ELREXFIO™ Shows Median Overall Survival of More Than Two Years in People with Relapsed or Refractory Multiple Myeloma

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Patients in MagnetisMM-3 demonstrated a median overall survival (OS) of 24.6 months, with median progression-free survival (PFS) of 17.2 months

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced detailed overall survival (OS) results from the Phase 2 MagnetisMM-3 study of ELREXFIO™ (elranatamab-bcmm) in patients with heavily pretreated relapsed or refractory multiple myeloma (RRMM). The study demonstrated a median OS of 24.6 (95% CI, 13.4, NE) months in cohort A (n=123) of the pivotal single arm trial.

These data from MagnetisMM-3 will be presented during a poster session (#932) at the European Hematology Association (EHA) Hybrid Congress in Madrid, Spain, from June 13-16. Additional presentations at EHA 2024 will highlight ELREXFIO data across the comprehensive MagnetisMM clinical trial program.

“These compelling overall survival data support the clinical benefit ELREXFIO has already demonstrated and its potential to be a transformative treatment option for people with multiple myeloma,” said Roger Dansey, M.D., Chief Development Officer, Oncology,

Pfizer. “The latest results from MagnetisMM-3 reinforce the very promising efficacy observed with ELREXFIO in a relapsed or refractory setting, with deep and durable responses and although definitive conclusions cannot be drawn across studies, the longest reported median progression-free survival among B-cell maturation antigen bispecific antibodies.”

After more than two years of follow-up in the MagnetisMM-3 trial, the overall response rate (ORR) for patients on ELREXFIO was 61.0% (37.4% ≥complete response rate (CRR)), with responses deepening over time, and the median duration of response (DOR) was not reached. At two years, the estimated DOR rate was 66.9% (95% CI: 54.4, 76.7) for all responders, and 87.9% (95% CI: 73.1, 94.8) for patients with CR or better response. Median progression-free survival (PFS) was 17.2 months (95% CI: 9.8 months-NE). For patients with CR or better response, the median PFS was not reached, and at two years, the estimated PFS rate was 90.6% (95% CI: 76.9, 96.4).

“People with relapsed or refractory multiple myeloma often have limited therapeutic options as their disease progresses due to treatment resistance, resulting in increasingly shorter remission and duration of response,” said MagnetisMM-3 clinical trial investigator Mohamad Mohty, M.D., Ph.D., Professor of Hematology and Head of the Hematology and Cellular Therapy Department at the Saint-Antoine Hospital and Sorbonne University, Paris, France. “These impactful overall survival data are particularly encouraging given the very advanced patient population with characteristics associated with poorer outcomes.”

The safety and tolerability of ELREXFIO in MagnetisMM-3 were consistent with what have been previously observed. Five patients (4.1%) experienced secondary primary malignancies (SPMs), all cases being squamous cell carcinoma of the skin, consistent with SPMs often observed in patients with multiple myeloma (MM), while no hematological SPMs were reported. Due to the risk of cytokine release syndrome (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.

Based on results of the MagnetisMM-3 trial, ELREXFIO received accelerated approval in August 2023 from the U.S. Food and Drug Administration for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody.

Continued approval for this indication is contingent upon verification of clinical benefit in a confirmatory trial. In December 2023, the European Commission granted conditional marketing authorization for ELREXFIO for the treatment of adult patients with 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 has also received approval in Switzerland, Brazil and Canada under Project Orbis, a framework for the concurrent submission and review of oncology drugs among international partners to potentially expedite approvals. Two other countries (Australia and Singapore) are participating in Project Orbis. The Medicines and Healthcare products Regulatory Agency (MHRA) granted ELREXFIO authorization for Great Britain for RRMM.

Pfizer’s comprehensive ongoing MagnetisMM clinical development program is investigating the use of elranatamab across the entire spectrum of patients with MM, from RRMM to newly diagnosed MM. Ongoing registrational-intent trials are comparing elranatamab to current standards of care both as monotherapy and in combination with standard or novel therapies. These include MagnetisMM-4 investigating elranatamab treatment with other anti-cancer therapies, MagnetisMM-5 in the double-class exposed setting, MagnetisMM-6 in newly diagnosed patients who are ineligible for stem cell transplant, MagnetisMM-7 in newly diagnosed patients after transplant, and MagnetisMM-32 in patients with prior anti-CD38-directed therapy.

About MagnetisMM-3

MagnetisMM-3 is an open-label, multicenter, non-randomized Phase 2 study of ELREXFIO monotherapy in participants with multiple myeloma who are refractory to at least one proteasome inhibitor, one immunomodulatory drug, and one anti-cluster of differentiation 38 antibody. The study enrolled two cohorts of participants: one with and one without prior treatment with a B-cell maturation antigen-directed antibody-drug conjugate or chimeric antigen receptor T-cell therapy. Participants received subcutaneous ELREXFIO as two step-up priming doses followed by a weekly 76 mg injection. The primary endpoint is objective response rate as assessed by Blinded Independent Central Review (BICR). Key secondary endpoints include duration of response, progression-free survival, minimal residual disease negativity rate, overall survival, and safety. For more information about the trial, visit www.clinicaltrials.gov (NCT04649359).

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 over 187,000 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 4 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 relapsing or refractory MM is to achieve disease control with acceptable toxicity and improved quality of life.7

About ELREXFIO (elranatamab-bcmm)

ELREXFIO is a subcutaneously delivered B-cell maturation antigen (BCMA)-cluster of differentiation (CD)3-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. 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 highertrouble breathingchillsdizziness or light-headednessfast heartbeatheadacheincreased liver enzymes in your bloodagitation, 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 thingsproblems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasmsnumbness and tingling (feeling like "pins and needles")burning, throbbing, or stabbing painchanges 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 1For your second dose, you will receive a larger "step-up" dose of ELREXFIO, which is usually given on day 4 of treatmentFor 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 infectionare 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 ELREXFIOare 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 ELREXFIOTell 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 unwellPeople 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:

tirednessloss of appetitepain in your right upper stomach-areadark urineyellowing of your skin or the white part of your eyes
The most common side effects of ELREXFIO include:

tirednessinjection site reaction, such as redness, itching, pain, bruising, rash, swelling, and tendernessdiarrheamuscle and bone paindecreased appetiterashcoughnauseafever
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 bispecific antibodies, including other immune-oncology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast 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 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 June 14, 2024. 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 and ELREXFIO (elranatamab-bcmm), a B-cell maturation antigen (BCMA) CD3-directed bispecific antibody, including its potential benefits and the MagnetisMM clinical program, 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 such applications, 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, 2023 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.

References

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