cell, mucinous, or sarcomatous histology, mixed tumours containing any of the above histologies, or low-grade or borderline ovarian tumour. ❖ Primary platinum-refractory disease, defined as disease that did not respond to or has progressed within 3 months of the last dose of first line platinum-containing chemotherapy. ❖ Prior wide-field radiotherapy affecting at least 20% of the bone marrow. ❖ > Grade 1 peripheral neuropathy. ❖ Active or chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring treatment (uncontrolled glaucoma, wet age-related macular degeneration, active diabetic retinopathy with macular oedema, macular degeneration, presence of papilledema, and /or monocular vision). ❖ Serious concurrent illness or clinically relevant active infection. ❖ History of multiple sclerosis or other demyelinating disease and/or Lambert-Eaton syndrome. ❖ Clinically significant cardiac disease. ❖ Patients were assigned to PLD stratum only. ❖ History of hemorrhagic/ischemic stroke within six months prior to study. ❖ History of cirrhotic liver disease (Child-Pugh Class B or C). ❖ Previous clinical diagnosis of non-infectious interstitial lung disease, including non-infectious pneumonitis. ❖ Required use of folate-containing supplements. ❖ Prior hypersensitivity to monoclonal antibodies.	❖ Median age (range) yr: 64 (32–88) vs 62 (29–87) ❖ ≥65 yr — no. (%): 107 (47.1) vs 92 (40.7) ❖ Race — no. (%) o White: 156 (68.7) vs 145 (64.2) o Black: 8 (3.5) vs 5 (2.2) o Asian: 28 (12.3) vs 25 (11.1) o Not reported: 32 (14.1) vs 49 (21.7) o Other 3: (1.3) vs 2 (0.9) ❖ Ethnic group — no. (%) o Hispanic or Latino: 12 (5.3) vs 15 (6.6) o Not Hispanic or Latino: 177 (78.0) vs 163 (72.1) o Unknown: 2 (0.9) vs 2 (0.9) o Not reported: 35 (15.4) vs 45 (19.9) o Missing data: 1 (0.4) vs 1 (0.4) ❖ Primary cancer diagnosis — no. (%) o Epithelial ovarian cancer: 182 (80.2) vs 182 (80.5) o Fallopian tube cancer: 27 (11.9) vs 23 (10.2) o Primary peritoneal cancer: 16 (7.0) vs 20 (8.8) o Other: 2 (0.9) vs 1 (0.4) ❖ Stage at initial diagnosis — no. (%) o IA or IIA: 7 (3.1) vs 1 (0.4) o IIB or IIC: 2 (0.9) vs 8 (3.5) o IIIA 14: (6.2) vs 16 (7.1) o IIIB 16: (7.0) vs 11 (4.9) o IIIC 107: (47.1) vs 120 (53.1) o IV: 76 (33.5) vs 65 (28.8) o Missing data: 5 (2.2) vs 5 (2.2) ❖ ECOG performance-status score — no. (%) o 0: 130 (57.3) vs 120 (53.1)

[3] Paclitaxel (80 mg per square meter of body-surface area, administered i.v. on days 1, 8, 15, and 22 of a 4-week cycle), pegylated liposomal doxorubicin (40 mg per square meter, administered i.v. on day 1 of a 4-week cycle), or topotecan (4 mg per square meter, administered i.v. on days 1, 8, and 15 of a 4-week cycle, or 1.25 mg per square meter, administered i.v. on days 1 to 5 of a 3-week cycle).

[4] For detailed in-and exclusion criteria, please see trial protocol.

