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Johnson&Johnson

For UK medical, pharmaceutical trade and national health correspondents

NICE lifts restriction and recommends bispecific antibody TECVAYLI®▼ (teclistamab) for all 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 only after three or more lines of treatment when the myeloma has progressed[1]

Eligible patients throughout England and Wales are now able to access this first-in-class bispecific antibody, which has been shown to extend life-expectancy compared to previous standard of care[1,2]

High Wycombe, UK (10 October 2024) – Johnson & Johnson (J&J) is pleased to have received positive final draft guidance from the National Institute for Health and Care Excellence (NICE) recommending TECVAYLI®▼ (teclistamab) in England and Wales as an option for treating relapsed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 only after three or more lines of treatment (including an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody), when the myeloma has progressed on their last treatment.[1]

This final draft guidance follows a positive but restricted Draft Guidance Consultation from NICE in July 2024 which recommended teclistamab as an option for this patient group, only if pomalidomide plus dexamethasone (pom-dex) would otherwise be offered. The restriction has been lifted following further consultation with stakeholders and a second appraisal committee meeting, which highlighted the critical unmet need in patients for whom pom-dex is not a treatment option. J&J is delighted that NICE has recognised the critical need of this patient population having access to additional treatment options that could improve prognosis.[1] The Scottish Medicines Consortium (SMC) accepted teclistamab for this patient group, without a pom-dex restriction, in September 2024.[2]

“This is fantastic news and a hard-earned victory for all involved. Teclistamab is the first of a new class of drugs to be approved on the NHS in England and Wales and has the potential to enable some people who have not responded well to previous treatments to experience their very first complete remission,” said Caroline Donoghue, Senior Policy Officer, blood cancer charity Myeloma UK. “Approvals like this highlight why we continue to fight for treatment, submit evidence on behalf of the myeloma community, attend committee meetings and push for access to pioneering drugs. The initial decision to impose restrictions was deeply unfair for some patients that needed it most. Over the last few weeks we have worked tirelessly to get everyone back around the table, come up with a solution, and give people with myeloma a fighting chance to spend more quality time with their loved ones. 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.”

Multiple myeloma is an incurable blood cancer and nearly all patients will relapse and require subsequent therapy.[3,4] Before the July 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.[1,5]

Teclistamab* is a first-in-class bispecific antibody that targets B-cell maturation antigen (BCMA) and CD3 receptors.[6,7] It works by redirecting T-cells to multiple myeloma cells and helping to destroy them.[4] Latest data showed patients with RRMM who had received three previous prior therapies had an overall response rate (ORR) of 63%, a median overall survival (OS) of 22.2 months when treated with teclistamab and a median progression-free survival (PFS) of 11.4 months when treated with teclistamab.[1] Further data comparing teclistamab to 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 but generally manageable and included cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome (ICANS) which were mostly grade 1 or 2 as well as grade 3 or 4 cytopenias and infections, while dose reductions and discontinuations owing to adverse events were infrequent.[7]

“We’re delighted that NICE has updated its recommendation to be unrestricted in this group of patients after three previous lines of treatment,” said Roz Bekker, Managing Director, Johnson & Johnson Innovative Medicine UK and Ireland. “At J&J, our teams are continuously working to get in front of the most complex diseases affecting patients and their families, but we know that these treatments only matter if patients can access them when they need them. Today’s decision enables patients in England and Wales to access the same treatments as patients in Scotland and is an excellent example of how cross-stakeholder collaboration can truly achieve positive results in advancing patient equity. We hope that such positive outcomes can continue to be seen for similar appraisals, now and in the future, to ensure UK patients can reap the full benefit of clinical progress and innovative treatment options.”

#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.[4]

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.[7]

In September 2024, the Scottish Medicines Consortium (SMC) accepted teclistamab 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.[2]

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.[9] When damaged, these plasma cells rapidly spread and replace normal cells with tumours in the bone marrow.[9] There are around 5,900 new multiple myeloma cases diagnosed in the UK every year.[9] 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.[10]

About Johnson & Johnson
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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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