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Updated Results from the Phase 1 Study of the BCMAxCD3 Bispecific Teclistamab Show Preliminary Efficacy in Patients with Heavily Pretreated Relapsed or Refractory Multiple Myeloma

First-reported results for the subcutaneous formulation and updated results for the intravenous formulation presented at ASH 2020

December 5, 2020 (RARITAN, N.J.) – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today updated results from an ongoing Phase 1 first-in-human dose escalation study (NCT03145181) of teclistamab (JNJ-64007957) for the treatment of relapsed or refractory multiple myeloma. In heavily pretreated patients, the overall response rate (ORR) with teclistamab was 73 percent (16/22) at the recommended subcutaneous (SC) Phase 2 dose (RP2D).[1] Those results for the SC formulation support the recommended dose for the pivotal Phase 2 registration trial, which has started. In addition, updated results for the intravenous (IV) formulation demonstrate the durability of responses. The data will be featured during the American Society of Hematology (ASH) 2020 Annual Meeting as an oral presentation on Saturday, December 5 at 3:45 p.m. ET (Abstract #180).

"The data presented today for the subcutaneous formulation build on promising results presented earlier this year for the intravenous regimen," said Alfred Garfall, M.D., Assistant Professor of

Medicine, Perelman School of Medicine, University of Pennsylvania, and presenting author. "The preliminary efficacy, including durability of responses, combined with the initial safety profile in this highly-pretreated population is encouraging and supports further studies of teclistamab in patients with relapsed or refractory multiple myeloma who are in need of additional treatment options."

The study is conducted in two parts: dose escalation (part 1) and dose expansion (part 2). The study enrolled patients with multiple myeloma who had relapsed or were refractory to established therapies and had previously been treated with a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD).[1] Patients had received a median of six prior lines of treatment (range, 2-14); 96 percent were triple-class exposed, 81 percent were triple-class refractory, 91 percent were refractory to the last line of therapy, and 39 percent were penta-drug refractory to two or more immunomodulatory agents, two or more PIs, and an anti-CD38 therapy.[1] Patients with triple-class refractory and penta-drug refractory multiple myeloma have poor survival outcomes as treatment options are limited.[1]

The RP2D was identified as 1500 µg/kg SC, and the maximum tolerated dose has not been identified. Fifty-five percent of patients achieved a very good partial response or better (12/22), and 23 percent of patients (5/22) achieved a complete response (CR) or better with RP2D SC dosing. After median follow-up of 3.9 months (range, 1.7–7.4 months), 94 percent (15/16) of responders treated with the RP2D were alive and progression-free.1 Responses appeared durable and deepened over time at the RP2D.

Of the 11 patients who achieved CR and were evaluable for minimal residual disease (MRD) analysis across all IV and SC doses, eight patients attained MRD-negative CR at a threshold of 10^{-6} and one at a 10^{-5} threshold. Sustained MRD-negativity was confirmed for all five evaluable patients across the IV and SC cohorts.[1]

At the SC RP2D, 64 percent of patients experienced cytokine release syndrome (CRS) events, all of which were Grade 1 or 2 and generally confined to step-up, or a gradual increase in dosing, and first full doses. No patients discontinued treatment due to CRS. Of 33 treated patients at the RP2D, only one neurotoxicity event, which was Grade 1 and reversible, was observed. Selection of the 1500ug/kg SC RP2D is supported by promising safety, efficacy, pharmacokinetics and pharmacodynamics. The SC formulation may provide an opportunity for less frequent dosing for patients than the intravenous formulation, although this has not been explored in the current study.[1]

The most common adverse events (AEs) (all grade ≥20 percent) for the RP2D in the SC cohort were CRS (64 percent); neutropenia (52 percent); anemia (39 percent); thrombocytopenia (33 percent); leukopenia (33 percent); and fatigue (24 percent). In patients who experienced Grade 3 and above AEs (≥20 percent), the most common at the RP2D SC dose were neutropenia (33 percent); and anemia (21 percent).[1] One Grade 5 treatment related AE (pneumonia) was reported at the 80 µg/kg IV dose, but none at the RP2D.[1]

"We are committed to exploring treatment options that use promising modalities in multiple myeloma, including bispecific antibodies like teclistamab, that increase treatment responses through antigen targeting," said Yusri Elsayed, M.D., MHSc., Ph.D., Vice President, Global Head, Hematologic Malignancies, Janssen Research & Development, LLC. "Our research in multiple myeloma is broad, exploring multiple targets through a variety of approaches. We continue to identify new treatment options, particularly for patients who have relapsed or become refractory to existing therapies."

Additional pharmacokinetic and ex vivo data for teclistamab will be highlighted in a poster on Monday, December 7 from 10:00 am to 6:30 pm ET (Abstract #3194).[2] This study evaluated the ability of teclistamab to induce cytotoxicity and T-cell activation.

About Teclistamab

Teclistamab is an investigational 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 cytotoxicity of the targeted 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). The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.* In October and November 2020, the European Commission and the U.S. Food and Drug Administration (FDA), respectively, granted teclistamab orphan designation for the treatment of multiple myeloma respectively.

*DuoBody is a registered trademark of Genmab A/S.

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 2020, it is estimated that more than 32,000 people will be diagnosed and close to 13,000 will die from the disease in the U.S.[10] While some patients with multiple myeloma have no symptoms, most patients are diagnosed due to symptoms, which 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

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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 December 29, 2019, 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. Neither 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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