❖ Women of childbearing potential must agree to use highly effective contraceptive method. ❖ Women must have a negative pregnancy test within 4 days prior to the first dose of study drug.	❖ Women who are pregnant or lactating. ❖ Prior treatment with MIRV or other FRα targeting agents. ❖ Untreated or symptomatic central nervous system metastases. ❖ History of other malignancy within 3 years prior to randomisation. ❖ Prior hypersensitivity reactions to study drugs and/or any of their excipients. ❖ People who are detained through a court or administrative decision, receiving psychiatric care against their will, adults who are the subject of a legal protection order. ❖ Simultaneous participation in another research study, in countries or localities where this is the health authority guidance.	o 1: 97 (42.7) vs 101 (44.7) o 2: 0 vs 3 (1.3) o Missing data: 0 vs 2 (0.9) ❖ BRCA mutation — no. (%) o BRCA1 positive: 24 (10.6) vs 29 (12.8) o BRCA2 positive: 9 (4.0) vs 7 (3.1) o Negative or unknown: 198 (87.2) vs 190 (84.1) ❖ Previous lines of systemic therapy o 1: 29 (12.8) vs 34 (15.0) o 2: 90 (39.6) vs 88 (38.9) o 3: 108 (47.6) vs 104 (46.0) ❖ Previous exposure — no. (%) o Bevacizumab: 138 (60.8) vs 143 (63.3) o PARP inhibitor: 124 (54.6) vs 127 (56.2) o Taxane: 227 (100) vs 224 (99.1) o Doxorubicin: or pegylated liposomal doxorubicin 130 (57.3) vs 133 (58.8) o Topotecan: 1 (0.4) vs 2 (0.9) ❖ Primary platinum-free interval — no. (%) o ≤12 mo: 146 (64.3) vs 142 (62.8) o >12 mo: 80 (35.2) vs 84 (37.2) o Missing data 1 (0.4) vs 0 ❖ Platinum-free interval — no. (%) o ≤3 mo: 88 (38.8) vs 99 (43.8) o >3 to ≤6 mo: 138 (60.8) vs 124 (54.9) o >6 mo: 1 (0.4) vs 3 (1.3)

Efficacy (I vs. C)	**Safety** (I vs. C, n=218 vs. n=207)
Data cutoff date (March 6, 2023) **PFS:** median, 5.62 months (95% CI, 4.34-5.95) vs median, 3.98 months (95% CI, 2.86-4.47); P<0.001. **PFS mean restricted at 12 months:** 6.13 months (95% CI, 5.62-6.64) vs 4.72 months (95% CI, 4.21-5.23). **Investigator-assessed objective response:** 42.3% (95% CI, 35.8-49.0) vs 15.9% (95% CI, 11.4-21.4); odds ratio, 3.81 (95% CI, 2.44-5.94); P<0.001. **Complete response:** 12 (5.3%) vs 0; **Partial response:** 84 (37.0%) vs 36 (15.9%). **OS:** median, 16.46 months (95% CI, 14.46-24.57) vs 12.75 months (95% CI,10.91-14.36); hazard ratio for death, 0.67 (95% CI, 0.50-0.89); P = 0.005 **Duration of response:** median, 6.77 months (95% CI, 5.62-8.31) among 96 participants vs 4.47 months (95% CI, 4.17-5.82) among 36 participants; hazard ratio, 0.62 (95% CI, 0.40-0.97). **CA-125 response:** 58.0% vs. 30.3% (95% CI, 17.5-37.9).	**TRAEs of any grade:** 86.2% vs 80.7% **Grade ≥3 AEs**: 91.5% vs. 85.6% **SAEs:** 44 (20.2%) vs 59 (28.5%) **Discontinuation[5]:** 20 (9.2%) vs 33 (15.9%) **Adverse event leading to death:** 5 (2.3%) vs 5 (2.4%) **Treatment-related adverse event leading to death:** 1 (0.5%) vs 1 (0.5%)

Patient-reported outcomes (I vs. C) **[7]**

The primary PRO assessment was defined as the number of patients achieving at least 15-point improvement at week 8/9 in the abdominal/ GI symptom scale of EORTC QLQ-OV28.
15-point improvement at week 8/9 was met in 21% of patient's vs 15.3% of patients (P= 0.2611).
In the abdominal/GI symptom scale at week 8/9 there was a difference of −5.0 (95 % CI: −8.3 – -1.6; P=0.0041) favouring MIRV with continuous improvement at week 24 of −6.0 (−10.2 – -1.8; P=0.0056).

[5] discontinuation due to AE(s)

Anchor-based analyses demonstrated that an 11-point change in subscale score was clinically meaningful. Sensitivity analysis using the 11-point threshold showed that 29% of patient's vs 18% of patients met the improvement threshold at week 8/9 (P=0.0318).

