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News Release

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DARZALEX® (daratumumab) Subcutaneous Formulation-based Quadruplet Therapy Regimen Shows Significant Improvement in Outcomes for Patients with Transplant-eligible Newly Diagnosed Multiple Myeloma

Daratumumab subcutaneous-based induction, consolidation and maintenance regimen reduced risk of progression or death by 58 percent compared to standard of care regimen[1]

First presentation of data from Phase 3 PERSEUS study highlighted in late-breaking abstract session at 2023 ASH Annual Meeting and simultaneously published in The New England Journal of Medicine[1,2]

BEERSE, BELGIUM, 12 December, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the first data from the Phase 3 PERSEUS study highlighting significant clinical improvement with a DARZALEX® (daratumumab) subcutaneous (SC) formulation-based quadruplet induction, consolidation regimen and doublet maintenance regimen in the treatment of transplant-eligible (TE) newly diagnosed multiple myeloma (NDMM).[1] The data, showing significantly improved progression-free survival (PFS) in the Phase 3 study evaluating TE NDMM and clinically significant improvement in rates of overall complete response (CR) or better and minimal residual disease (MRD) negativity over the comparator arm,[1] were featured as a late-breaking oral presentation at the 2023 American Society of Hematology (ASH) Annual Meeting (Abstract #LBA-1), taking place in San Diego,

California from 9-12 December. The data were published simultaneously in *The New England Journal of Medicine*.[2]

The PERSEUS study, conducted in collaboration with the European Myeloma Network, found that induction and consolidation treatment with daratumumab SC in combination with bortezomib, lenalidomide and dexamethasone (D-VRd), followed by daratumumab SC and lenalidomide (D-R) maintenance, reduced the risk of disease progression or death by 58 percent (Hazard Ratio [HR], 0.42; 95 percent Confidence Interval [CI] 0.30-0.59; *P* <0.0001), compared to bortezomib, lenalidomide and dexamethasone (VRd) alone followed by lenalidomide (R) maintenance.[1] The quadruplet regimen also significantly increased the depth of response compared to treatment with VRd alone, with higher rates of CR or better, stringent CR (sCR), and MRD negativity.[1]

"The progression-free survival that was achieved in transplant-eligible patients who were treated with the daratumumab subcutaneous-based induction, consolidation and maintenance therapy regimen is unprecedented in a Phase 3 clinical study evaluating this patient population, but it is not unexpected as these findings build on a number of studies that previously demonstrated clinical benefit with daratumumab-based regimens in this patient population," said Pieter Sonneveld, M.D., Ph.D., Professor of Hematology at the Erasmus University of Rotterdam and Chair of the Erasmus MC Cancer Institute, Rotterdam, Netherlands.[†] "The results we see across clinically relevant subgroups, including in patients who present with advanced disease or who are considered high risk, are promising for clinicians who are on the frontlines of treating patients who are newly diagnosed with this complex disease."

The estimated 48-month PFS rates were 84.3 percent for D-VRd vs 67.7 percent for VRd.[1] The consistent PFS improvement with D-VRd vs VRd was observed across most clinically relevant subgroups, including patients with International Staging System (ISS) stage III disease (HR, 0.42; 95 percent CI, 0.22-0.83) or high cytogenetic risk (HR, 0.59; 95 percent CI, 0.36-0.99).[1] Treatment with D-VRd also resulted in deeper responses compared with VRd, including higher rates of sCR (69.3 percent vs 44.6 percent; *P*<0.0001), and ≥CR (87.9 percent vs 70.1 percent; *P*<0.0001).[1] Overall MRD negativity rates (10^{-5}) were higher with D-VRd versus VRd (75.2 percent vs 47.5 percent; *P*<0.0001).[1] Sustained MRD negativity rates (for ≥12 months) more than doubled with D-VRd (64.8 percent vs 29.7 percent;

P<0.0001).[1] Overall survival (OS) data are not yet mature but trending favourably for the D-VRd arm compared to VRd.[1]

"The impressive results from the PERSEUS study highlight the potential of a daratumumab subcutaneous-based, quadruplet therapy combination to improve outcomes for patients with newly diagnosed multiple myeloma," said Edmond Chan, MBChB, M.D. (Res), EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. "We are encouraged by these results, and the opportunity to provide one more treatment option for patients. The results of PERSEUS reinforce our commitment to developing transformative treatment regimens, as we work towards our wider goal of curing multiple myeloma."

