

Pfizer's ELREXFIO Significantly Improves Progression-Free Survival for Double-Class Exposed Patients with Relapsed or Refractory Multiple Myeloma

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- *Primary endpoint met at the interim analysis in MagnetisMM-5 trial demonstrating a statistically significant and clinically meaningful improvement in progression-free survival*
- *Safety was consistent with the known ELREXFIO profile, with no new safety signals identified*
- *Trial remains ongoing to assess overall survival, a key secondary endpoint*
- *Interim efficacy results further strengthen confidence in development strategy for ELREXFIO as monotherapy and in combination, across multiple lines of therapy*

NEW YORK--(BUSINESS WIRE)-- [Pfizer Inc.](#) (NYSE: PFE) today announced positive topline results from the Phase 3 MagnetisMM-5 study evaluating ELREXFIO[®] (elranatamab) as monotherapy in adults with relapsed or refractory multiple myeloma (RRMM) who received at least one prior line of treatment. The study demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of progression-free survival (PFS), as assessed by blinded independent central review (BICR), versus standard-of-care daratumumab plus pomalidomide and dexamethasone (DPd). The safety and tolerability of ELREXFIO was consistent with its known safety profile.

The PFS results exceeded the pre-specified interim analysis target hazard ratio for efficacy, with most ELREXFIO-treated patients remaining progression-free. The trial remains ongoing to assess overall survival, a key secondary endpoint, which was not yet mature at the time of this interim analysis. These data will be discussed with global health authorities, and detailed results from MagnetisMM-5 will be submitted for presentation at a future medical congress.

Multiple myeloma is an aggressive and currently incurable blood cancer that affects plasma cells made in the bone marrow:

- It is the second most common type of blood cancer worldwide, with over 36,000 new cases each year in the United States and over 187,000 globally. ^{1,2,3}
- Despite treatment advances, most patients relapse and develop relapsed or refractory disease, often requiring multiple lines of therapy, with approximately 40% not surviving beyond five years. ^{2,4}
- Multiple myeloma can significantly impact quality of life, with immune suppression increasing susceptibility to infection, and symptoms such as fatigue, bone pain, and psychological distress making everyday activities more difficult. ⁵⁻⁷

“Effective intervention earlier in the course of disease represents a critical opportunity to improve outcomes for people living with multiple myeloma,” said Jeff Legos, Chief Oncology Officer, Pfizer. “ELREXFIO has already

helped address a significant unmet need in heavily pre-treated patients, delivering deep, durable, and clinically meaningful responses. The MagnetisMM-5 results reinforce our confidence in ELREXFIO's potential to benefit patients earlier in their treatment journey and support our comprehensive strategy to evaluate ELREXFIO both as monotherapy and as part of combination approaches across multiple lines of therapy.”

ELREXFIO is approved in more than 35 countries worldwide, including in the United States where it received accelerated approval for use in adults with RRMM who have received at least four prior lines of therapy, and in the European Union where it was granted conditional marketing authorization for adults with RRMM who have received at least three prior therapies and have demonstrated disease progression on the last therapy.

MagnetisMM-5 is part of a comprehensive development program in double-class exposed MM patients. The program includes the fully recruited Phase 3 MagnetisMM-32 study, which is designed to evaluate ELREXFIO in patients who have previously received daratumumab as part of standard-of-care front-line MM treatment.

About Multiple Myeloma

Multiple myeloma 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.⁶ While disease trajectory varies for each person, relapses are nearly inevitable.⁹ The goal of therapy for people with relapsing or refractory multiple myeloma is to achieve disease control with acceptable toxicity and improved quality of life.¹⁰

About MagnetisMM-5

MagnetisMM-5 is an open-label, multicenter, randomized Phase 3 study to evaluate the efficacy and safety of ELREXFIO versus standard-of-care daratumumab plus oral pomalidomide and dexamethasone in patients with RRMM. The study enrolled 497 patients across 26 countries who have received at least one line of previous treatment, including lenalidomide and a proteasome inhibitor (PI). Participants received subcutaneous ELREXFIO as two step-up priming doses followed by a weekly 76 mg injection, with frequency adjusted to every two weeks after 24 weeks if a partial response was achieved for more than two months, and again to every four weeks for all patients after 48 weeks on treatment. The primary endpoint is progression-free survival (PFS), as assessed by blinded independent central review (BICR). A key secondary endpoint is overall survival.

Pfizer continues to evaluate ELREXFIO both as a monotherapy and as a combination regimen as part of the MagnetisMM clinical trial program.

About ELREXFIO (elranatamab)

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

U.S. Important Safety Information and 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 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 four 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 four months after your last dose of ELREXFIO

Tell your healthcare provider about all of the medications you take, including prescription 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 the U.S. Food and Drug Administration (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 at the forefront of a new era in cancer care. Our industry-leading portfolio and extensive pipeline includes three core mechanisms of action to attack cancer from multiple angles, including small molecules, antibody-drug conjugates (ADCs), and multispecific antibodies, including other immunology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, gastrointestinal cancer, genitourinary cancer, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to help people with cancer live better and longer lives.

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 175 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 X at [@Pfizer](https://twitter.com/Pfizer) and [@Pfizer News](https://twitter.com/PfizerNews), [LinkedIn](https://www.linkedin.com/company/pfizer), [YouTube](https://www.youtube.com/channel/UCv31111111111111111111) and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

Pfizer Disclosure Notice

The information contained in this release is as of April 29, 2026. 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 Pfizer Oncology, ELREXFIO® (elranatamab), including its potential benefits, the development program for ELREXFIO, the MagnetisMM-5 results, and plans to share the results with global health authorities for potential regulatory submissions, 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; whether the MagnetisMM-5 trial will meet the key secondary endpoint for overall survival; the risks associated with initial, preliminary or interim 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 applications for ELREXFIO may be filed in particular jurisdictions for any potential indications; whether and when any such applications for ELREXFIO that may be pending or filed may be approved by regulatory authorities, 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; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; 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, 2025, 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.

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