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Scottish Medicines Consortium Accepts Darzalex®▼ (daratumumab) in Combination with Bortezomib, Thalidomide and Dexamethasone (VTd) for Patients in Scotland with Newly Diagnosed Multiple Myeloma

- *SMC recommends Darzalex®▼ (daratumumab) in combination with VTd as an option for treating newly diagnosed multiple myeloma patients who are eligible for autologous stem cell transplant* [1]
- *The decision was based on the phase III CASSIOPEIA study which showed that daratumumab and VTd was associated with a significant improvement in stringent complete response rates in patients with newly diagnosed multiple myeloma who were eligible for autologous stem cell transplant*[2]

High Wycombe, 18 January 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson welcomes the Scottish Medicines Consortium's (SMC) decision to accept daratumumab as a combination therapy with bortezomib, thalidomide and dexamethasone (VTd) for use by NHS Scotland for adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).[1]

In making its recommendation, the SMC considered evidence from the Phase III, CASSIOPEIA study, which compared daratumumab and VTd (bortezomib, thalidomide and dexamethasone) to standard of care (VTd alone) in newly diagnosed multiple myeloma patients eligible for ASCT. The primary endpoint was the proportion of patients who achieved a stringent complete response (sCR) after consolidation. The daratumumab-VTd group achieved a statistically significant improvement in the sCR rate (28.9 vs 20.3, P=0.0010) post-consolidation (100 days post-ASCT) compared with the VTd group. In addition, the daratumumab-VTd arm also showed improvements in key secondary endpoints, including minimal residual disease (MRD) and progression-free survival (PFS) versus VTd alone. Patients in the daratumumab-VTd group showed an 18-month PFS rate of 93 per cent compared to 85 per cent for those in the VTd group.[2]

There are around 24,000 people living with multiple myeloma in the UK[3] and around 457 new cases in Scotland every year.[4] Multiple myeloma is usually an incurable blood cancer.[5] Although treatment may result in remission, unfortunately patients will relapse as there is currently no cure.

"Today's decision is hugely welcome as it provides transplant-eligible patients in Scotland with a new option that improves on the standard of care by giving valuable extra time and redefines treatment for those newly diagnosed with multiple myeloma," commented Amanda Cunnington, Director of Health Economics, Market Access, Reimbursement (HEMAR) & Advocacy, Janssen-Cilag Limited. *"Janssen is fully committed to delivering advances to meet the evolving needs of people living with this disease and in developing innovative solutions across the treatment continuum."*

The SMC decision represents a significant step forward in terms of its acceptance of MRD as a valid surrogate endpoint for PFS in people newly diagnosed with multiple myeloma. The SMC recognises that, in the absence of overall survival data from CASSIOPEIA which remains immature, the deeper responses of surrogate endpoints shown by daratumumab and VTd, for both primary and secondary endpoints, translates to longer remission and improved length and quality of life for those diagnosed with multiple myeloma.[1]

Although the SMC advice is for the full licensed (intravenous) indication, because of recent changes to the SMC process, access has been extended to include the new subcutaneous (SC) formulation of daratumumab without the need for a separate abbreviated submission. This is good news for patients who will spend considerably less time in hospital, helping free up vital capacity in the healthcare system.

Daratumumab SC formulation injection is already funded in NHS England and Wales, and in Northern Ireland, and available in Scotland through NHS Scotland Patient Access Scheme (PAS) arrangement.

-ENDS-

About daratumumab[6] [7]

Daratumumab is indicated:

- 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
- 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
- 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

- 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.

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.

Adverse events should be reported.▼ This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Healthcare professionals are asked to report any suspected adverse events via the MHRA. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com.

About the CASSIOPEIA study[2,8]
The randomised, open-label, multicentre, Phase 3 study is sponsored by the French Intergroupe Francophone du Myelome in collaboration with the Dutch-Belgian Cooperative Trial Group for Hematology Oncology and Janssen Research & Development, LLC.

The study included 1,085 newly diagnosed patients with previously untreated, symptomatic multiple myeloma who were eligible for high-dose chemotherapy and stem cell transplant. In the first part of the study, patients were randomised to receive induction treatment with VTd alone or in combination with daratumumab, high-dose therapy and ASCT, and consolidation therapy with VTd alone or in combination with daratumumab. The primary endpoint in this part of the study is the proportion of patients who achieve an sCR 100 days after transplant.

In the second part of the study, which is ongoing, patients who achieved a partial response or better in part one will undergo a second randomisation to receive maintenance treatment with daratumumab 16 mg/kg every eight weeks for up to two years or will be observed with no further treatment. The primary endpoint in this part of the study is progression-free survival (PFS).

Results from this first part of the trial showed that after consolidation, the stringent complete response (sCR) rate in the daratumumab-VTd arm was 29 per cent compared to VTd alone 20 per cent (Odds Ratio [OR] = 1.60; 95 per cent confidence interval [CI], 1.21-2.12; P<0.0010). PFS at a median follow-up of 18.8 months, was improved in the daratumumab-VTd group compared to VTd alone (Hazard Ratio [HR] = 0.47; 95 per cent CI, 0.33-0.67; P<0.0001), and median PFS was not reached in either arm. The rate of 18-month PFS was 93 per cent for daratumumab + VTd compared to 85 per cent for VTd alone.

The most common (≥10%) Grade 3/4 treatment-emergent adverse events (TEAEs) for daratumumab-VTd and VTd, respectively, were neutropenia (28 per cent vs. 15 per cent), lymphopenia (17 per cent vs. 10 per cent), stomatitis (13 per cent vs. 16 per cent) and thrombocytopenia (11 per cent vs. 7 per cent). Infusion-related reactions occurred in 35 per cent of patients in daratumumab-VTd combination arm.

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.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding DARZALEX® (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-Cilag Limited, 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 December 29, 2019, 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:

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5 National Health Service. Treatment: Multiple Myeloma. Available at: https://www.nhs.uk/conditions/multiple-myeloma/treatment/. Last accessed : January 2021

6 DARZALEX. Summary of Product Characteristics. Solution for injection Available at https://www.medicines.org.uk/emc/product/11488/smpc . Last accessed : January 2021

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8 ClinicalTrials.gov. A study to evaluate daratumumab in transplant eligible participants with previously untreated multiple myeloma (Cassiopeia). NCT02541383. Available at: https://clinicaltrials.gov/ct2/show/NCT02541383 Last accessed January 2021.