Elranatamab (Elrexfio®) as monotherapy for the treatment of relapsed and refractory multiple myeloma (MM)

General information [1]

Drug description

The active substance of Elrexfio® is elranatamab, a bispecific monoclonal antibody that targets the CD3 receptor expressed on the surface of T cells and B-cell maturation antigen (BCMA) expressed on the surface of plasma cells, including malignant MM cells.

Indication

Elranatamab (Elrexfio®) is indicated as monotherapy for the treatment of adult patients with relapsed and refractory MM, who have received at least 3 prior therapies, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Incidence [2]

In Austria, in 2020, a total of 521 persons were newly diagnosed with plasmacytoma/myeloma. The age-standardised incidence rate[1] was 7.3 per 100,000 men and 4.3 per 100,000 women.

Current treatment [3]

- For the treatment of MM (third-line and beyond), Onkopedia recommends the following:
  - The choice of therapy in patients with relapsed or refractory disease after second-line therapy depends on the patient´s aims and, essentially, on the patient´s experiences with prior therapies.
  - Recent data, regarding patients who received at least 2 lines of therapie, can be summarised as follows:
    - Repetition of second-line therapy in patients with long, deep remission and good tolerability.
    - New double- or triple combinations of second-line therapy agents.
    - Additional options:
      - Panobinostat, combined with bortezomib/dexamethasone (as compared to bortezomib/dexamethasone) leads to prolongation of PFS, but not of OS.
      - Pomalidomide combined with low-dosed dexamethasone (as compared with high-dosed dexamethasone) lead to a prolonged PFS and OS and increases the remission rate. The additional combination with cyclophosphamide increases the response rate, but also the haematological toxicity.
      - With daratumumab monotherapy, 30% of heavily pretreated patients achieve at least partial remission and a median PFS of 4 months.
- Cytostatic agents: Efficient "classical" cytostatic agents are bendamustine, cyclophosphamide, doxorubicin and melphalan, each as monotherapy or as combination therapy. This also includes therapy regimens such as DCEP or DT-PACE that are partially administered by continuous infusion.

Regulatory status

EMA [1]	FDA [4]
Approval status for this indication: On 12 October 2023, the CHMP adopted a positive opinion, recommending the granting of a conditional marketing authorisation for Elrexfio®. The full indication is: ❖ Elrexfio® is indicated as monotherapy for the treatment of adult patients with relapsed and refractory MM, who have received at least **three** prior therapies, including an immunomodulatory agent, a PI, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. **Other indications**: none	**Approval status for this indication**: not approved On 14 August 2023, the FDA granted accelerated approval to elranatamab-bcmm (Elrexfio®), for adults with relapsed or refractory MM who have received at least **four** prior lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. ✓ Priority review ✓ Breakthrough designation ✓ Orphan drug designation

[1] European Standard Population 2013.

✓ **Orphan status** ✓ **Medicine received a conditional marketing authorisation**[2]	**Other indications**: none

Manufacturer

Elrexfio® is manufactured by Pfizer.

Costs

Currently, there is no cost information available.

Posology[3] [5]

- Administer Elrexfio® subcutaneously according to the step-up dosing schedule to reduce the incidence and severity of cytokine release syndrome (CRS).
- Elrexfio® should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and neurologic toxicity, including ICANS.
- Due to the risk of CRS, patients should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.
- Administer the following **pre-treatment medications** approximately 1 hour before the first three doses of Elrexfio® in the step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose to reduce the risk of CRS:
  - acetaminophen (or equivalent) 650 mg orally
  - dexamethasone (or equivalent) 20 mg orally or IV
  - diphenhydramine (or equivalent) 25 mg orally.

Warnings and precautions [5]

- **CRS**
  - CRS, including life-threatening or fatal reactions, can occur in patients receiving Elrexfio®.
  - Initiate treatment with Elrexfio® step-up dosing schedule to reduce risk of CRS.
  - Withhold Elrexfio until CRS resolves or permanently discontinue based on severity.
- **Neurologic toxicity**
  - Neurologic toxicity, including ICANS, and serious and life-threatening reactions, can occur in patients receiving Elrexfio®.
  - Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment.
  - Withhold Elrexfio® until the neurologic toxicity resolves or permanently discontinue based on severity.
- **Infections**
  - Can cause severe, life-threatening, or fatal infections.
  - Monitor patients for signs and symptoms of infection and treat appropriately.
  - Do not initiate treatment in patients with active infections.
- **Neutropenia**
  - Monitor complete blood cell counts at baseline and periodically during treatment.
- **Hepatotoxicity**
  - Can cause elevated ALT, AST, and bilirubin. Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated.
- **Embryo-fetal toxicity**

[2] The approval of a medicine that address unmet medical needs of patients on the basis of less comprehensive data than normally required. The available data must indicate that the medicine's benefits outweigh its risks and the applicant should be in a position to provide the comprehensive clinical data in the future.

