



## **News Release**

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

*U.S. Milestone Follows European Medicines Agency PRIME Designation for this BCMA Bispecific Antibody for the Treatment of Relapsed or Refractory Multiple Myeloma*

**June 1, 2021 (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 teclistamab in the treatment of relapsed or refractory multiple myeloma. This distinction for teclistamab, an off-the-shelf, T-cell redirecting, bispecific antibody targeting both B-cell maturation antigen (BCMA) and CD3 receptors, follows a PRIME (PRIority MEdicines) designation from the European Medicines Agency (EMA) received earlier this year. Today's BTD marks the 11<sup>th</sup> received by Janssen's Oncology Therapeutic Area.

"We are pleased to have received Breakthrough Therapy and PRIME Designations for our novel bispecific antibody, teclistamab," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "This program exemplifies our commitment to advancing science for patients living with multiple myeloma, and it builds upon our robust portfolio in this disease."

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 on at least one clinically significant endpoint over available therapy.<sup>1</sup> PRIME designation offers enhanced interaction and early dialogue to optimize development plans and speed up the evaluation of scientific advances that target a high unmet medical need.<sup>2</sup>

The Breakthrough and PRIME designations are supported by data from the Phase 1 MajesTEC-1 study ([NCT03145181](#)), an open-label, multicenter clinical trial evaluating the safety and efficacy of teclistamab in adults with measurable multiple myeloma that is relapsed or refractory to established therapies or be intolerant of those established multiple myeloma therapies.<sup>3</sup>

Updated results from the MajesTEC-1 study will be presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on June 8.

### **About Teclistamab**

Teclistamab is an off-the-shelf, T-Cell redirecting, bispecific antibody targeting both BCMA and CD3 receptors. BCMA is expressed at high levels on multiple myeloma cells.<sup>4,5,6,7,8</sup> Teclistamab redirects CD3-positive T-cells to BCMA-expressing myeloma cells to induce killing of tumor cells.<sup>6,7</sup> Results from preclinical studies demonstrate that teclistamab kills myeloma cell lines and bone marrow-derived myeloma cells from heavily pretreated patients.<sup>7</sup>

Teclistamab is currently being evaluated in a Phase 2 clinical study for the treatment of relapsed or refractory multiple myeloma ([NCT04557098](#)) and is also being explored in combination studies ([NCT04586426](#), [NCT04108195](#), [NCT04722146](#)). In 2020, the European Commission and the U.S. Food and Drug Administration each granted teclistamab orphan drug designation for the treatment of multiple myeloma. In January 2021, teclistamab was granted PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA). PRIME offers enhanced interaction and early dialogue to optimize drug development plans and speed up evaluation of cutting-edge, scientific advances that target a high unmet medical need.<sup>9</sup>

## **About Multiple Myeloma**

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.<sup>10,11</sup> When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2021, it is estimated that nearly 35,000 people will be diagnosed and more than 12,000 will die from the disease in the U.S.<sup>12</sup> While some patients 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.<sup>13</sup>

## **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 where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [@JanssenUS](https://twitter.com/JanssenUS) and [@JanssenGlobal](https://twitter.com/JanssenGlobal). Janssen Research & Development, LLC is one 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 teclistamab. 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 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://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.

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<sup>1</sup> 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

<sup>2</sup> European Medicines Agency. PRIME Factsheet. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines> Last accessed: May 2021

<sup>3</sup> Dose Escalation Study of Teclistamab, a Humanized BCMA CD3 DuoBody® Antibody, in Participants With Relapsed or Refractory Multiple Myeloma Last accessed: May 2021  
<https://www.clinicaltrials.gov/ct2/show/NCT03145181?term=NCT03145181&draw=2&rank=1> Last accessed: May 2021

<sup>4</sup> Labrijn AF et al. Proc Natl Acad Sci USA. 2013;110:5145.

<sup>5</sup> Frerichs KA et al. Clin Cancer Res. 2020; doi: 10.1158/1078-0432.CCR-19-2299.

<sup>6</sup> Cancer Research Institute. "Adoptive Cell Therapy: TIL, TCR, CAR T, AND NK CELL THERAPIES." Available at: <https://www.cancerresearch.org/immunotherapy/treatment-types/adoptive-cell-therapy>

<sup>7</sup> Cho SF et al. Frontiers in Immunology. 2018; 9: 1821.

<sup>8</sup> Benonis H et al. Molecular Cancer Therapeutics. 2019 (18) (2) 312-322.

<sup>9</sup> European Medicines Agency. PRIME Factsheet. Available at: <https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines> Accessed May 2021.

<sup>10</sup> Kumar SK, et al. Leukemia. 2012 Jan; 26(1):149-57.

<sup>11</sup> American Cancer Society. "What Is Multiple Myeloma?." Available at: <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Last accessed: May 2021

<sup>12</sup> American Cancer Society: Cancer Facts & Statistics. American Cancer Society | Cancer Facts & Statistics. <https://cancerstatisticscenter.cancer.org/#!/cancer-site/Myeloma>. Last accessed: May 2021.

<sup>13</sup> American Cancer Society. "Key Statistics About Multiple Myeloma." Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html>. Last accessed: May 2021.