PRESS RELEASE
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National Institute for Health and Care Excellence gives green light to Darzalex® (daratumumab) with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma

- *Daratumumab combination is recommended for use within the NHS in England and Wales for treating adults with newly diagnosed multiple myeloma where a stem cell transplant is unsuitable*
- *Eligible patients throughout England and Wales can now access alternative combination treatment option which has been shown to delay disease progression and extend life-expectancy*

High Wycombe, 22 September 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson are pleased to announce that the National Institute for Health and Care Excellence (NICE) has recommended Darzalex® (daratumumab) in combination with lenalidomide and dexamethasone (DLd) for untreated multiple myeloma (MM) for routine use on the NHS in England and Wales.[1] The therapy is now recommended within an NHS setting for the treatment of adults with newly diagnosed MM where an autologous stem cell transplant (ASCT) is unsuitable.[1]

Multiple myeloma is a treatable but incurable blood cancer arising in plasma cells, with approximately 24,000 people living with the disease in the UK, and over 5,000 people in England and 260 in Wales diagnosed annually.[2,3] The disease can significantly impact patients' quality of life, with bone pain and fractures, anaemia, recurring infections, kidney dysfunction and nerve damage all possible presenting features.[1,4] Among the potential treatment options is ASCT, an intensive therapy which can improve survival.[5] However, many patients are not candidates to receive or unable to tolerate ASCT, which means access to other well-tolerated treatment options are crucial to improving survival of patients.[1]

"DLd is a game changer that will make a tremendous difference to patients' quality of life and help to close the gap in survival between people who are eligible for a stem cell transplant and those who are not. Not only has DLd been shown to nearly double current remission times, but it gets myeloma under control faster. Approximately two-thirds of newly-diagnosed myeloma patients are not eligible for a transplant, and now, at long last, they'll be able to benefit from a potentially life-extending treatment that could give them precious time with their loved ones," said Shelagh McKinlay, Director of Research and Advocacy at blood cancer charity Myeloma UK.* "We will continue to campaign to make sure that people living with myeloma receive access to the latest, most effective treatments when they need them, and we are committed to working with NICE, NHS

England and other key partners towards this goal. Until we find a cure, it is vital that all myeloma patients are allowed to live a full life for as long as possible."

DLd is licensed and has been available for use in Europe since 2019.[6] The positive Final Draft Guidance (FDG) follows a positive acceptance from the Scottish Medicines Consortium (SMC) for routine use in NHS Scotland this month.[7] NICE's decision to recommend DLd is based on approximately seven years of data from the ongoing registrational MAIA trial, an international, randomised, parallel group, open-label, Phase 3 study comparing daratumumab plus lenalidomide and dexamethasone (n=368) with lenalidomide plus dexamethasone (n=369).[1,8]

"We are delighted that eligible patients in England are now able to access this much needed combination therapy, which has been shown to improve outcomes by delaying the progression of disease and extending life-expectancy," said Amanda Cunnington, Senior Director of Patient Access and Health Affairs, Janssen-Cilag Limited. "We have worked diligently with NICE and NHS England over a number of years to navigate system challenges and achieve this outcome for patients. We hope that with further evolution of the access system in the UK and continued collaborations such as this, the UK life sciences industry can continue its efforts to address unmet needs for people living with blood cancer."

**Shelagh McKinlay, Myeloma UK, has provided this quote voluntarily, and neither she nor others at Myeloma UK have been compensated for any media work.*

#ENDS#

About daratumumab
Daratumumab is a human monoclonal antibody targeting the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells.[9]

It is licensed for use in the UK:

- in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.[10,11]
- in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.[10,11]
- in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. [10,11]
- in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy.[10]
- as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an

immunomodulatory agent and who have demonstrated disease progression on the last therapy.[10,11]

- in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic light chain (AL) amyloidosis.[10]

In August 2012, Janssen Biotech, Inc. entered into a global license and development agreement with Genmab A/S, which granted Janssen an exclusive license to develop, manufacture and commercialise daratumumab.

Important safety information
For a full list of side effects and information on dosage and administration, contraindications and other precautions when using daratumumab, please refer to the Summary of Product Characteristics for further information.

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, & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension. Learn more at www.janssen.com/uk . Follow us at www.twitter.com/JanssenUK . Janssen-Cilag Limited is a Janssen Pharmaceutical Company of Johnson & Johnson.

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. 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 Pharmaceutica NV, Janssen-Cilag Limited, 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 behavior 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 2, 2022, 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 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.

References

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