[3] Since there is currently no EMA-EPAR for Elrexfio® available, chapters "Posology" and "Warnings and precautions" refer to the FDA label information.

- May cause fetal harm.
- Advise females of reproductive potential of the potential risk to the fetus and to use effective contraception.

❖ Elrexfio® is available only through a restricted program called the Elrexfio® **Risk Evaluation and Mitigation Strategy**.

Study characteristics [6-9]

Trial name	*n*	Intervention (I)	Comparator (C)	PE	Median follow-up	Characteristics	Biomarker	Funding	Publication(s)
MagnetisMM-3 NCT04649359	123	subcutaneous elranatamab 76 mg once weekly in 28-d cycles after two step-up priming doses of 12 mg and 32 mg given on day 1 and day 4 of cycle 1[4]	-	ORR by BICR per IMWG criteria	14.7 months	**ongoing**[5], multicenter, open-label, single-arm, phase 2 study	CD3	Pfizer	MagnetisMM-3 [8]

Inclusion criteria[6]

- ❖ Male or female participants age ≥18 years.
- ❖ Prior diagnosis of MM as defined according to IMWG criteria.
- ❖ Measurable disease based on IMWG criteria as defined by at least 1 of the following:
  - Serum M-protein >0.5 g/dL by SPEP
  - Urinary M-protein excretion >200 mg/24 hours by UPEP
  - Serum immunoglobulin FLC ≥10 mg/dL (≥100 mg/L) AND abnormal serum immunoglobulin kappa to lambda FLC ratio (<0.26 or >1.65).
- ❖ Refractory[7] to at least one IMiD.
- ❖ Refractory to at least one PI.
- ❖ Refractory to at least one anti-CD38 antibody.
- ❖ Relapsed or refractory to last anti-MM regimen.
- ❖ Cohort A: Has not received prior BCMA-directed therapy.
- ❖ Cohort B: Has received prior BCMA-directed ADC or BCMA-directed CAR T-cell therapy, either approved or investigational.
- ❖ ECOG PS ≤2.
- ❖ LVEF ≥40% as determined by a MUGA scan or ECHO.
- ❖ Adequate hepatic function characterized by the following:
  - Total bilirubin ≤2 x ULN (≤3 x ULN if documented Gilbert's syndrome);
  - AST ≤2.5 x ULN; and

Exclusion criteria

- ❖ Smoldering MM.
- ❖ Active plasma cell leukaemia.
- ❖ Amyloidosis.
- ❖ POEMS syndrome.
- ❖ Stem cell transplant within 12 weeks prior to enrolment or active GVHD.
- ❖ Impaired cardiovascular function or clinically significant cardiovascular diseases, defined as any of the following within 6 months prior to enrolment:
  - Acute myocardial infarction or acute coronary syndromes
  - Clinically significant cardiac arrhythmias
  - Thromboembolic or cerebrovascular events
  - Prolonged QT syndrome (or triplicate average QTcF >470 msec at screening).
- ❖ Ongoing Grade ≥2 peripheral sensory or motor neuropathy.
- ❖ History of any grade peripheral sensory or motor neuropathy with prior BCMA-directed therapy (Cohort B).
- ❖ History of GBS or GBS variants, or history of any Grade ≥3 peripheral motor polyneuropathy.
- ❖ Active HBV, HCV, SARS-CoV2, HIV, or any active, uncontrolled bacterial, fungal, or viral infection.
- ❖ Any other active malignancy within 3 years prior to enrolment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ.

Patient characteristics at baseline (n=123)

- ❖ Median age: 68.0 years (range, 36–89)
- ❖ Male: 55.3%
- ❖ Race:
  - White: 58.5%
  - Asian: 13.0%
  - Black or African American: 7.3%
  - Not reported or unknown: 21.1%
- ❖ ECOG performance status:
  - 0: 36.6%
  - 1: 57.7%
  - 2: 5.7%
- ❖ Type of myeloma:
  - IgG: 52.8%
    - Non-IgG: 17.1%
    - IgA: 16.3%
  - IgD: 0.8%
  - Light chain: 19.5%
  - Unknown: 10.6%
- ❖ R-ISS disease stage:
  - I: 22.8%
  - II: 55.3%
  - III: 15.4%
  - Unknown: 6.5%
- ❖ Cytogenetic risk:
  - Standard: 67.5%
  - High: 25.2%
  - Missing: 7.3%

[4] After 6 cycles, persistent responders (PR or better lasting at least 2 months) switched to a dosing interval of once every 2 weeks.
[5] MagnetisMM-3 trial is currently ongoing; the estimated study completion date is 01/2024.
[6] For detailed in- and exclusion criteria, please see trial protocol.
[7] Refractory is defined as having disease progression while on therapy or within 60 days of last dose in any line, regardless of response.

