



# Pfizer Presents First Data from Planned Interim Analysis of Pivotal Phase 2 MagnetisMM-3 Trial of BCMA-CD3 Bispecific Antibody Elranatamab Under Investigation for Relapsed/Refractory Multiple Myeloma

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Safety results suggest a manageable safety profile for elranatamab in this patient population with advanced multiple myeloma. With a median follow up of 3.71 months, initial efficacy results showed the objective response rate for elranatamab was 60.6%.

NEW YORK, NY, June 5, 2022 – Pfizer Inc. (NYSE: PFE) today announced new data from a planned interim analysis of the Phase 2 MagnetisMM-3 registration-enabling trial of elranatamab in people with relapsed/refractory multiple myeloma (RRMM) whose disease is refractory to at least one agent in each of three major classes of medications approved for the disease. These data are being presented today during an oral abstract session at the 2022 American Society of Clinical Oncology Annual Meeting (ASCO) (Abstract # 8006).

Elranatamab is an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody in development for the treatment of multiple myeloma (MM). MagnetisMM-3 is an open-label, multicenter, single arm, Phase 2 study evaluating the safety and efficacy of elranatamab monotherapy in patients with RRMM. The participants included in this study represent a particularly difficult-to-treat MM patient population: 95.7% of participants in the current interim analysis population had triple-class refractory

disease and 39.4% had penta-drug refractory disease.<sup>1</sup>

In this interim analysis, safety and efficacy was analyzed in 94 patients who had received at least one dose of elranatamab (Cohort A – BCMA-naïve) as of the data cutoff on March 23, 2022. Patients received subcutaneous (SC) elranatamab 76 mg weekly (QW) with a 2-step-up priming dose regimen administered during the first week. With a median follow up of 3.71 months, initial efficacy results showed that the objective response rate for elranatamab was 60.6%. As of the data cut-off, 89.5% of objective responders were ongoing without confirmed progression or death.

“Bispecific antibodies hold promise as the next breakthrough in the treatment of multiple myeloma. These data represent an important step forward as we look to bring elranatamab as a potential innovative new treatment to people living with relapsed or refractory multiple myeloma, where there is high need,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. “We are encouraged by these early efficacy and safety results, which suggest elranatamab may have a manageable safety profile coupled with early promising clinical responses. We look forward to the final analysis from MagnetisMM-3, which is expected later this year.”

The results also suggested 76 mg of elranatamab QW may have a manageable safety profile in patients with triple-class refractory MM. The most common treatment emergent adverse events (TEAEs) were hematologic AEs- anemia (43.6%), neutropenia (38.3%), thrombocytopenia (28.7%) and lymphopenia (25.5%); and cytokine release syndrome (CRS) (60.6%). The 2-step-up priming regimen is intended to help mitigate the rate and severity of CRS, and the CRS profile appears to be predictable with the majority of events confined to the first two doses (88.4%) or first three doses (98.6%). Of the 90 patients who received the 2-step-up priming regimen, all CRS were Grade 1 (40.0%) or 2 (18.9%). Additionally, immune effector cell-associated neurotoxicity syndrome (ICANS) occurred in 2.2% of patients, all Grade 2 or less.

These results being presented at ASCO are the first data to be disclosed from the MagnetisMM-3 study. The trial is still ongoing to the primary endpoint analysis with results expected later this year, which, if positive, would form the basis of potential regulatory filings. These data also support continued development of elranatamab in the robust MagnetisMM program, with other trials planned or ongoing both as monotherapy and in combination with standard or novel therapies.

The abstract “Initial safety results for MagnetisMM-3: A phase 2 trial of elranatamab, a B-cell maturation antigen (BCMA)-CD3 bispecific antibody, in patients with

relapsed/refractory multiple myeloma,” and oral presentation are available at <https://meetings.asco.org/abstracts-presentations/207301>.

**About the MagnetisMM-3 Phase 2 Trial** MagnetisMM-3 is an open-label, multicenter, nonrandomized Phase 2 study of elranatamab monotherapy in people with multiple myeloma who are refractory to at least one proteasome inhibitor, one immunomodulatory drug and one anti-CD38 monoclonal antibody. This study enrolled two independent cohorts of participants: one with (Cohort A, n=123) and one without (Cohort B, n=64) prior treatment with a BCMA-directed antibody-drug Conjugate (ADC) or CAR-T therapy. Participants received a weekly 76 mg SC injection of elranatamab following 2-step-up priming doses of 12 mg and 32 mg SC on Days 1 and 4, respectively, in the first week. The primary endpoint is objective response rate as assessed by blinded independent central review. 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](http://www.clinicaltrials.gov).

**About MM** 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 approximately 34,470 new cases of MM diagnosed annually in the U.S and 176,000 globally. <sup>2,3</sup> Despite treatment advances, MM remains incurable. The median survival is just over five years, and most patients receive four or more lines of therapy. <sup>4</sup>

**About Elranatamab** Elranatamab is an investigational B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody. Binding affinity to BCMA and CD3 has been optimized, to potentially elicit potent T-cell-mediated anti-myeloma activity. Elranatamab is being investigated as a fixed dose subcutaneous administration, which is intended to allow higher doses than intravenous administration without increasing adverse events. Elranatamab has been granted Orphan Drug Designations by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (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 MM who are refractory to at least one proteasome inhibitor, one immunomodulatory drug, and one anti-CD38 antibody.

**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](http://www.Pfizer.com). In addition, to learn more, please visit us on [www.Pfizer.com](http://www.Pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

**DISCLOSURE NOTICE:** *The information contained in this release is as of June 5, 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 the final data MagnetisMM-3 will differ significantly from the 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 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).*

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1 Triple-class refers to at least 1 proteasome inhibitor, 1 immunomodulatory drug, and 1 anti-CD38 antibody. Penta-drug refers to at least 2 proteasome inhibitors, 2 immunomodulatory drugs, and 1 anti-CD38 antibody.

2 American Cancer Society. <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.