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Janssen Announces Results from Phase 3 MAIA Study Showing Significant Overall Survival Benefits for Treatment with DARZALEX®▼ (daratumumab) in Patients with Newly Diagnosed Multiple Myeloma Who are Transplant Ineligible

After nearly five years of follow-up, median progression-free survival was not reached, and a significant overall survival benefit was observed; data will be presented as a late-breaking abstract at the European Hematology Association (EHA) Virtual Congress

BEERSE, BELGIUM, 12 June, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced overall survival (OS) results from the Phase 3 MAIA (NCT02252172) study showing the addition of DARZALEX® ▼(daratumumab) to lenalidomide and dexamethasone (D-Rd) resulted in a statistically significant survival benefit over lenalidomide and dexamethasone (Rd) alone in patients with newly diagnosed multiple myeloma (NDMM) who were ineligible for autologous stem cell transplant (ASCT) and were treated to progression.[1] These data were featured in the European Hematology Association (EHA) 2021 Virtual Press Briefing and will be presented as a late-breaking abstract during the EHA Virtual Congress (Abstract #LB1901).

The prespecified interim analysis for OS found that after a median follow-up of nearly five years (56.2 months), a 32 percent reduction in the risk of death was observed in the D-Rd treatment arm vs. Rd arm.[1] Median OS was not reached in either arm [hazard ratio (HR): 0.68, 95 percent confidence interval (CI), 0.53-0.86; p=0.0013].[1] Median progression-free survival (PFS) was not reached after nearly five years and the PFS benefit observed with D-Rd was maintained, with a 47

percent reduction in risk of disease progression or death [HR: 0.53; 95 percent CI, 0.43-0.66; $p<0.0001$].[1] These data are expected to form the basis of future regulatory submissions.

"The treatment of multiple myeloma becomes more complex with each relapse. Therefore, it is critical to achieve deep treatment responses and improved survival with frontline therapy," said Thierry Facon*, M.D., Professor of Haematology at Lille University Hospital, Lille, France and study investigator. "These results strongly support the use of daratumumab, lenalidomide and dexamethasone as a new standard of care to extend survival and improve clinical outcomes in transplant ineligible patients with newly diagnosed multiple myeloma."

All patients enrolled in the MAIA study (n=737) were diagnosed with NDMM, were ineligible for high-dose chemotherapy and ASCT, and received 28-day cycles of D-Rd (n=368) or Rd (n=369). Patients were treated until disease progression or unacceptable toxicity.[1] The median age of patients was 73 years (range, 45-90 years). Median PFS was not reached with D-Rd vs. 34.4 months with Rd [HR, 0.53; 95 percent CI, 0.43-0.66; $p<0.0001$]. Of the 186 patients in the Rd arm who received subsequent therapy, 46 percent received daratumumab.[1]

Additional New Findings from the MAIA Longer-Term Follow-Up Analysis:

- Estimated five-year OS rate of 66 percent with D-Rd vs. 53 percent with Rd (HR: 0.68; 95 percent CI, 0.53-0.86; $p=0.0013$).[1]
- Estimated five-year PFS rate of 53 percent with D-Rd vs. 29 percent with Rd [HR: 0.53; 95 percent CI, 0.43-0.66; $p<0.0001$].[1]
- Median time to next treatment was not reached with D-Rd vs. 42.4 months with Rd [HR, 0.47; 95 percent CI, 0.37-0.59 $p<0.0001$].[1]
- Updated overall response rate (ORR) of 93 percent with D-Rd vs. 82 percent with Rd.[1]

No new safety concerns were identified in the D-Rd arm. The most common Grade 3 or 4 treatment-emergent adverse events were neutropenia (D-Rd: 54 percent; Rd: 37 percent); pneumonia (D-Rd: 19 percent; Rd: 11 percent); anaemia (D-Rd: 17 percent; Rd: 22 percent); and lymphopenia (D-Rd: 16 percent; Rd: 11 percent).[1]

"These latest findings from the MAIA study demonstrate the impact of this daratumumab combination regimen on long-term survival in the frontline setting, further establishing the importance of daratumumab as a backbone therapy in the treatment of multiple myeloma," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. "These results provide hope and confidence for newly diagnosed patients with

multiple myeloma seeking effective treatment regimens that improve long term outcomes and reflect our commitment to continuing to explore the full potential of daratumumab in multiple myeloma."

"Despite multiple myeloma being a difficult to treat, incurable blood cancer, we are pleased to see this daratumumab-based regimen in combination with lenalidomide and dexamethasone continue to deliver positive overall survival and progression-free results to patients with newly diagnosed multiple myeloma within this extended follow-up" said Edmond Chan, EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Ltd. "The new findings from the MAIA study reinforce the transformative role of daratumumab in multiple myeloma and highlight our ongoing commitment to changing what a multiple myeloma diagnosis means to patients".