• ALT ≤2.5 x ULN ❖ Adequate renal function defined by an estimated creatinine clearance ≥30 mL/min. ❖ Adequate BM function characterized by the following: • ANC ≥1.0 × 109/L (use of granulocyte-colony stimulating factors is permitted if completed at least 7 days prior to planned start of dosing); • Platelets ≥25 × 109/L (transfusion support is permitted if completed at least 7 days prior to planned start of dosing); and • Haemoglobin ≥8 g/dL (transfusion support is permitted if completed at least 7 days prior to planned start of dosing). ❖ Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade ≤1. ❖ A female participant is eligible to participate if she is not pregnant or breastfeeding. ❖ Participants who are willing and able to comply with all scheduled visits, treatment plan, laboratory tests, lifestyle considerations, and other study procedures. ❖ Capable of giving signed informed consent.	❖ Other surgical, medical or psychiatric conditions including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study. ❖ Previous treatment with an anti-BCMA bispecific antibody. ❖ Previous administration with an investigational drug within 30 days (or as determined by the local requirement) or 5 half-lives preceding the first dose of study intervention used in this study (whichever is longer). ❖ Investigator site staff or sponsor employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members. ❖ Known or suspected hypersensitivity to the study intervention or any of its excipients. ❖ Live attenuated vaccine must not be administered within 4 weeks of the first dose of study intervention.	❖ Extramedullary disease by BICR: 31.7% ❖ Bone marrow plasma cells: • <50%: 72.4% • ≥50%: 21.1% • Missing: 6.5% ❖ ≥1 poor prognosis feature: 76.4% ❖ Median no. of prior antimyeloma lines of therapy: 5 (range, 2–22) ❖ Prior stem cell transplant: 70.7% ❖ Exposure status: • Triple-class: 100% • Penta-drug: 70.7% ❖ Refractory status: • Triple-class: 96.7% • Penta-drug: 42.3% ❖ Refractory to last line of therapy: 95.9%

Efficacy (n=123)	**Safety** (n=123)
<u>Data cutoff: 14 March 2023; median follow-up 14.4 months</u> Patients still receiving elranatamab at data cutoff: 33.3% Median duration of treatment: 5.6 months (range, 0.03–24.4 months), 48.0% were treated for at least 6 months and 35.8% for at least 12 months. Median relative dose intensity for all treatment cycles: 78.4% (range, 8.9–101.3%) **ORR by BICR**: 61.0% (95% CI, 51.8–69.6) **CR or better (≥CR):** 35.0% **VGPR or better**: 56.1% **MRD negativity**: 89.7% of patients with ≥CR and who were evaluable for MRD (n = 29) **Median TTR in responders**: 1.2 months (range, 0.9–7.4 months) **Median DOR**: NR (95% CI: not estimable) **The Kaplan–Meier probability of maintaining the response at 15 months**: 71.5% (95% CI, 58.8–80.9) in the overall population and 89.2% (95% CI: 73.5–95.8) in patients with ≥CR **Median time to ≥CR**: 6.1 months (range, 1.2–14.3 months) **Median DOCR in patients with ≥CR**: not reached (95% CI, NE)	**TEAEs:** 100% **TEAEs of grade 3 or 4**: 70.7% **Haematologic TEAEs:** 17.1% **Infections:** 69.9% **Infections grade 3 or 4**: 39.8% **Fatal infections**: 6.5% **CRS grade 1 or 2**: 56.3% **ICANS grade 1 or 2:** 3.4% **Treatment discontinuation due to AEs**: 13.8% **Deaths:** 44.7% **Deaths due to disease progression**: 30.1% **Deaths that were considered related to elranatamab by the investigator**: n=4[8]

[8] Adenoviral hepatitis, adenovirus infection and pneumonia adenoviral, pneumonia pseudomonal and failure to thrive (n=1 each).

