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Pfizer’s Elranatamab Receives FDA and EMA Filing Acceptance

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- *Submissions based on favorable MagnetisMM-3 trial results in patients with relapsed or refractory multiple myeloma*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the company’s Biologics License Application (BLA) for elranatamab, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody (BsAb), for the treatment of patients with relapsed or refractory multiple myeloma (RRMM). Priority Review is intended to direct attention and resources from regulatory authorities toward drugs that, if approved, could offer significant improvements over existing options for serious conditions in order to make these drugs available to patients faster. The FDA’s decision on the application is expected in 2023. The European Medicines Agency (EMA) has also accepted elranatamab’s marketing authorization application (MAA). The company is working closely with the EMA to facilitate their review and will provide updates on timing as appropriate.

"Today, multiple myeloma is a fatal hematologic malignancy, with a median survival of just over five years. As an off-the-shelf treatment, BCMA bispecific antibodies are heralding a new treatment paradigm that can greatly impact the lives of people with this disease.” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development. “We believe that elranatamab, if approved, has the potential to become the next standard of care for multiple myeloma given its favorable clinical results and convenient subcutaneous route of administration. We look forward to working with the FDA and EMA to bring this new innovative medicine to patients globally.”

Elranatamab is designed to bind to BCMA, which is highly expressed on the surface of multiple myeloma (MM) cells, and CD3 receptors found on the surface of T-cells, bridging them together and activating the T-cells to kill the myeloma cells. The BLA and MAA for elranatamab are primarily based on data from cohort A (BCMA-naïve - n=123) of MagnetisMM-3 (NCT04649359), an ongoing, open-label, multicenter, single-arm, Phase 2 study designed to evaluate the safety and efficacy of elranatamab monotherapy in patients with RRMM. Enrolled patients represent a heavily pretreated population, who previously received at least three classes of therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

With a median follow up of 10.4 months, patients who received elranatamab as their first BCMA-targeted therapy achieved a high objective response rate of 61% (55% had a very good partial response rate or better), with an 84% probability of maintaining the response at nine months. The MagnetisMM-3 results also suggest elranatamab has a manageable safety profile. The two-step-up priming dose regimen (12/32 mg) helped mitigate the rate and severity of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) among the 119 patients in cohort A who were treated with this priming regimen. All cases of CRS were Grade 1 or 2 and the majority occurred after the first (43% of patients) or second (24% of patients)

dose, with only 6% of patients experiencing CRS after dose 3 and fewer than 1% experiencing CRS after dose 4. Observed cases of ICANS (3%) were neither common nor severe (Grade 1/2 only were reported). No fatal neurotoxicity events were observed. These data were presented at the 64th American Society of Hematology Annual Meeting and Exposition in December 2022.

This study is part of the MagnetisMM clinical research program that expands to additional patient populations over time, with ongoing registrational-intent trials that explore elranatamab both as monotherapy and in combination with standard or novel therapies, spanning multiple patient populations, from newly diagnosed MM to RRMM. This includes MagnetisMM-5 (NCT05020236) in the double class exposed setting, MagnetisMM-6 (NCT05623020) in transplant ineligible newly diagnosed patients, and MagnetisMM-7 (NCT05317416) as maintenance treatment in newly diagnosed patients after transplant, all of which are currently enrolling.

In November 2022, Pfizer announced that elranatamab was granted Breakthrough Therapy Designation by the FDA. In addition, elranatamab has been granted Orphan Drug Designation by the FDA and the EMA for the treatment of MM. The FDA and EMA have also granted elranatamab Fast Track Designation and the PRIME scheme, respectively, for the treatment of patients with RRMM. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has granted elranatamab Innovative Medicine Designation and the Innovation Passport for the treatment of MM. The FDA has accepted elranatamab for Project ORBIS, which is a framework for the concurrent submission and review of oncology products to potentially expedite approvals in certain countries outside of the US; currently 5 countries (Switzerland, Brazil, Canada, Australia, and Singapore) have accepted to participate.

About Elranatamab

Elranatamab is an investigational, off-the-shelf, humanized BCMA CD3-targeted BsAb. BsAbs are a novel form of cancer immunotherapy that bind to and engage two different targets at once. One arm binds directly to specific antigens on cancer cells and the other arm binds to T-cells, bringing both cell types together. The binding affinity of elranatamab for BCMA and CD3 has been engineered to elicit potent T-cell-mediated anti-myeloma activity. Elranatamab is administered subcutaneously, which offers more convenience over intravenous administration.

About MagnetisMM-3

MagnetisMM-3 (NCT04649359) is an ongoing, open-label, multicenter, single-arm, Phase 2 study designed to evaluate the safety and efficacy of elranatamab monotherapy in patients with RRMM. Patients received subcutaneous (SC) elranatamab 76 mg weekly (QW) on a 28-day cycle with a step-up priming dose regimen, wherein 12 mg and 32 mg are administered on Day 1 and Day 4, respectively, during Cycle 1. For patients receiving 6 or more cycles and achieving a partial response or better for at least 2 months, the dosing interval was once every two weeks (Q2W).

About Multiple Myeloma

MM is a blood cancer that affects plasma cells made in the bone marrow. Healthy plasma cells make antibodies that help the body fight infection. There are over 34,000 new cases of MM diagnosed annually in the U.S. and 176,000 globally.[1,2] Despite treatment advances, there is currently no cure. The median survival is just over five years, and most patients receive four or more lines of therapy.[3]

About Pfizer in Hematology

At Pfizer, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars, including seven therapies to treat hematologic malignancies. We have taken bold new approaches over the past decade to translate scientific research into transformative medicines for people living with blood cancer. For the millions living with blood cancer today and for those diagnosed tomorrow, we work tirelessly to deliver on our mission: Breakthroughs that change patients' 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 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 February 22, 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 elranatamab, an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody, including its potential benefits, 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, 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; risks associated with interim data, including the risk that additional data from MagnetisMM-3 could differ from the data discussed in this release; 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 elranatamab may be filed in any other jurisdictions; whether and when the FDA and EMA may approve the pending applications for elranatamab for the treatment of people with RRMM and whether and when regulatory authorities in any jurisdictions may approve any such other applications that may be pending or filed for elranatamab, 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 elranatamab 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 elranatamab; 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, 2021 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 .

Category: Medicines

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[1] American Cancer Society. Multiple Myeloma. Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed February 20, 2023.
[2] World Health Organization. Globocan 2020: Multiple Myeloma. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/35-Multiple-myeloma-fact-sheet.pdf. Accessed February 20, 2023.
[3] 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

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