FOR EUROPEAN AND UK TRADE AND MEDICAL MEDIA ONLY

Media contacts:
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

Updated Data Demonstrate Significant Improvement in Haematologic Complete Response with DARZALEX®▼ (daratumumab) Subcutaneous (SC) Formulation in Patients with Newly Diagnosed Light Chain (AL) Amyloidosis

Further analysis from the Phase 3 ANDROMEDA study presented at the 2021 ASCO Annual Meeting also show doubling rates of organ response with no new safety signals

BEERSE, BELGIUM, 26 May, 2021– The Janssen Pharmaceutical Companies of Johnson & Johnson today announced updated results from the Phase 3 ANDROMEDA study, which evaluated DARZALEX®▼ (daratumumab) subcutaneous (SC) formulation for the treatment of patients with newly diagnosed light chain (AL) amyloidosis, a rare blood cell disorder associated with the deterioration of vital organs, most notably the heart, kidneys and liver.[1] Longer-term results from a median follow up of 20.3 months showed rates of haematologic complete response (hemCR) remained significantly higher in patients treated with daratumumab SC in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd) compared to VCd alone (Abstract #8003).[2] These data will be featured in an oral presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting on Tuesday, June 8, and following at the 26th European Hematology Association (EHA) Congress on Friday, June 11.

"Patients with AL amyloidosis, including those with organ dysfunction, often face poor outcomes, and as many as 30 percent die within the first year of diagnosis," said Efstathios Kastritis, M.D.*, Professor of Clinical Therapeutics at the National and Kapodistrian University of Athens School of Medicine, Athens, Greece and study investigator. "The longer-term results from the ANDROMEDA

CP-234626
May 2021

study show sustained overall deep haematologic responses and further establish the potential of the subcutaneous formulation of daratumumab as a new treatment regimen in patients with AL amyloidosis, and I'm also encouraged to see additional investigational data showing cardiac and renal responses in these patients."

Earlier findings from the Phase 3 study supported the recent Positive Opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending use of daratumumab in combination with VCd for the treatment of adult patients with newly diagnosed systemic AL amyloidosis. A decision by the European Commission (EC) is expected in the coming weeks.

"There remains a high unmet treatment need for patients with AL amyloidosis, with no approved therapies currently available in Europe," said Edmond Chan, EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Ltd. "The positive results from the ANDROMEDA study provide an encouraging step forward in our mission to improve outcomes for people living with complex blood disorders."

Key Findings from the ANDROMEDA Oral Presentation (Abstract #8003):

- In the study comparing D-VCd (n=193) to VCd (n=188), the primary endpoint, hemCR, remained significantly higher with D-VCd compared to VCd, increasing from 53 percent vs. 18 percent (at median follow-up of 11.4 months) to 59 percent vs. 19 percent (at 20.3 months).[2] At 20.3 months median follow-up, more patients achieved a very good partial response or better (≥VGPR) with D-VCd than VCd (79 percent vs 50 percent).[2]
    - Median time from randomisation to ≥VGPR was shorter in patients receiving D-VCd compared to VCd.[2]
- Among cardiac responders treated with D-VCd (n=118) compared to VCd (n=117), response rates increased from 42 percent to 57 percent at 12 months for those treated with D-VCd compared to an increase of 22 percent to 28 percent at 12 months for VCd.[2]
- Among patients who had renal responses treated with D-VCd (n=117) compared to VCd (n=113), rates remained stable increasing from 54 percent to 57 percent at 12 months for those treated with D-VCd and remaining at 27 percent at 12 months for VCd.[2]

At longer-term follow-up, no new safety signals were observed for daratumumab SC.[2] The most common adverse reactions (≥25 percent) were diarrhoea, peripheral oedema, constipation,

peripheral sensory neuropathy, fatigue, nausea, upper respiratory tract infection and insomnia. Grade 3 or 4 treatment emergent adverse events (TEAE) occurred in ≥five percent of patients and included diarrhoea, peripheral oedema, lymphopenia, neutropenia, pneumonia, syncope and cardiac failure. From cycle 7 onward, no Grade 3 or 4 TEAEs occurred in ≥five percent of patients.[2]