Probability of maintaining ≥CR at 9 months: 89.0% (95% CI, 69.6–96.4)
Probability of maintaining the response at 15 months among responders in poor prognosis subgroups: 77.9% (95% CI, 45.9–92.3) vs. 70.6% (95% CI, 56.4–81.0) in patients with and without extramedullary disease, respectively; 63.8% (95% CI, 37.5–81.3) vs. 74.6% (95% CI, 59.5–84.7) in patients with and without penta-refractory disease, respectively and 76.3% (95% CI, 63.1–85.3) vs. 26.7% (95% CI, 1.0–68.6) in patients with R-ISS stages I–II and III disease, respectively.
Median PFS: NR (95% CI, 9.9 months-NE),
Kaplan–Meier estimate of PFS at 15 months: 50.9% (95% CI, 40.9–60.0)
Median duration of OS: NR (95% CI, 13.9 months-NE)
Kaplan–Meier estimate of OS at 15 months: 56.7% (95% CI, 47.4–65.1)
Kaplan–Meier estimates of PFS and OS at 15 months for patients in ≥CR: 89.5% (95% CI, 74.3–95.9) and 92.6% (95% CI, 78.7–97.6)

Efficacy and safety with Q2W dosing (n = 50)

- Response maintained or improved at least 6 months after the switch: 80.0%, with deepening of response observed in 40.0% of patients, including 38.0% who improved their response to ≥CR.
- Of the remaining 20.0%, 4.0% had confirmed PD, 6.0% died and 10.0% permanently discontinued elranatamab while in response.
- Of all 58 patients who switched to Q2W dosing, the incidence of grade 3 or 4 AEs decreased from 58.6% to 46.6%.

Patient-reported outcomes

Patient-reported outcomes were defined as exploratory endpoints of the MagnetisMM-3 trial; currently, results are not available.

ESMO-MCBS for Haematological Malignancies [10]

Scale	Int.	Form	MG ST	MG	HR (95% CI)	Score calculation	PM	Toxicity	QoL	AJ	FM
Original	NC	3	-	ORR: 61%	-	ORR (PR+CR) ≥60%	3	-	-	-	3

Risk of bias - study level (case series) [11]

1.	2.	3.	4.	5.	6.	7.	8.	9.
Was the hypothesis/ aim/ objective of the study clearly stated?	Were the cases collected in more than one centre?	Were patients recruited consecutively?	Were the eligibility criteria (inclusion and exclusion criteria) for entry into the study clearly stated?	Did participants enter the study at similar point in the disease?	Was the intervention clearly described?	Were additional interventions (co-interventions) clearly described?	Were relevant outcome measures established a priori?	Were outcome assessors blinded to the intervention that patients received?
yes	yes	yes	yes	partial[9]	yes	yes	yes	partial[10]
10.	11.	12.	13.	14.	15.	16.	17.	18.
Were the relevant outcomes measured using appropriate objective/ subjective methods?	Were the relevant outcomes measured before and after intervention?	Were the statistical tests used to assess the relevant outcomes appropriate?	Was the length of follow-up reported?	Was the loss to follow-up reported?	Did the study provide estimates of random variability in the data analysis of relevant outcomes?	Were adverse events reported?	Were the conclusions of the study supported by results?	Were both competing interest and source of support for the study reported?
yes	yes	yes	yes	yes	yes	yes	partial[11]	yes

[9] According to the baseline characteristics, patients had different stages of disease (R-ISS stage I, II or III) when entering the trial.
[10] In general, MagnetisMM-3 is an open-label trial; however, the primary endpoint ORR was assessed by BICR.
[11] The MagnetisMM-3 trial is currently ongoing; final analysis data is not (yet) available.

Overall risk of bias: low

Ongoing trials [12]

NCT number/trial name	Description	Estimated study completion date
MagnetisMM-3/ NCT04649359	Please see above.	01/2024
MAGNETISMM-5/ NCT05020236	An open-label, 3-arm, multicentre, randomized phase 3 study to evaluate the efficacy and safety of elranatamab monotherapy and elranatamab + daratumumab vs. daratumumab vs. daratumumab + pomalidomide + dexamethasone in participants with relapsed/refractory MM who have received at least 1 prior line of therapy including lenalidomide and a PI.	09/2026

Available assessments

- In October 2021, NIHR published a Health Technology Briefing "Elranatamab for treating relapsed /refractory multiple myeloma" [13].
- No further assessments were identified via NICE, ICER, CADTH or G-BA.

