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European Commission Approves Pfizer's ELREXFIO® for Relapsed and Refractory Multiple Myeloma

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- *Conditional marketing authorization is based on clinically meaningful response rates, duration of response, and safety from the Phase 2 MagnetisMM-3 trial*
- *ELREXFIO is an off-the-shelf (ready-to-use), fixed-dose, subcutaneous BCMA-directed bispecific antibody immunotherapy with reduced dosing after 24 weeks for responding patients*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced the European Commission (EC) has granted conditional marketing authorization for ELREXFIO® (elranatamab). ELREFXIO is a targeted immunotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. ELREXFIO is an off-the-shelf (ready-to-use) B-cell maturation antigen (BCMA)-CD3-directed bispecific antibody (BsAb) immunotherapy that induces deep and durable responses, with a manageable tolerability profile as well as convenient subcutaneous dosing.

"More than 50,000 Europeans are diagnosed with multiple myeloma each year, and too often, they face relapse and treatment resistance," said Chris Boshoff, Chief Oncology Research and Development Officer and Executive Vice President, Pfizer. "Today's approval provides a new, broadly available option for people with hard-to-treat multiple myeloma, and we continue to explore the use of ELREXFIO in earlier lines of treatment so that more people may ultimately benefit from this therapy."

The conditional marketing authorization for ELREXFIO is valid in all 27 EU member states as well as Iceland, Liechtenstein, and Norway. This authorization follows the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) recommendation for a conditional marketing authorization on October 12, 2023.

Authorization was based on data from cohort A of the Phase 2 MagnetisMM-3 study (NCT04649359) showing meaningful responses among heavily pretreated RRMM patients – at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody – who received ELREXFIO as their first BCMA-directed therapy. In an analysis of these patients (n=123), the objective response rate was 61%, with a 71% probability of maintaining a response at 15 months.

The results from MagnetisMM-3 also established once-every-other-week dosing with ELREXFIO for all responding patients after 24 weeks of weekly therapy, which means less time at the clinic and potentially greater long-term treatment tolerability. Among responding patients who switched to every-other-week dosing at least six months prior to the data cut-off date (n=50), 80% maintained or improved their response after the switch, with 38% attaining a complete response (CR) or better after the switch. These data were published in *Nature Medicine*.

The most common adverse reactions to ELREXFIO are cytokine release syndrome (CRS) (58%), anemia (54%), neutropenia (45%), fatigue (44%), upper respiratory tract infection (39%), injection site reaction (38%), diarrhea (38%), pneumonia (37%), thrombocytopenia (36%), lymphopenia (30%), decreased appetite (27%), rash (26%), joint pain (arthralgia) (25%), fever (pyrexia) (27%), hypokalemia (23%), nausea (21%), and dry skin (21%). Serious adverse reactions are pneumonia (31%), sepsis (15%), CRS (13%), anemia (6%), upper respiratory tract infection (5%), urinary tract infection (3%), febrile neutropenia (3%), dyspnea (2%), and pyrexia (2%). Most cases of CRS were Grade 1 (44% of patients), with Grade 2 in 14% and Grade 3 in less than 1% of patients.

Due to the risk of CRS and immune effector cell-associated neurotoxicity syndrome (ICANS), patients should be monitored for signs and symptoms for 48 hours after administration of each of the two step-up doses within the ELREXFIO dosing schedule and instructed to remain in proximity of a healthcare facility. In the EU, precautionary hospitalization is not required. Patients are not required to stay near a healthcare facility for the 76-mg first treatment dose.

About Multiple Myeloma

Multiple myeloma (MM) is an aggressive and currently incurable blood cancer that affects plasma cells made in the bone marrow. Healthy plasma cells make antibodies that help the body fight infection.[1] MM is the second most common type of blood cancer, with over 50,000 new cases diagnosed annually in Europe and 176,000 new cases diagnosed globally each year.[2,3] About 40% of those diagnosed with MM won't survive beyond five years,[4] and most will receive four or more lines of therapy due to relapse.[5] While disease trajectory varies for each person, relapses are nearly inevitable.[6] The goal of therapy for people with RRMM is to achieve disease control with acceptable toxicity and improved quality of life.[7]

About ELREXFIO® (elranatamab)

ELREXFIO is a subcutaneously delivered B-cell maturation antigen (BCMA)-CD3-directed bispecific antibody (BsAb) immunotherapy that binds to BCMA on myeloma cells and CD3 on T-cells, activating the T-cells to kill myeloma cells.