The overall safety profile of D-VRd was consistent with the known safety profiles for daratumumab SC and VRd. The most common (>10 percent) grade 3/4 haematologic and non-haematologic adverse events (AEs) with D-VRd vs VRd were neutropenia (62.1 percent vs 51.0 percent), thrombocytopenia (29.1 percent vs 17.3 percent), diarrhoea (10.5 percent vs 7.8 percent), pneumonia (10.5 percent vs 6.1 percent), and febrile neutropenia (9.4 percent vs 10.1 percent).[1]

"We now have evidence supporting this daratumumab subcutaneous-based quadruplet induction and consolidation regimen and doublet maintenance regimen as a potential standard of care in transplant-eligible disease, complementing data from the Phase 3 MAIA study, which established a daratumumab-based triplet therapy as standard of care in transplant-ineligible disease," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Johnson & Johnson Innovative Medicine. "We will continue to advance innovative regimens and approaches with daratumumab to deliver on our commitment of transforming outcomes for patients with multiple myeloma."

#ENDS#

About the PERSEUS Study

The PERSEUS study is being conducted in collaboration with the European Myeloma Network as a sponsor. PERSEUS is an ongoing, randomised, open-label, Phase 3 study comparing the efficacy and safety of D-VRd followed by D-R maintenance versus VRd followed by R maintenance in patients with transplant-eligible NDMM.[3] The primary endpoint was PFS, and

secondary endpoints included overall CR or better rate, overall MRD-negativity (in patients with CR or better), and overall survival.[1] The median age is 61.0 (32-70) years for patients in the D-VRd arm and 59.0 (31-70) years for patients in the VRd arm.[1] The study is being conducted in 14 countries across Europe and Australia.[2]

About daratumumab and daratumumab SC

Janssen is committed to exploring the potential of daratumumab for patients with multiple myeloma across the spectrum of the disease. Daratumumab has been approved in eight indications for multiple myeloma, three of which are in the frontline setting, including newly diagnosed patients who are transplant-eligible and ineligible.[4]

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialise daratumumab. Since launch, daratumumab has become a foundational therapy in the treatment of multiple myeloma, having been used in the treatment of more than 452,000 patients worldwide.[5] Daratumumab is the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma.[4] [4]Daratumumab SC is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.[6]

CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.[4] Daratumumab binds to CD38 and inhibits tumour cell growth causing myeloma cell death.[4] Daratumumab may also have an effect on normal cells.[4] Data across eight Phase 3 clinical trials, in both the frontline and relapsed settings, have shown that daratumumab-based regimens resulted in significant improvement in PFS and/or OS.[7,8,9,10,11,12,13,14]

For further information on daratumumab, please see the Summary of Product Characteristics at: https://www.ema.europa.eu/en/documents/product-information/darzalex-epar-product-information_en.pdf.

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.[15,16] In multiple myeloma, these malignant plasma cells change and grow out of control.[17] In the European Union, it is

estimated that more than 35,300 people were diagnosed with multiple myeloma in 2022, and more than 22,700 patients died.[18] While some patients with multiple myeloma initially have no symptoms, others can have common signs and symptoms of the disease, which can include bone fracture or pain, low red blood cell counts, fatigue, high calcium levels, infections or kidney damage.[19]

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: Oncology, Immunology, Neuroscience, Cardiovascular, Pulmonary Hypertension, and Retina.

Learn more at www.janssen.com/emea. Follow us at www.linkedin.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech and Janssen Research & Development, LLC are part of Johnson & Johnson.

† *Prof. Sonneveld has provided consulting, advisory, and speaking services to Janssen; he has not been paid for any media work.*

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 daratumumab. 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 Pharmaceutica NV, Janssen-Cilag Limited, Jassen Biotech, Janssen Research and Development, LLC, 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 January 1, 2023, 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 http://www.sec.gov/, http://www.jnj.com/ or on request from Johnson & Johnson. None of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Janssen Research and Development, LLC, 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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