News Release

Media Contact:
Noah Reymond
Mobile: +31 621 38 5718
Email: NReymond@its.jnj.com

Investor Relations:
Christopher DelOrefice
Office: +1 732 524 2955

Jennifer McIntyre
Office: +1 732 524 3922

Janssen Presents First Data from Phase 1 Study of BCMAxCD3 Bispecific Teclistamab in Patients with Heavily Pre-treated Relapsed or Refractory Multiple Myeloma

Teclistamab Data Featured as an Oral Presentation During ASCO Virtual Scientific Programme

BEERSE, BELGIUM, May 18, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today results reported for the first time from a Phase 1 first-in-human dose escalation study (NCT03145181) of teclistamab (JNJ-7957), an investigational bispecific antibody targeting both B-cell maturation antigen (BCMA) and CD3 receptors on T-cells, in the treatment of patients with relapsed or refractory multiple myeloma. Initial results suggest a manageable safety profile across all teclistamab doses evaluated.[1,2] Investigators reported that patients achieved deep responses which persisted, including some minimal residual disease (MRD)-negative complete responses (CR) at 10^{-6}, with one durable beyond

12 months.[1] The data will be featured during the American Society of Clinical Oncology (ASCO) Virtual Scientific Programme as an oral presentation on Saturday, May 30 at 1:00 p.m. ET/6:00 p.m. BST (Abstract #100).

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).[1,2] Patients had received a median of six prior lines of treatment (range, 2-14) before starting the study; 92 percent were triple-class exposed, 86 percent were refractory to the last line of therapy, 80 percent were triple-class refractory, and 41 percent were penta-drug refractory, meaning their cancer did not respond to treatment or had relapsed within 60 days with 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 face poorer survival outcomes as treatment options are limited.[3]

"While the treatment of multiple myeloma has significantly advanced over recent years, finding additional treatment options for patients who relapse and become resistant to existing therapies remains critical," said Saad Usmani, M.D., FACP, Department of Hematologic Oncology and Blood Disorders, Levine Cancer Institute/Carolinas HealthCare System, and lead study investigator. "Initial findings for teclistamab in this heavily pre-treated population support further study of this investigational dual-targeting immunotherapeutic."

The study will be conducted in two parts: dose escalation (part 1) and dose expansion (part 2).[1,2] Results from the Phase 1 portion of the study showed deep responses among patients (n=78) who were treated with teclistamab across dose groups, ranging from 0.3 µg/kg-720 µg/kg. At the 270 µg/kg dose (n=12), the overall response rate (ORR) was 67 percent (8/12); 50 percent (6/12) of patients achieved a very good partial response (VGPR) or better, and three patients achieved CR.[1] Responses were deep and persisted. At the time of data cut-off, 76 percent (16/21) of patients who achieved a response across all doses remained in

the study with an ongoing response, and 80 percent (4/5) who were evaluable for MRD analysis were MRD-negative, with two patients having a MRD-negative CR. Maintained MRD-negativity was confirmed for both patients who could be evaluated.[1] Additional dose escalation and expansion of the study is ongoing.[1]

"We are continuing to pursue scientific advances in cancer types that we know best, like multiple myeloma, where we can achieve the optimal impact," said Patrick Laroche, M.D., Haematology Therapy Area Lead, Europe, Middle East and Africa (EMEA), Janssen-Cilag. "With teclistamab we aim to make a difference to the lives of the most vulnerable patients."

"We are committed to a multiplatform approach in our scientific strategy to address patients' needs and provide treatment options for all patients with multiple myeloma," said Yusri Elsayed, M.D., M.H.Sc., Ph.D. Vice President, Global Head, Hematologic Malignancies, Janssen Research & Development, LLC. "Teclistamab is an example of one of our bispecific antibodies where we look to harness our immunotherapy expertise to advance potentially new options for patients whose disease has sadly progressed."

In the Phase 1 study, the most common adverse events (AEs) (all grade) were anaemia (58 percent); cytokine release syndrome (CRS) (56 percent); neutropenia (45 percent); thrombocytopenia (40 percent); and pyrexia (31 percent). In patients who experienced Grade 3 and above AEs (≥20 percent), the most common were neutropenia (38 percent); anaemia (36 percent); and thrombocytopenia (24 percent).[1] One Grade 5 AE, respiratory failure in the setting of pneumonia, was reported but deemed by the investigator to be unrelated to the treatment.[1] CRS events were all mild or moderate (Grade 1–2) and generally confined to first step-up and full doses, which may support the use of step-up dosing to mitigate CRS.[1]

About Teclistamab

Teclistamab (JNJ-7957) is an investigational bispecific antibody targeting both BCMA and CD3.[1] CD3 is involved in activating the immune system's response to fight infection, and BCMA is expressed at significantly higher levels in people with

multiple myeloma.[4,5,6] Teclistamab redirects CD3 T-cells to BCMA-expressing myeloma cells to induce cytotoxicity of the targeted cells.[4,5] Results from preclinical studies demonstrate that teclistamab kills myeloma cell lines and myeloma bone marrow cells from heavily pre-treated patients.[4]

Teclistamab is currently being evaluated in a Phase 1 clinical study for the treatment of relapsed or refractory multiple myeloma and is also being explored in combination studies. The production and development of the antibody followed Janssen Biotech, Inc.'s licensing agreement with Genmab for use of its DuoBody® technology platform.*

About Multiple Myeloma

Multiple myeloma (MM) is an incurable blood cancer that starts in the bone marrow and is characterised by an excessive proliferation of plasma cells.[7] In Europe, more than 48,200 people were diagnosed with MM in 2018, and more than 30,800 patients died.[8] Around 50 percent of newly diagnosed patients do not reach five-year survival,[7,9] and almost 29 percent of patients with multiple myeloma will die within one year of diagnosis.[10]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[11] Relapsed and refractory myeloma is defined as disease that is nonresponsive while on salvage therapy, or progresses within 60 days of last therapy in patients who have achieved minimal response (MR) or better at some point previously before then progressing in their disease course.[12] While some patients with MM have no symptoms at all, others are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[13] Patients who relapse after treatment with standard therapies,

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

including protease inhibitors and immunomodulatory agents, have poor prognoses and require new therapies for continued disease control.[14]

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/emea. Follow us at www.twitter.com/janssenEMEA for our latest news.

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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 behaviour 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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May 2020

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