ENDS

About the ANDROMEDA Study[3]

ANDROMEDA (NCT03201965) is an ongoing Phase 3, randomised, open-label study investigating the safety and efficacy of daratumumab SC in combination with bortezomib, cyclophosphamide and dexamethasone (D-VCd), compared to VCd alone, for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis. The study includes 388 patients with newly diagnosed AL amyloidosis with measurable haematologic disease and one or more organs affected. The primary endpoint is overall complete haematologic response rate by intent-to-treat (ITT). Patients received daratumumab SC 1,800 mg/ 30,000 units administered subcutaneously once weekly from weeks one to eight, once every two weeks from weeks nine to 24 and once every four weeks starting with week 25 until disease progression or unacceptable toxicity or a maximum of two years. Among patients who received D-VCd, 74 percent were exposed for six months or longer and 32 percent were exposed for greater than one year.[3]

About daratumumab and daratumumab SC

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered into 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.[4] Daratumumab SC is the only CD38-directed antibody approved to be given subcutaneously to treat patients with multiple myeloma. Daratumumab SC is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology.[5]

Data across nine Phase 3 clinical trials in the frontline and relapsed settings for multiple myeloma 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 SC 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 AL Amyloidosis

Light chain (AL) amyloidosis is a rare and potentially fatal haematologic disorder that can affect the function of multiple organs.[16,17] The disease occurs when bone marrow produces abnormal antibodies called light chains, which clump together to form a substance called amyloid. These clumps of amyloid are deposited in tissues and vital organs and interfere with normal organ function, eventually causing organ deterioration.[16,17] AL amyloidosis is the most common type of systemic amyloidosis.[18] It frequently affects the heart, kidneys, digestive tract, liver and nervous system.[16,17] Diagnosis is often delayed, and prognosis is poor due to advanced, multi-organ, particularly cardiac, involvement. Approximately 30,000 to 45,000 patients in the European Union and the United States have AL amyloidosis.[1]

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

*Dr. Kastritis has served as a consultant to Janssen and has not been paid for any media work.

Cautions Concerning Forward-Looking Statements

FOR EUROPEAN AND UK TRADE AND MEDICAL MEDIA ONLY

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-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.

ENHANZE® is a registered trademark of Halozyme.

# # #

References:

[1] Lousada I, Comenzo RL, Landau H, et al. Light chain amyloidosis: patient experience survey from the Amyloidosis Research Consortium. Advances in Therapy. 2015;32(10):920-928.

[2] Efstathios, K., & Merlini, G. (2021). Subcutaneous Daratumumab + Bortezomib, Cyclophosphamide, and Dexamethasone (VCd) in Patients With Newly Diagnosed Light Chain (AL) Amyloidosis: Updated Results From the Phase 3 ANDROMEDA Study. *ASCO 2021*.

[3] 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. NCT03201965. Available at: https://clinicaltrials.gov/ct2/show/NCT03201965 Last accessed: May 2021.

[4] Janssen [data on file]. Number of patients treated with DARZALEX worldwide as of March 2021. RF-171498.

[5] 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-Grants-Marketing-Authorisation-for-DARZALEX%C2%AE%E2%96%BC-daratumumab-Subcutaneous-Formulation-for-all-Currently-Approved-Daratumumab-Intravenous-Formulation-Indications. Last accessed: May 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: May 2021.

CP-234626
May 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: May 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: May 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: May 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: May 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: May 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: May 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: May 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: May 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: May 2021.
[16] Desport E, Bridoux F, Sirac C, Delbes S, Bender S, Fernandez B, Quellard N, Lacombe C, Goujon JM, Lavergne D, Abraham J. AL amyloidosis. Orphanet journal of rare diseases. 2012 Dec;7(1):54.
[17] Merlini G, Comenzo RL, Seldin DC, Wechalekar A, Gertz MA. Immunoglobulin light chain amyloidosis. *Expert review of hematology.* 2014 Feb 1;7(1):143-56.
[18] National Organization for Rare Disorders. Amyloidosis. Available at: https://rarediseases.org/rare-diseases/amyloidosis/. Last accessed May 2021.