ESMO-MCBS version 1.1 [8, 9]

Scale	Int.	Form	MG ST	MG	HR (95% CI)	Score calculation	PM	Toxicity	QoL	AJ	FM
Original	NC	2a	>12 - ≤24 months	OS: 3.7 months	0.67 (0.50-0.89)	HR ≤0.70 AND gain ≥3-<5 months	3	-	NA	-	3
Adapted	NC	2a	>12 - ≤24 months	OS: 3.7 months	0.67 (0.50-0.89)	HR ≤0.70 AND gain ≥3-<5 months	3	-	NA	-	3

Risk of bias (RCT) [10]

Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding	Selective outcome reporting unlikely	Other aspects which increase the risk of bias	**Risk of bias**
unclear[6] unclear risk	-	no high risk	yes low risk	yes[7] high risk	unclear[8]

Ongoing trials [11]

NCT number/trial name	Description	Estimated study completion date
NCT05445778 (GLORIOSA)	Mirvetuximab Soravtansine With Bevacizumab Versus Bevacizumab as Maintenance in Platinum-sensitive Ovarian, Fallopian Tube, or Peritoneal Cancer	04/2029
NCT06682988	A Study to Assess Adverse Events and Change in Disease Activity in Participants With Platinum-Resistant Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers With High Folate Receptor-Alpha Expression Treated With Intravenously (IV) Infused Mirvetuximab Soravtansine	03/2028

Available assessments

NICE assessment on Mirvetuximab soravtansine for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer is in progress [12].

Other aspects and conclusions

- On **September 19, 2024**, the CHMP adopted a positive opinion, recommending marketing authorisation for the medicinal product Elahere® for the treatment of adults with folate receptor-alpha (FRα) positive epithelial ovarian, fallopian tube and primary peritoneal cancer. This indication has also been approved by the FDA.
- MIRASOL (NCT04209855) is a phase 3, international, randomised, open-label trial comparing the efficacy and safety of MIRV with the investigator's choice of chemotherapy in the treatment of platinum-resistant, high-grade serous ovarian cancer. The study included female patients ≥ 18 years of age, with at least one but no more than three prior systemic lines of anticancer therapy and with a tumour positive for FRα expression. Key exclusion criteria included other histological cervical cancer subtypes; FIGO 2014 stage IVB disease; previous hysterectomy; and previous systemic therapy, immunotherapy, definitive surgery, or radiation.
- **The primary endpoint, median PFS,** was 5.62 months (95% CI, 4.34-5.95) in the intervention group vs 3.98 months (95% CI, 2.86-4.47) in the control group; P<0.001.
- The **original and adapted ESMO-MCBS** were applied, resulting in a magnitude of clinical benefit of grade 3 with both scales.
- The **risk of bias was unclear** since it was not clear if a randomisation sequence was used, and this risk was further increased based on an open-label design and industry-funded background.
- Besides MIRASOL, for this specific indication, there is another study NCT06682988 investigating "Adverse Events and Change in Disease Activity in Participants With Platinum-Resistant Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers With High Folate Receptor-Alpha Expression Treated With Intravenously (IV) Infused Mirvetuximab Soravtansine", as searched from ClinicalsTrials.gov.
- Based on the final analysis, efficacy has been shown in terms of improved PFS. However, it has to be noted that half of the patients had an ECOG performance score of 0. The difference in the main predefined PRO was not statistically significant. The statistically significant change in the improvement using the 11-point scale is of limited value, as it has not been pre-specified in the Protocol.

[6] Protocol does not state if any randomization sequence was used.
[7] The study was sponsored by ImmunoGen (Acquired by Abbvie in 02/2024).
[8] Based on the unclear randomization process.

Abbreviations: AE=adverse event, AIBW=Adjusted Ideal Body Weight, AJ=adjustment, C=comparator, CHMP=Committee for Medicinal Products for Human Use, CI=confidence interval, ECOG=Eastern Cooperative Oncology Group, EMA=European Medicines Agency, EOC=epithelial ovarian cancer, ESMO-MCBS= European Society of Medical Oncology – Magnitude of Clinical Benefit Scale, FRα=folate receptor alpha, MCBS=Magnitude of Clinical Benefit Scale, MG=median gain, FDA=Food and Drug Administration, FM=final magnitude of clinical benefit grade, HR=hazard ratio, I=intervention, IBW=Ideal Body Weight, Int.=intention, i.v.=intravenously, MIRV=Mirvetuximab soravtansine-gynx, n=number of patients, NICE=National Institute for Health Care Excellence, OS=overall survival, PE=primary endpoint, PFS=progression-free survival, PLD=pegylated liposomal doxorubicin, PM=preliminary grade, PRO= patient reported outcome, SAE=serious adverse event, ST=standard treatment.