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About the MAIA Trial[2]

The randomised, open-label, multicentre Phase 3 study included 737 newly diagnosed patients with multiple myeloma ineligible for high-dose chemotherapy and ASCT, aged 45-90 years (median age of 73).[1] Patients were randomised to receive either daratumumab-Rd (D-Rd) or Rd alone in 28-day cycles. In the D-Rd arm, patients received daratumumab 16 milligrams per kilogram (mg/kg) IV weekly for Cycles 1 – 2, every two weeks for Cycles 3 – 6 and every 4 weeks for Cycle 7 and thereafter.[1] Patients in the D-Rd and Rd treatment arms received 25 mg of lenalidomide on Days 1 – 21 of each 28-day cycle, and dexamethasone at 40 mg once a week for each cycle. Patients in both treatment arms continued until disease progression or unacceptable toxicity.[1]

Earlier results from the MAIA study supported the European Commission (EC) approval of daratumumab in combination with Rd, marking the first approval of a CD-38 monoclonal antibody for patients with transplant ineligible NDMM. These data were also published in *The New England Journal of Medicine* in 2019.

About daratumumab

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, it is estimated that nearly 190,000 patients have been treated with daratumumab worldwide.[3] Daratumumab is also the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma (MM). Daratumumab SC is co-formulated

with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.[4]

CD38 is a surface protein that is highly expressed across MM cells, regardless of the stage of disease. Daratumumab binds to CD38 and induces myeloma cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as well as through apoptosis, in which a series of molecular steps in a cell lead to its death.[5]

Data across nine Phase 3 clinical trials in the frontline and relapsed settings for MM and newly diagnosed light chain (AL) amyloidosis, have shown that daratumumab-based regimens resulted in significant improvement in progression-free survival and/or overall survival.[6,7,8,9,10,11,12,13,14] Additional studies have been designed to assess the efficacy and safety of daratumumab in the treatment of other malignant and pre-malignant haematologic diseases in which CD38 is expressed.[15]

For further information on daratumumab, please see the Summary of Product Characteristics at https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex

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.[16] In Europe, more than 50,900 people were diagnosed with MM in 2020, and more than 32,500 patients died.[17] Around 50 percent of newly diagnosed patients do not reach five-year survival,[18,19] and almost 29 percent of patients with MM will die within one year of diagnosis.[20]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[21] Relapsed and refractory MM 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.[22] 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.[23] Patients who relapse after treatment with standard therapies, including proteasome inhibitors and immunomodulatory agents, have poor prognoses and require new therapies for continued disease control.[24]

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. Janssen Research & Development, LLC, Janssen-Cilag Ltd., Janssen Pharmaceutica NV and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

*Dr. Facon has served as a consultant 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 daratumumab subcutaneous formulation for the treatment of patients with light chain amyloidosis. 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, Janssen-Cilag Ltd., Janssen Pharmaceutica NV, Janssen Biotech, Inc., 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 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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References:

[1] Facon T et al. Overall Survival Results With Daratumumab, Lenalidomide and Dexamethasone Versus Lenalidomide and Dexamethasone in Transplant-ineligible Newly Diagnosed Multiple Myeloma: Phase 3 MAIA Study. Abstract #LB1901. Presented at 2021 European Hematology Association Virtual Congress.
[2] Clinical Trals.gov. Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Participants With Previously Untreated Multiple Myeloma [identifier: NCT02252172]. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02252172. Last accessed: June 2021.
[3] Janssen [data on file]. Number of patients treated with DARZALEX worldwide as of March 2021. RF-171498.
[4] Janssen EMEA. European Commission Grants Marketing Authorisation for DARZALEX®▼(Daratumumab) Subcutaneous Formulation for All Currently Approved Daratumumab Intravenous Formulation Indications. Available at: www.businesswire.com/news/home/20200604005487/en/European-Commission-GrantsMarketing-Authorisation-for-DARZALEX%C2%AE%E2%96%BC-daratumumab-Subcutaneous-Formulation-forall-Currently-Approved-Daratumumab-Intravenous-Formulation-Indications. Last accessed: June 2021.
[5] European Medicines Agency. DARZALEX Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/darzalex-epar-productinformation_en.pdf. Last accessed: June 2021.
[6] Janssen Research & Development, LLC. A Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at: https://clinicaltrials.gov/ct2/show/NCT02076009?term=mmy3003&rank=1 Identifier: NCT02076009. Last accessed: June 2021.
[7] Janssen Research & Development, LLC. Addition of Daratumumab to Combination of Bortezomib and Dexamethasone in Participants With Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24]. Available at: https://clinicaltrials.gov/ct2/show/NCT02136134?term=mmy3004&rank=1 Identifier: NCT02136134. Last accessed: June 2021.
[8] Janssen Research & Development, LLC. A Study to Evaluate Daratumumab in Transplant Eligible Participants With Previously Untreated Multiple Myeloma (Cassiopeia). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24]. Available at: https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmy3006 Identifier: NCT02541383. Last accessed: June 2021.
[9] Janssen Research & Development, LLC. A Study of Combination of Daratumumab and Velcade (Bortezomib) Melphalan-Prednisone (DVMP) Compared to Velcade Melphalan-Prednisone (VMP) in Participants With Previously Untreated Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24]. Available at: https://clinicaltrials.gov/ct2/show/NCT02195479?term=mmy3007&rank=1 Identifier: NCT02195479. Last accessed: June 2021.
[10] Janssen Research & Development, LLC. Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Participants With Previously Untreated Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24]. Available at: https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmy3008&rank=1 Identifier: NCT02252172. Last accessed: June 2021.
[11] Janssen Research & Development, LLC. A Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination With VMP (D-VMP), in Participants With Previously Untreated Multiple Myeloma Who Are Ineligible for High-Dose Therapy (Asia Pacific Region). In: ClinicalTrials.gov

[Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24]. Available at: https://clinicaltrials.gov/ct2/show/NCT03217812?term=MMY3011&rank=1 Identifier: NCT03217812. Last accessed: June 2021.

[12] European Myeloma Network. Compare Progression Free Survival Btw Daratumumab/Pomalidomide/Dexamethasone vs Pomalidomide/Dexamethasone (EMN14). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24] Available at: https://clinicaltrials.gov/ct2/show/NCT03180736?term=MMY3013&rank=2 Identifier: NCT03180736. Last accessed: June 2021.

[13] Amgen. Study of Carfilzomib, Daratumumab and Dexamethasone for Patients With Relapsed and/or Refractory Multiple Myeloma. (CANDOR). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 [cited 2018 July 24] Available at: https://clinicaltrials.gov/ct2/show/NCT03158688?term=NCT03158688&rank=1 Identifier: NCT03158688. Last accessed: June 2021.

[14] ClinicalTrials.Gov. A Study to Evaluate the Efficacy and Safety of Daratumumab in Combination With Cyclophosphamide, Bortezomib and Dexamethasone (CyBorD) Compared to CyBorD Alone in Newly Diagnosed Systemic Amyloid Light-chain (AL) Amyloidosis. Available at: https://clinicaltrials.gov/ct2/show/NCT03201965 Last accessed: June 2021.

[15] ClinicalTrials.Gov. A Study of Subcutaneous Daratumumab Versus Active Monitoring in Participants With High-Risk Smoldering Multiple Myeloma. Available at: https://clinicaltrials.gov/ct2/show/NCT03301220 Last accessed: June 2021.

[16] American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction Last accessed: June 2021.

[17] GLOBOCAN 2020. Cancer Today Population Factsheets: Europe Region. Available at: https://gco.iarc.fr/today/data/factsheets/populations/908-europe-fact-sheets.pdf Last accessed: June 2021.

[18] American Society of Clinical Oncology. Multiple Myeloma: Statistics. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/statistics Last accessed: June 2021.

[19] Cancer Research UK. Myeloma statistics. Available at: https://www.cancerresearchuk.org/healthprofessional/cancer-statistics/statistics-by-cancer-type/myeloma Last accessed: June 2021.

[20] Costa LJ, Gonsalves WI, Kumar SK. Early mortality in multiple myeloma. Leukemia. 2015;29:16168.

[21] Abdi J, Chen G, Chang H, et al. Drug resistance in multiple myeloma: latest findings and new concepts on molecular mechanisms. Oncotarget. 2013;4:2186–207.

[22] Rajkumar SV, Harousseau JL, Durie B, Anderson KC, Dimopoulos M, Kyle R, Blade J, Richardson P, Orlowski R, Siegel D, Jagannath S. Consensus recommendations for the uniform reporting of clinical trials: report of the International Myeloma Workshop Consensus Panel 1. Blood, The Journal of the American Society of Hematology. 2011 May 5;117(18):4691-5.

[23] American Cancer Society. Multiple myeloma: early detection, diagnosis and staging. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/8740.00.pdf. Last accessed: June 2021.

[24] Kumar SK, Lee JH, Lahuerta JJ, et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. Leukemia. 2012;26:149-57.