In August 2023, ELREXFIO was approved by the U.S. Food and Drug Administration (FDA) under its Accelerated Approval Program, which allows for earlier approval of drugs that treat serious conditions and fill an unmet medical need. ELREXFIO has also received approval in Switzerland and Brazil under Project Orbis, a framework for the concurrent submission and review of oncology drugs among international partners to potentially expedite approvals. Three other countries (Canada, Australia, and Singapore) are participating in Project Orbis. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has granted ELREXFIO Innovative Medicine Designation and the Innovation Passport for the treatment of MM.

Pfizer's extensive MagnetisMM clinical development program is continuing to investigate ELREXFIO's use across the entire spectrum of patients with MM, from RRMM to newly diagnosed MM. Ongoing registrational-intent trials are exploring ELREXFIO both as monotherapy and in combination with standard or novel therapies. These include MagnetisMM-5 in the double-class exposed setting, MagnetisMM-6 in newly diagnosed patients who are ineligible for stem cell transplant, and MagnetisMM-7 in newly diagnosed patients after transplant.

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

U.S. INDICATION

ELREXFIO may cause side effects that are serious, life-threatening, or can lead to death, including cytokine release syndrome (CRS) and neurologic problems. CRS is common during treatment with ELREXFIO.

Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS or neurologic problems, including:

- fever of 100.4°F (38°C) or higher
- trouble breathing
- chills
- dizziness or light-headedness
- fast heartbeat
- headache
- increased liver enzymes in your blood
- agitation, trouble staying awake, confusion or disorientation, or seeing or hearing things that are not real (hallucinations)
- trouble speaking, thinking, remembering things, paying attention, or understanding things
- problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms
- numbness and tingling (feeling like "pins and needles")
- burning, throbbing, or stabbing pain
- changes in your handwriting

Due to the risk of CRS, you will receive ELREXFIO on a "step-up" dosing schedule and should be hospitalized for 48 hours after the first "step-up" dose and for 24 hours after the second "step-up" dose of ELREXFIO.

- For your first dose, you will receive a smaller "step-up" dose of ELREXFIO on day 1
- For your second dose, you will receive a larger "step-up" dose of ELREXFIO, which is usually given on day 4 of treatment
- For your third dose, you will receive the first "treatment" dose of ELREXFIO, which is usually given on day 8

If your dose of ELREXFIO is delayed for any reason, you may need to repeat step-up dosing. Before each dose of ELREXFIO you receive during the step-up dosing schedule, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.

ELREXFIO is available only through the ELREXFIO Risk Evaluation and Mitigation Strategy (REMS) Program due to the risk of CRS and neurologic problems. You will receive an ELREXFIO Patient Wallet Card from your healthcare provider. **Carry the ELREXFIO Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The ELREXFIO Patient Wallet Card lists signs and symptoms of CRS and neurologic problems. **Get medical help right away if you develop any of the signs and symptoms listed on the ELREXFIO Patient Wallet Card.** You may need to be treated in a hospital.

Before taking ELREXFIO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. ELREXFIO may harm your unborn baby. **Females who are able to become pregnant** should do a pregnancy test before starting treatment with ELREXFIO and should use effective birth control during treatment and for 4 months after your last dose of ELREXFIO. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment

with ELREXFIO
- are breastfeeding or plan to breastfeed. It is not known if ELREXFIO passes into your breast milk. Do not breastfeed during treatment and for 4 months after your last dose of ELREXFIO

Tell your healthcare provider about all of the medications you take, includingprescription and over-the-counter medications, vitamins, and herbal supplements.

Do not drive, operate heavy or potentially dangerous machinery, or do other dangerous activities during treatment with ELREXFIO:

- for 48 hours after completing each of the 2 doses of ELREXFIO that are part of the "step-up dosing schedule" and your first full treatment dose, **and**
- at any time during treatment with ELREXFIO if you develop any new neurologic symptoms, such as dizziness, confusion, shaking (tremors), sleepiness, or any other symptom that impairs consciousness, until the symptoms go away.

