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For UK national health correspondents, Scottish consumer media, and industry and medical media

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# SMC accepts bispecific antibody TECVAYLI®▼ (teclistamab) for eligible patients with relapsed and refractory multiple myeloma

*Scotland becomes the first UK nation to accept teclistamab within its full licensed indication.*

*Patients in Scotland with relapsed and refractory multiple myeloma who have received at least three prior therapies will now be able to access this first-in-class bispecific antibody which has been shown to extend their life-expectancy.*

*Before today's advice, patients in Scotland who had undergone three lines of therapy faced a significant lack of efficacious treatment options and a poor prognosis.*

**High Wycombe, UK (9 September 2024)** – Johnson & Johnson is pleased to announce the Scottish Medicines Consortium (SMC) has today accepted TECVAYLI®▼ (teclistamab) in Scotland as an option for treating relapsed and refractory multiple myeloma (RRMM) in adults 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.[1]

Multiple myeloma is an incurable blood cancer affecting approximately 500 people in Scotland each year, and nearly all patients will relapse and require subsequent therapy.[1,2,3] Before the SMC acceptance, patients in Scotland who had undergone three lines of therapy faced a significant lack of efficacious treatment options and poor prognosis.[1] Typically, the efficacy 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]

Scott Purdon, Head of Patient Advocacy at blood cancer charity Myeloma UK, said: "We're absolutely delighted. Teclistamab is part of the first new class of drugs to be approved in Scotland in seven years and could be a lifeline for people who are close to running out of treatment options. It has shown excellent results in clinical trials and allowed some people who have never responded well to treatment to experience their very first complete remission. Until we have a cure, it is absolutely vital that all myeloma patients are given as many options to tackle their cancer as possible – no matter where they are on their treatment journey."

Teclistamab* is a first-in-class bispecific antibody that targets B-cell maturation antigen (BCMA) and cluster of differentiation 3 (CD3) receptors.[5,6] It works by redirecting T-cells to multiple myeloma cells and helping to destroy them.[3] Latest data from the Phase 1/2 MajesTEC-1 study shows 63% of patients had an overall response to treatment, with 46% having a complete response or better.[7] Further data comparing teclistamab to pomalidomide plus dexamethasone (pom-dex) concluded that teclistamab decreased the risk of disease progression or death by 44% and extended median time to next treatment (proxy for progression-free survival) by 5.36 months (12.39 versus 7.03 months; representing a 1.76-fold increase).[8] Compared to pom-dex, teclistamab reduced the risk of death by 48% (HR of 0.52; 95% CI 0.36-0.74;p<0.001) and extended median overall survival by 12.43 months (22.21 versus 9.78 months; 2.27-fold increase).[8] Teclistamab was also shown to have a tolerable safety profile; adverse events were common and included cytokine release syndrome (72%), thrombocytopenia (40%), neutropenia (71%), pneumonia (28%), sepsis (7.9%), COVID-19 (18%), upper respiratory tract infection (37%), cellulitis (4.2%) and immune effector cell-associated neurotoxicity syndrome (ICANS) (3%), while dose reductions and discontinuations owing to adverse events were infrequent.[6]

"For people living with multiple myeloma, the recurring nature of the disease presents significant hurdles, highlighting the importance of access to 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. "We are delighted that teclistamab has been accepted for use for the full licensed population – with Scotland being the first nation in the UK to make the treatment available on the NHS without any access restrictions. This milestone reflects J&J's continued commitment to supporting the multiple myeloma community and improving outcomes for patients."

**#ENDS#**

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

Teclistamab is licensed for use in Great Britain and Northern Ireland 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.[6,9]

**About MajesTEC-1**
The MajesTEC-1 trial is a Phase 1/2, single-arm, open-label, multicentre study, evaluating the efficacy and safety of teclistamab in 165 triple-class exposed patients with RRMM, naive to BCMA therapy that had previously received an immunomodulatory drug (IMiD), a proteasome inhibitor (PI) and anti-CD38 antibody.[7] Median follow-up was 30.4 months.[10] Patients received step-up doses in Week 1 followed by weekly subcutaneous injections of teclistamab.[7]

**Important safety information**
For a full list of side effects and information on dosage and administration, contraindications, special warnings and 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.[11] When damaged, these plasma cells rapidly spread and replace normal cells with tumours in the bone marrow.[1111] There are around 477 new multiple myeloma cases diagnosed in Scotland every year.[1] 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.[12]

**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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