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Pfizer’s Elranatamab Granted FDA Breakthrough Therapy Designation for Relapsed or Refractory Multiple Myeloma

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- *Breakthrough Therapy Designation based on updated data from Phase 2 MagnetisMM-3 study that showed an overall response rate of 61.0% and a manageable safety profile after a median follow-up of 6.8 months*
- *Data to be presented at the 64th American Society of Hematology Annual Meeting and Exposition 2022 (ASH 2022)*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced its investigational cancer immunotherapy, elranatamab, received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of people with relapsed or refractory multiple myeloma (RRMM). Elranatamab is a B-cell maturation antigen (BCMA)-CD3-targeted bispecific antibody (BsAb).

“The FDA’s Breakthrough Designation recognizes the potential of elranatamab as an innovative medicine for people with multiple myeloma whose disease has relapsed or is refractory to existing treatments, which at present leaves very few avenues for staving off this currently incurable cancer,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development. “This marks Pfizer’s twelfth FDA Breakthrough Therapy Designation in Oncology, a testament to our relentless commitment to developing transformational cancer medicines in areas of high unmet need. We look forward to working with the FDA to accelerate the development of this therapy.”

The FDA’s Breakthrough Therapy Designation is intended to expedite the development and review of a medicine that is intended to treat a serious or life-threatening disease and preliminary clinical evidence indicates the drug may demonstrate substantial improvement over existing therapies.[1]

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. Elranatamab is designed to bind to BCMA, which is highly expressed on the surface of multiple myeloma (MM) cells, and the CD3 receptor found on the surface of T-cells, bridging them together and activating the T-cells to kill the myeloma cells. 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, and may mitigate the risk of potential adverse events, such as cytokine release syndrome (CRS).

The Breakthrough Therapy Designation is based on six-month follow-up data from cohort A (n=123) of MagnetisMM-3, an open-label, multicenter, single arm, Phase 2 study evaluating the safety and efficacy of elranatamab monotherapy in patients with RRMM. Patients received subcutaneous (SC) elranatamab 76 mg

weekly (QW) with a 2-step-up priming dose regimen administered during the first week. The study showed elranatamab demonstrated a manageable safety profile, and at a median follow-up of 6.8 months, patients achieved an overall response rate (ORR) of 61.0%. Among responders, there was 90.4% probability of maintaining a response ?6 months. The most common treatment-emergent adverse event (TEAE) regardless of causality was CRS (57.9%), with the majority of events reported being either Grade 1 (43.2%) or Grade 2 (14.2%). Updated data from MagnetisMM-3 will be presented at the 64th American Society of Hematology Annual Meeting and Exposition 2022 (ASH 2022), taking place December 10-13, 2022, in New Orleans.

MagnetisMM-3 is part of the robust MagnetisMM clinical research program, which has registration-intent trials planned or ongoing that explore elranatamab both as monotherapy and in combination with standard or novel therapies, spanning multiple patient populations from newly diagnosed multiple myeloma (NDMM), double-class exposed disease and RRMM.

In addition to the Breakthrough Therapy Designation, elranatamab has been granted Orphan Drug Designation by the FDA and the European Medicines Agency (EMA) for the treatment of MM. The FDA and EMA have 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 also granted elranatamab Innovative Medicine Designation and the Innovation Passport, for the treatment of MM.

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. According to the latest figures available, there are over 34,000 new cases of MM diagnosed annually in the U.S. and 176,000 globally.[2, 3] Despite treatment advances, MM remains incurable. The median overall survival is just over five years, and most patients receive four or more lines of therapy.[4]

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 November 3, 2022. 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 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 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 .

[1] U.S. Food and Drug Administration. Breakthrough Therapy Designation. Available at: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy Accessed September 23, 2022.

[2] American Cancer Society. Multiple Myeloma. Available at: https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html. Accessed May 25, 2022.

[3] World Health Organization. Globocan 2020: Multiple Myeloma. Available at: https://gco.iarc.fr/today/data/factsheets/cancers/35-Multiple-myeloma-fact-sheet.pdf. Accessed May 25, 2022.

[4] 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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