Other aspects and conclusions

- In October 2023, the **CHMP adopted a positive opinion**, recommending the granting of a conditional marketing authorisation for Elrexfio® as monotherapy for the treatment of adult patients with relapsed and refractory MM, who have received at least **three prior therapies**, including an immunomodulatory agent, a PI, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. This indication is **not approved by the FDA**. However, the FDA granted accelerated approval to Elrexfio® for adults with relapsed or refractory MM who have received **at least four prior lines of therapy**, including a PI, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- **MagnetisMM-3** (NCT04649359), is an **ongoing**, multicentre, open-label, single-arm, phase 2 study investigating the efficacy and safety of elranatamab in patients with relapsed or refractory MM. Eligible patients were ≥18 years with a prior diagnosis of MM and measurable disease per IMWG criteria, adequate bone marrow, hepatic and renal function, and an ECOG PS of ≤2. Patients had to have disease refractory to at least one PI, one immunomodulatory drug and one anti-CD38 antibody, and disease relapsed or refractory to their last antimyeloma regimen. Patients were excluded if they had smoldering MM, active plasma cell leukaemia, amyloidosis or polyneuropathy, organomegaly, endocrinopathy, monoclonal plasma cell disorder, skin changes syndrome (POEMS), a stem cell transplant ≤12 weeks before enrolment or active graft versus host disease, or any active, uncontrolled bacterial, fungal or viral infection.
- The **primary endpoint** was confirmed **ORR by BICR**; it was met with an ORR of 61.0%.
- Although defined as an exploratory endpoint in the study protocol, **patient-reported outcomes are not (yet) available**.
- The **risk of bias** of the MagnetisMM-3 trial was considered as **low;** it is increased by the ongoing status of the trial, partially different patient characteristics at baseline and the open-label trial design.
- The **ESMO-MCBS for Haematological Malignancies** was applied, resulting in a final adjusted **magnitude of clinical benefit grade of 3**.
- Beside the herein described phase 2 MagnetisMM-trial, **one ongoing phase 3 trial**, evaluating the efficacy and safety of elranatamab monotherapy and elranatamab + daratumumab vs. daratumumab vs. daratumumab + pomalidomide + dexamethasone in pretreated patients with relapsed/refractory MM, was identified.
- Final analysis data from the MagnetisMM-3 trial, including patient-reported outcomes, as well as robust phase 3 data are required to confirm the efficacy and safety of Elrexfio® treatment in heavily pretreated MM patients.

First published: 11/2023

Abbreviations: ADC=antibody-drug conjugate, AE=adverse event, AJ=adjustment, ALT=alanine transaminase, AST=aspartate aminotransferase, BCMA=B-cell maturation antigen, BICR=blinded independent central review, BM=bone marrow, ≥CR=complete response or better, C=comparator, CADTH=Canada´s Drug and Health Technology Agency, CAR-T=chimeric antigen receptor T-cell therapy, CHMP=Committee for Medicinal Products for Human Use, CI=confidence interval, CRS=cytokine release syndrome, CTCAE=Common Terminology Criteria for Adverse Events, DCEP=dexamethasone, cyclophosphamide, etoposide, and cisplatin, DT-PACE=dexamethasone, thalidomide, cisplatin, doxorubicin, cyclophosphamide, etoposide, ECHO=Echocardiogram, ECOG PS=Eastern Cooperative Oncology Group Performance Status, EMA=European Medicines Agency, ESMO-MCBS= European Society of Medical Oncology – Magnitude of Clinical Benefit Scale, FDA=Food and Drug Administration, FLC=FLC free light chain, FM=final magnitude of clinical benefit grade, G-BA=Gemeinsamer Bundesausschuss, GVHD=graft versus host disease, HBV=hepatitis B virus, HCV=hepatitis C virus, HIV=human immunodeficiency virus, HR=hazard ratio, I=intervention, ICANS=immune effector cell-associated neurotoxicity syndrome, ICER=Institute for Clinical and Economic Review, IMiD=immunomodulatory drug, Int.=intention, LVEF= left ventricular ejection fraction, MG=median gain, MM=multiple myeloma, MRD=minimal residual disease MUGA=multigated acquisition, n=number of patients, NICE=National Institute for Health Care Excellence, NIHR=National Institute for Health Research, ORR=objective response rate, OS=overall survival, PE=primary endpoint, PFS=progression-free survival, PI=proteasome inhibitor, PM=preliminary grade, POEMS=polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes, Q2W=once every 2 weeks, QoL=quality of life, R-ISS=Revised International Staging System,

SAE=serious adverse event, SARS-CoV-2=severe acute respiratory syndrome coronavirus 2, SPEP=serum protein electrophoresis, ST=standard treatment, TEAE=treatment-emergent adverse events, UPEP=urine protein electrophoresis, ULN=upper limit of normal, VGPR=very good partial response

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