



# Pfizer Presents Updated Favorable Elranatamab Data from Pivotal Phase 2 MagnetisMM-3 Trial

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Data showed high objective response rate of 61% in RRMM patients with no prior BCMA-targeted treatment, with 84% probability of maintaining the response at nine months. Results showed early and deep responses, and a manageable safety profile for elranatamab in heavily pretreated patients with advanced multiple myeloma.

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE:PFE) today announced 10.4 month follow-up data from the pivotal Phase 2 MagnetisMM-3 clinical trial suggesting elranatamab, a B-cell maturation antigen (BCMA)-CD3-targeted bispecific antibody (BsAb), is efficacious and has a manageable safety profile in patients with relapsed or refractory multiple myeloma (RRMM) in a heavily pretreated population, who have received at least three classes of prior therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (i.e. triple-class refractory or exposed). These data are being presented today in an oral session at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition 2022 (abstract 159).

“Although there are approved treatments for multiple myeloma, none are currently curative, and patients often find themselves with dwindling therapeutic options as their disease relapses or becomes refractory to successive medicines,” said Nizar Bahlis, M.D., Associate Professor, Arnie Charbonneau Cancer Institute, University of Calgary, Canada, and lead investigator. “These longer-term results show early and deep responses with elranatamab in a heavily pretreated patient population, adding to the growing body of evidence showing elranatamab has the potential to be a transformative option in an area of high need.”

Elranatamab is an investigational humanized BsAb that targets both BCMA-expressing multiple myeloma cells and CD3-expressing T-cells, bridging them together and activating the T-cells to kill the myeloma cells. The binding affinities of elranatamab for BCMA and CD3 have been engineered to elicit potent T-cell-mediated anti-myeloma activity. Given factors currently limiting the availability of novel therapies in the triple-class exposed setting, elranatamab has the potential to reach a broader and greater number of patients as an off-the-shelf option that is administered subcutaneously (SC), which offers more convenience over intravenous administration.

In this analysis, safety and efficacy were analyzed in 123 patients who had received at least one dose of elranatamab (cohort A - BCMA-naïve) as of the data cut-off on October 14, 2022. Patients received SC elranatamab 76 mg weekly (QW) on a 28-day cycle with a step-up priming dose regimen, 12 mg and 32 mg administered on Day 1 and Day 4, respectively, during Cycle 1. With a median follow up of 10.4 months, patients who received elranatamab achieved a high objective response rate of 61%, with 84% probability of maintaining response at nine months. Probability of progression-free survival and overall survival were 63% and 70%, respectively, at nine months. The results also suggest elranatamab has a manageable safety profile and that the two-step-up priming dose regimen (12/32 mg) mitigated the rate and severity of cytokine release syndrome (CRS) (58%, all Grade 1/2) and immune effector cell-associated neurotoxicity syndrome (ICANS, 3%, all Grade 1/2) in cohort A of MagnetisMM-3 (n=119). The most common hematologic treatment emergent adverse events (TEAEs) of any grade were - anemia (48%), neutropenia (48%), thrombocytopenia (30%) and lymphopenia (26%).

“Discovered and developed at Pfizer, elranatamab is just one example of our focus on investing in breakthrough science. We're applying our expertise in hematology developed over a decade to advance elranatamab as an innovative treatment for multiple myeloma,” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development. “We are excited to be sharing our latest research at ASH, which further supports the efficacy and safety of elranatamab, and will continue to evaluate its potential benefits through the MagnetisMM clinical trial program across earlier and broader populations, including newly diagnosed patients. We are excited by the potential for elranatamab, if approved, to reach a greater number of patients globally across the treatment paradigm.”

Additional Pfizer elranatamab presentations at ASH include:

Elranatamab, a BCMA Targeted T-Cell Engaging Bispecific Antibody, Induces Durable Clinical and Molecular Responses for Patients with RRMM (abstract 158, oral)  
MagnetisMM-1 Phase 1/2 first in human MagnetisMM-1 study (NCT03269136) Safety and

preliminary efficacy results from Part 1 (safety lead-in cohort) of MagnetisMM-5, a Phase 3 study of elranatamab + daratumumab in patients with RRMM (NCT05020236) (poster 1921) MagnetisMM-4: An Open Label, Phase 1b/2 Umbrella Study of Elranatamab in Combination with Other Anti-cancer Treatments for Patients with Multiple Myeloma (poster 4567) Phase 1b/2 MagnetisMM-4 (NCT05090566) ongoing clinical trial Dose Optimization to Mitigate the Risk of CRS with Elranatamab in Multiple Myeloma (poster 3192) Dose-optimization analysis from across MagnetisMM-1 (NCT03269136), MagnetisMM-2 (NCT04798586), MagnetisMM-3 (NCT04649359) and MagnetisMM-9 (NCT05014412) A Systematic Meta-analysis of Cytokine Release Syndrome Incidence in B-Cell Maturation Antigen-Targeting Chimeric Antigen Receptor T-Cell Therapy and Bispecific Antibodies for Patients with Relapsed and/or Refractory Multiple Myeloma (poster 4509) Meta-analysis of CRS among patients treated with BCMA-targeting CAR-Ts and BsAbs across 53 studies

MagnetisMM-3 (NCT04649359) is an ongoing open-label, multicenter, non-randomized study designed to evaluate the safety and efficacy of elranatamab as monotherapy in patients with RRMM. Additional data continue to be collected and will be shared as they mature. Prior to enrollment, participants had received a median of five lines of treatment. The participants included in this study represent a difficult-to-treat multiple myeloma patient population; almost all (97%) of the 123 patients included in this analysis were triple-class refractory and nearly half (42%) were penta-drug refractory\*. The trial is part of the robust MagnetisMM multiple indication clinical research program that expands to additional patient populations over time, with ongoing registration-intent trials that explore elranatamab both as monotherapy and in combination with standard or novel therapies, spanning multiple patient populations from newly diagnosed multiple myeloma, double-class exposed disease and RRMM.

In November 2022, Pfizer announced elranatamab received Breakthrough Therapy Designation from the Food and Drug Administration (FDA) for the treatment of RRMM. Elranatamab has also 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.

\* Penta-drug refers to at least 2 proteasome inhibitors, 2 immunomodulatory drugs, and 1 anti-CD38 antibody.

## About Multiple Myeloma

Multiple myeloma 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 multiple myeloma diagnosed annually in the U.S. and 176,000 globally.<sup>1,2</sup> Despite treatment advances, there is currently no cure. The median overall survival is just over five years, and most patients receive four or more lines of therapy.<sup>3</sup>

## 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](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 December 10, 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](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com) .

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