References:

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[11] U.S. National Library of Medicine, ClinicalTrials.gov [cited 21.11.2024]. Available from: https://clinicaltrials.gov/.

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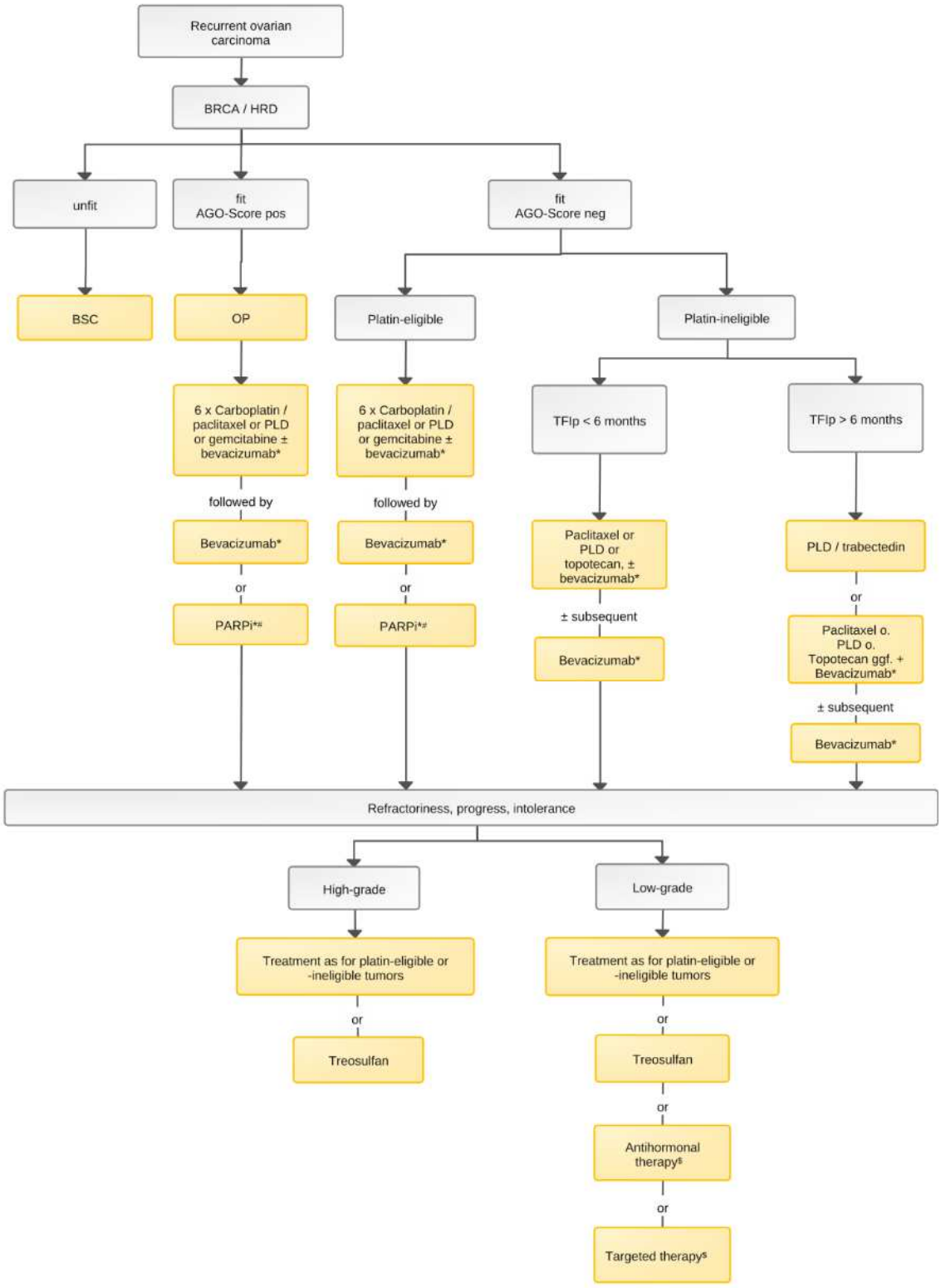
Appendix – Figure 1:

Therapy algorithm for recurrent ovarian cancer



Legend:
Therapy with non-curative intent
** note prior therapy and see approval status (German Version only)*
 # Olaparib, niraparib, or rucaparib
$ see approval status (German Version only)
TFIp, platinum-free interval; PARPi, PARP inhibitor
PLD, pegylated liposomal doxorubicin