



News Release

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Janssen Announces U.S. FDA Breakthrough Therapy Designation Granted for Talquetamab for the Treatment of Relapsed or Refractory Multiple Myeloma

Novel GPRC5DxCD3 Bispecific Antibody Receives Breakthrough Therapy Designation Based Upon Results from the Phase 1/2 MonumentAL-1 Study

June 29, 2022 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for talquetamab for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. Talquetamab is an investigational, off-the-shelf, T-cell redirecting bispecific antibody targeting both GPRC5D, a novel drug target, on multiple myeloma cells and CD3 on T-cells. This distinction for talquetamab follows a PRIME (PRiority MEdicines) designation from the European Medicines Agency (EMA) on January 29, 2021, and an Orphan Drug Designation (ODD) from the FDA on May 3, 2021. Today's milestone marks the 12th BTD received by Janssen in oncology and the third such designation for the company's portfolio of bispecific antibodies.

“This Breakthrough Therapy Designation marks an important step in the continued development of talquetamab, a first-in-class bispecific antibody T-cell engager using GPRC5D, a novel target for the treatment of patients with relapsed or refractory multiple myeloma,” said Sen Zhuang, M.D., Ph.D., Vice President, Clinical Research and Development, Janssen Research & Development, LLC. “Despite the therapies available for patients with relapsed or refractory multiple myeloma, new targets and treatments are needed because of the heterogeneity of the disease, which can impact a patient’s response to treatment. We are resolute in our commitment to advance science and develop new therapies and regimens for patients with the goal of delivering the best possible outcomes while driving toward cures.”

The Breakthrough Therapy Designation is supported by data from the Phase 1/2, first-in-human dose-escalation MonumentAL-1 study of talquetamab ([Phase 1: NCT03399799](#); [Phase 2: NCT04634552](#)) for the treatment of heavily pretreated patients with relapsed or refractory multiple myeloma.¹

Data from the MonumentAL-1 study were featured during the 2022 European Hematology Association (EHA) Annual Congress as an oral presentation (Abstract [#S182](#))² and were presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting ([Abstract #8015](#)).³

The FDA grants BTB to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition and is based on preliminary clinical evidence that demonstrates the drug may have substantial improvement in at least one clinically significant endpoint over available therapy.⁴

About Talquetamab

Talquetamab is a potential first-in-class, investigational T-cell redirecting bispecific antibody targeting both GPRC5D, a novel multiple myeloma target that does not shed over time, and CD3, a component of the T-cell receptor.¹ CD3 is involved in activating T-cells, and GPRC5D is highly expressed on multiple myeloma cells.^{5,6} Results from preclinical studies in mouse models demonstrate that talquetamab induces T-cell-mediated killing of GPRC5D-expressing multiple myeloma cells through the recruitment and activation of CD3-positive T-cells and inhibits tumor formation and growth.⁷

Talquetamab is currently being evaluated in a Phase 1/2 clinical study for the treatment of relapsed or refractory multiple myeloma ([NCT03399799](#)) and is also being explored in combination studies ([NCT04586426](#)).

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that affects white blood cells called plasma cells, which are found in the bone marrow.⁸ When malignant, these plasma cells rapidly spread and replace normal cells in the bone marrow. In 2020, an estimated 176,000 people worldwide were diagnosed with multiple myeloma.⁹ In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S.¹⁰ While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.¹¹

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine in which we can make the biggest difference: Cardiovascular, Metabolism, & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at [@JanssenGlobal](#). Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of talquetamab. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC or any of the other Janssen Pharmaceutical

Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

¹ Pillarisetti K et al. *Blood*. 2020;135(15):1232-1243.

² Minnema M et al. Efficacy and safety of talquetamab, a G protein-coupled receptor family C group 5 member D x CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma (RRMM): updated results from MonumenTAL-1. European Hematology Association 2022 Hybrid Congress. June 2022.

³ Minnema M et al. Efficacy and safety of talquetamab, a G protein-coupled receptor family C group 5 member D x CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma (RRMM): updated results from MonumenTAL-1. American Society of Clinical Oncology 2022 Annual Meeting. June 2022.

⁴ The U.S. Food and Drug Administration. "Expedited Programs for Serious Conditions." Available at: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf> Last accessed: May 2021

⁵ Labrijn AF et al. *Proc Natl Acad Sci USA*. 2013;110:5145.

⁶ Cohen, Y., et al. *Hematology*. 2013 Nov; 18(6):348-51.

⁷ Kumar SK et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. *Leukemia*. 2012 Jan;26(1):149-57.

⁸ Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. *Am J Hematol*. 2020;95(5):548-567. <http://www.ncbi.nlm.nih.gov/pubmed/32212178>

⁹ Cancer.Net. "Multiple Myeloma: Statistics." Available at: <https://www.cancer.net/cancer-types/multiple-myeloma/statistics#:~:text=Worldwide%2C%20an%20estimated%20176%2C404%20people,worldwide%20died%20from%20multiple%20myeloma>. Accessed June 3, 2022.

¹⁰ American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: [https://cancerstatisticscenter.cancer.org/?_ga=2.84250769.967379196.1642100198-1705811479.1642100198#/#/](https://cancerstatisticscenter.cancer.org/?_ga=2.84250769.967379196.1642100198-1705811479.1642100198#/). Accessed June 2022.

¹¹ American Cancer Society. "What Is Multiple Myeloma?" Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/what-is-multiple-myeloma.html>. Accessed June 2022.