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For Immediate Release

DARZALEX® (daratumumab)-based quadruplet regimen receives positive CHMP opinion for transplant-eligible patients with newly diagnosed multiple myeloma

Recommendation supported by findings from quadruplet therapy PERSEUS study with daratumumab subcutaneous (SC) formulation in the frontline setting

Findings showed 60 percent reduction in risk of disease progression or death with daratumumab SC quadruplet regimen compared to current standard of care triplet regimen[1]

BEERSE, BELGIUM (20 September 2024) – Janssen-Cilag International NV, a Johnson & Johnson company, announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of a Type II variation for DARZALEX® (daratumumab) subcutaneous (SC) formulation. The recommendation is for daratumumab SC in combination with bortezomib, lenalidomide, and dexamethasone (D-VRd), for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem-cell transplant (ASCT).[2] SC formulation was previously approved by the European Commission in June 2020.[3]

“Optimising frontline therapy is crucial in disease control and improving long-term outcomes for patients with newly diagnosed multiple myeloma,” said Edmond Chan, MBChB, M.D. (Res), EMEA Therapeutic Area Lead Haematology, Johnson & Johnson Innovative Medicine. “By incorporating daratumumab SC into this novel quadruplet regimen, we aim to establish a new standard of care for eligible patients, enhancing progression-free survival and transforming the treatment landscape.”

The CHMP recommendation for daratumumab is supported by data from the Phase 3 PERSEUS (NCT03710603) study,[4] evaluating D-VRd induction and consolidation therapy, and daratumumab with lenalidomide (D-R) maintenance therapy, compared to VRd induction and consolidation, and R maintenance, in transplant eligible patients with newly diagnosed multiple myeloma.[1] Data from the study were recently presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.

“Since its initial European approval in 2016, daratumumab has become a foundational therapy for the treatment of multiple myeloma, and we have remained dedicated to harnessing its full potential for all patients at every stage of the disease,” said Jordan Schecter, M.D., Vice President, Disease Area Leader, Multiple Myeloma, Johnson & Johnson Innovative Medicine. “Today’s positive recommendation reflects our unwavering commitment to advancing novel therapies and transformative combination regimens, like D-VRd, towards the ultimate goal of eliminating this complex disease.”

Daratumumab is currently approved in eight indications for multiple myeloma, four of which are in the frontline setting, including as part of treatment regimens for newly diagnosed patients who are transplant-eligible or ineligible for ASCT.[3]

The positive CHMP opinion follows the recent U.S. Food and Drug Administration (FDA) approval of daratumumab SC in combination with D-VRd for induction and consolidation in patients with newly diagnosed multiple myeloma who are eligible for ASCT.

About daratumumab and daratumumab SC

Johnson & Johnson is committed to exploring the potential of daratumumab for patients with multiple myeloma across the spectrum of the disease.

In August 2012, Janssen Biotech, Inc., a Johnson & Johnson company and Genmab A/S entered a worldwide agreement, which granted Johnson & Johnson an exclusive licence 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 548,000 patients worldwide.[5] Daratumumab is the only CD38-directed

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antibody approved to be given subcutaneously to treat patients with multiple myeloma.[3] 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.[3] Daratumumab binds to CD38 and inhibits tumour cell growth causing myeloma cell death.[2] Daratumumab may also have an effect on normal cells.[3] Data across nine Phase 3 clinical trials, in both the frontline and relapsed settings, have shown that daratumumab-based regimens resulted in significant improvement in progression-free survival and/or overall survival.[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 currently 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 continue to proliferate, accumulating in the body and crowding out normal blood cells, as well as often causing bone destruction and other serious complications.[16] In the European Union, it is estimated that more than 35,000 people were diagnosed with multiple myeloma in 2022, and more than 22,700 patients died.[17] Whilst 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.[18]

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today, to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

Learn more at www.janssen.com/emea. Follow us at www.linkedin.com/jnj-innovative-medicine-emea. Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., and Janssen Research & Development, LLC are Johnson & Johnson companies.

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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., Janssen Research & 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 December 31, 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, Inc., Janssen Research & 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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