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Janssen's Updated Phase 1 Results for Teclistamab Suggest Deep, Durable Responses in Patients with Heavily Pretreated Multiple Myeloma

Subcutaneous administration of BCMAxCD3 T-cell redirecting bispecific antibody demonstrated clinical activity and a promising safety profile according to new data at ASCO

May 24, 2021 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today longer follow-up results from the Phase 1 MajesTEC-1 study, the first-in-human dose-escalation study of teclistamab, an off-the-shelf T-cell redirecting bispecific antibody, in the treatment of patients with relapsed or refractory multiple myeloma (NCT03145181). With a median follow-up of more than six months, an overall response rate (ORR) of 65 percent was observed at the recommended subcutaneous (SC) Phase 2 dose (RP2D) in a cohort of heavily pretreated patients (n=40) who had received a median of five prior lines of therapy.[1] These data will be featured during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting as an oral presentation on Tuesday, June 8 (Abstract #8007).[1]

Study results show that responses were durable and deepened over time – 58 percent of patients receiving teclistamab achieved a very good partial response (VGPR) or better, and 40 percent achieved a complete response (CR) or better at the RP2D. The median time to first confirmed response was one month.**Error! Bookmark not defined.** After a median follow-up of 7.1 months

(range, 3.0–12.2 months), median duration of response was not reached and 85 percent (22/26) of responders were alive and continuing treatment.**Error! Bookmark not defined.**

There were no dose-limiting toxicities at the RP2D in part 1 of the study. Grade 1 neurotoxicity was reported in one patient treated at the RP2D.**Error! Bookmark not defined.** The most common adverse events at the RP2D were cytokine release syndrome (70 percent; all Grade 1/2) and neutropenia (65 percent; 40 percent Grade 3/4). The promising safety, efficacy, pharmacokinetics and pharmacodynamics confirm the selection of the 1500 ug/kg SC as the RP2D.**Error! Bookmark not defined.**

Forty patients were treated at the RP2D, identified as 1500 µg/kg SC. [1] Patients receiving the RP2D of teclistamab in this study had received a median of five prior lines of therapy (range 2–11); 100 percent were triple-class (proteasome inhibitor [PI], immunomodulatory drug (IMiD), CD38 antibody) exposed; 65 percent (n=26) were penta-drug (2 PIs, 2 IMiDs, CD38 antibody) exposed; 83 percent (n=33) were triple-class refractory; 38 percent (n=15) were penta-drug refractory; 83 percent (n=33) were refractory to their last line of therapy.[1] Patients with triple-class refractory and penta-drug refractory multiple myeloma often experience poor survival outcomes as treatment options are limited.[1]

"We reported initial findings for teclistamab at ASCO 2020, and study updates have observed a deepening of responses that have shown to be durable in a significant percentage of patients with relapsed or refractory multiple myeloma," said Amrita Y. Krishnan, M.D., Director of the Judy and Bernard Briskin Center for Multiple Myeloma Research and Chief, Division of Multiple Myeloma, Department of Hematology and Hematopoietic Cell Transplantation at City of Hope, and study investigator. "Teclistamab exposure was sustained across the dosing interval and exceeded target levels, and consistent T-cell activation was observed. With this latest follow-up data, we present further evidence of promising clinical activity in heavily pretreated patients, who are in urgent need of new therapeutic options."

The primary objectives of the Phase 1 study were to identify the RP2D (part 1) and characterize the safety and tolerability of teclistamab at the RP2D (part 2).**Error! Bookmark not defined.** As of March 2021, the study had enrolled 157 patients with multiple myeloma whose disease was relapsed, refractory, or intolerant to established therapies.**Error! Bookmark not defined.**

"We remain committed to investigating new treatments and approaches for patients with multiple myeloma, including off-the-shelf, T-cell redirecting bispecific antibodies like teclistamab," said Yusri Elsayed, M.D., M.HSc., Ph.D., Vice President, Global Head, Hematologic Malignancies, Janssen Research & Development, LLC. "The encouraging efficacy data reported at ASCO and especially the durability of the deep responses support the further investigation of teclistamab use as a monotherapy and in combination with other agents."

Additional data for teclistamab will be highlighted in a poster at ASCO on Friday, June 4 (Abstract #8047).[2] The study evaluated soluble B-cell maturation antigen (sBCMA) in patients with relapsed or refractory multiple myeloma treated with teclistamab or the bispecific antibody talquetamab (GPRC5DxCD3) and showed that both bispecific therapies induced changes in levels of sBCMA that correlated with clinical activity.

About Teclistamab

Teclistamab is an investigational, T-cell redirecting bispecific antibody targeting both BCMA and CD3. BCMA, B-cell maturation antigen, is expressed at high levels on multiple myeloma cells.[3,4,5,6,7] Teclistamab redirects CD3-positive T-cells to BCMA-expressing myeloma cells to induce killing of tumor cells.[5,6] Results from preclinical studies demonstrate that teclistamab kills myeloma cell lines and bone marrow-derived myeloma cells from heavily pretreated patients.[6]

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.

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.[8,9] 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.[10] 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.[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 where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JanssenUS and @JanssenGlobal. Janssen Research & Development, LLC is a member of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*Dr. Krishnan has served as a paid consultant to Janssen; she has not been paid for any media work.

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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, 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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