Infections: Upper respiratory tract infection and pneumonia are common during treatment with ELREXFIO. ELREXFIO can cause bacterial and viral infections that are severe, life-threatening, or that may lead to death.

- Your healthcare provider may prescribe medications for you to help prevent infections and treat you as needed if you develop an infection during treatment with ELREXFIO
- Tell your healthcare provider right away if you develop any signs or symptoms of an infection during treatment with ELREXFIO, including: fever of 100.4°F (38°C) or higher, chills, cough, shortness of breath, chest pain, sore throat, pain during urination, or feeling weak or generally unwell
- People with active infections should not start ELREXFIO

Decreased white blood cell counts: Decreased white blood cell counts are common during treatment with ELREXFIO and can also be severe. A fever can occur with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will treat you as needed.

Liver problems: ELREXFIO can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Tell your healthcare provider if you develop any of the following signs or symptoms of a liver problem, including:

- tiredness
- loss of appetite
- pain in your right upper stomach-area
- dark urine
- yellowing of your skin or the white part of your eyes

The most common side effects of ELREXFIO include:

- tiredness
- injection site reaction, such as redness, itching, pain, bruising, rash, swelling, and tenderness
- diarrhea
- muscle and bone pain
- decreased appetite
- rash
- cough
- nausea
- fever

The most common severe abnormal lab test results with ELREXFIO include decreased white blood cells, red blood cells, and platelets.

Your healthcare provider may temporarily or permanently stop ELREXFIO if you have any of the side effects listed and they are severe. These are not all of the possible side effects of ELREXFIO.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What is ELREXFIO?

ELREXFIO is a prescription medication used to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody, to treat their multiple myeloma, **and**
- their cancer has come back or did not respond to prior treatment.

ELREXFIO was approved based on patient responses and durability of response. There are ongoing studies to confirm its clinical benefit. It is not known if ELREXFIO is safe and effective in children.

Please read full Prescribing Information , including BOXED WARNING, for ELREXFIO.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood, and lung cancers, as well as melanoma.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of December 8, 2023. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about ELREXFIO (elranatamab), a B-cell maturation antigen (BCMA) CD3-directed bispecific antibody, including its potential benefits, an approval by the European

Commission for the treatment of adult patients with relapsed and refractory multiple myeloma (RRMM) who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy, pending regulatory applications and the MagnetisMM clinical program to potentially expand ELREXFIO into earlier lines of treatment, as monotherapy and in combination with standard or novel therapies, and Pfizer Oncology, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of ELREXFIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications for any potential indications for ELREXFIO may be filed in any particular jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any applications that may be pending or filed for ELREXFIO, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether ELREXFIO will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of ELREXFIO; uncertainties regarding the impact of COVID-19 on Pfizer’s business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results,” as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

[1] Multiple Myeloma Research Foundation (MMRF): What is Multiple Myeloma?; Accessed August 22, 2023; Available at: https://themmrf.org/multiple-myeloma

[2] Myeloma Patients Europe: Myeloma A Patients Guide; Updated May 2022. Accessed August 2, 2023. Available at: https://www.mpeurope.org/wp-content/uploads/2023/01/Myeloma-Patients-Guide.pdf.

[3] World Health Organization: Globocan 2020: Multiple Myeloma; Accessed August 22, 2023. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/35-Multiple-myeloma-fact-sheet.pdf

[4] National Cancer Institute. Surveillance, Epidemiology, and End Results Program. Cancer Stat Facts: Myeloma. Accessed on Oct. 30, 2023. Available at: https://seer.cancer.gov/statfacts/html/mulmy.html

[5] Mikhael, J, Ismaila N, Cheung M, et al. Treatment of multiple myeloma: ASCO and CCO joint clinical practice guideline. *J Clin Oncol.* 37:1228-1263.

[6] Dimopoulos MA, Richardson P, Lonial S. Treatment options for patients with heavily pretreated relapsed and refractory multiple myeloma. *Clin Lymphoma Myeloma Leuk*. 2022;22(7):460-473. doi:10.1016/j.clml.2022.01.011

[7] Bazarbachi AH, Al Hamed R, Malard F, Harousseau JL, Mohty M. Relapsed refractory multiple myeloma: a comprehensive overview. *Leukemia*. 2019 Oct;33(10):2343-57.

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