Johnson&Johnson

Media contact:
Preetika Ramjoorawon
pramjoor@its.jnj.com
+44 (0)7920 417930

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

For UK medical, pharmaceutical trade and national health correspondents

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NICE issues draft guidance on bispecific antibody TECVAYLI®▼ (teclistamab) for eligible patients with relapsed and refractory multiple myeloma after three treatments

Teclistamab is recommended as an option for treating relapsed and refractory multiple myeloma in adults after three or more treatments when the myeloma has progressed, and only if pomalidomide plus dexamethasone would otherwise be offered

Eligible patients throughout England and Wales will be able to access this first-in-class bispecific antibody which has been shown to extend life-expectancy

High Wycombe, UK (19 July 2024) – Johnson & Johnson has received draft guidance from the National Institute for Health and Care Excellence (NICE) recommending TECVAYLI®▼ (teclistamab) in England and Wales as an option for treating relapsed and refractory multiple myeloma (RRMM) in adults after three or more treatments, when the myeloma has progressed on their last treatment, and only if pomalidomide plus dexamethasone (pom-dex) would otherwise be offered.[1]

Multiple myeloma is an incurable blood cancer and nearly all patients will relapse and require subsequent therapy.[2,3] Before this NICE recommendation, patients who had received three prior therapies faced a significant lack of available effective options.[1] Typically, the effectiveness of treatments diminishes with each additional therapy, and if a patient relapses after receiving three prior treatments, their average life expectancy is reduced to 9.7 months.[1,4]

Teclistamab* is a first-in-class bispecific antibody that targets B-cell maturation antigen (BCMA) and CD3 receptors.[5,6] It works by redirecting T-cells to multiple myeloma cells and helping to destroy them.[3] Latest data showed patients with RRMM who had received three previous prior therapies had a median overall survival (OS) of 22 months when treated with teclistamab and a median progression-free survival (PFS) of 11 months.[1] Further data comparing teclistamab to pom-dex concluded that teclistamab decreases the risk of disease progression by 44% and reduces the risk of death by 48%.[7] Teclistamab was also shown to have a tolerable safety profile; adverse events were common and included low-grade cytokine release syndrome and grade 3 or 4 cytopenia and infection, while dose reductions and discontinuations owing to adverse events were infrequent.[6]

“Patients with multiple myeloma face several challenges – not least coping with recurrent relapses – and it’s vital that they can access novel treatment options that offer the potential for sustained remission and improved quality of life,” said Amanda Cunnington, Senior Director of Patient Access, Johnson & Johnson Innovative Medicine UK. “While this draft guidance meets the needs of the majority of patients in this situation, we are very concerned that the proposed restriction applied by NICE removes this option from a group of patients who have been waiting for this treatment to be available on the NHS. We remain committed to supporting the multiple myeloma community to find potential solutions that can improve patient outcomes.”

#ENDS#

***About teclistamab**
Teclistamab is a bispecific antibody that binds both B-cell maturation antigen (BCMA) and protein complex CD3 (cluster of differentiation 3) receptors to redirect CD3-positive T-cells to BCMA-expressing multiple myeloma cells, helping to destroy them.[3]

Teclistamab is licensed for use in Great Britain as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.[6]

Important safety information
For a full list of side effects and information on dosage and administration, contraindications and other precautions when using teclistamab, 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 multiple myeloma
Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[8] When damaged, these plasma cells rapidly spread and replace normal cells with tumours in the bone marrow.[8] There are around 5,900 new multiple myeloma cases diagnosed in the UK every year.[8] While some patients with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone disease or pain, frequent infections, tiredness, high calcium levels, or kidney problems.[9]

About Johnson & Johnson
Janssen, the Pharmaceutical Companies of Johnson & Johnson, has become Johnson & Johnson Innovative Medicine. The Company is updating its brand and uniting both its pharmaceutical and MedTech segments under the Johnson & Johnson brand name.

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.

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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 product development and the potential benefits and treatment impact of teclistamab. 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 Research & Development, LLC, Janssen Biotech, Inc. 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 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 www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research & Development, LLC, Janssen Biotech, Inc. 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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