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Janssen Receives Positive CHMP Opinion for PONVORY™ ▼ (ponesimod) for the Treatment of Adults With Relapsing Forms of Multiple Sclerosis With Active Disease Defined by Clinical or Imaging Features

- *Positive opinion is based on the pivotal Phase 3 OPTIMUM study evaluating the efficacy and safety of ponesimod vs. teriflunomide, an active comparator and oral standard of care treatment in adult patients with relapsing multiple sclerosis*[1]
- *The OPTIMUM study demonstrated a statistically significant reduction in relapses and number of inflammatory lesions compared with teriflunomide*[2]

BEERSE, BELGIUM, MARCH 26, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending marketing authorisation for PONVORY™ ▼ (ponesimod) for the treatment of adult patients with relapsing multiple sclerosis (RMS) with active disease defined by clinical or imaging features.[3]

"Relapsing forms of multiple sclerosis (MS) have varied and often unpredictable symptoms, posing a unique human, societal and economic burden," said Catherine Taylor, M.D., Vice President, Medical Affairs Therapeutic Area Strategy, Europe, Middle East and Africa (EMEA), Johnson & Johnson Middle East FZ-LLC. "Despite

continuous innovations in the treatment landscape, unmet needs remain. If approved by the European Commission, ponesimod has the potential to help more people living with relapsing forms of MS."

The European marketing authorisation application (MAA) is based on data from the Phase 3 OPTIMUM trial,[1] a multicentre, randomised, double-blind, parallel-group, active-controlled superiority study of 1,133 adult patients (aged 18-55 years) in 28 countries. The trial was designed to evaluate the efficacy and safety of once daily oral ponesimod (20mg) vs. once daily teriflunomide (14mg), an approved and widely-used first-line oral standard of care, in adult patients with RMS.[1] The Phase 3 study showed superior efficacy of ponesimod 20mg on the primary endpoint, annualised relapse rate (ARR), with a rate reduction of 30.5% (p=0.0003) compared with teriflunomide. Ponesimod also showed statistically significant superiority on combined unique active lesions (CUAL), one of the secondary endpoints. Ponesimod significantly reduced the number of new inflammatory lesions on brain MRI by 56% (p<0.0001) at week 108 when compared to teriflunomide.[2]

Safety and tolerability of ponesimod have also been assessed,[4] with the safety profile of ponesimod qualitatively consistent with the known profile of other S1P receptor modulators, although a head-to-head comparison is not available. Overall, the number of treatment-emergent adverse events reported was similar between the ponesimod and teriflunomide treated groups, and the majority were mild/moderate and did not warrant treatment discontinuation.[4] The most commonly reported adverse events in the ponesimod 20mg group versus the teriflunomide 14mg group were Alanine Aminotransferase (ALT) enzyme elevations (19.5% vs. 9.4%), nasopharyngitis (19.3% vs. 16.8%), headache (11.5% vs. 12.7%) and upper respiratory tract infection (10.6% vs. 10.4%).[4]

"This is a significant milestone and an important step forward in our goal to make a positive impact for patients with significant unmet needs and unique societal challenges," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Janssen Research & Development, LLC. "The positive CHMP opinion for ponesimod is testament to nearly a decade of cumulative clinical research which ultimately showed the treatment offers RMS patients superior efficacy on the primary

endpoint of reduced annualised relapse rate compared to an established therapy, as well as a proven safety profile."

Janssen submitted its MAA to the EMA, in March 2020.[5] The MAA will now be reviewed by the European Commission (EC) for the treatment of adults with RMS. If approved, ponesimod will be the first therapy by Janssen for patients living with RMS with active disease defined by clinical or imaging features. The U.S. Food and Drug Administration (FDA) approved ponesimod for use in adults with relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease in March 2021.[6]

#ENDS#

About Ponesimod

Ponesimod is a highly selective S1P1 modulator that functionally inhibits S1P1 receptor activity and, in doing so, it is believed to reduce the number of circulating lymphocytes.[7] In patients with MS, inflammatory immune cells, including lymphocytes, can cross the blood brain barrier into the brain and damage myelin, the protective sheath that insulates nerve cells. Damage to myelin slows or halts nerve conduction, producing the neurologic signs and symptoms of MS.[8]

A member of the Janssen Pharmaceutical Companies of Johnson & Johnson, Actelion Pharmaceuticals Ltd, is party to a revenue sharing agreement with Idorsia Pharmaceuticals Ltd, which provides for certain payments to Idorsia related to the sales of ponesimod.

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. Adverse events should be reported to Janssen-Cilag Limited on 01494 567447 or at dsafety@its.jnj.com and to regulatory authorities.

About Multiple Sclerosis

MS is a chronic autoimmune inflammatory disease of the central nervous system, characterised by demyelination and axonal loss leading to neurological impairment and severe disability.[9,10] Relapsing forms of MS include clinically isolated syndrome, relapsing-remitting MS (which makes up approximately 85 percent of all MS cases), and secondary progressive MS.[11] It is one of the most common causes of neurological disability in young and middle-aged adults,[12] with females up to three times more frequently impacted than males.[13] While prevalence varies worldwide, it is highest in Europe and North America.[14] Symptoms of RMS vary from person to person and can change or fluctuate over time.[15] Alongside many common visible symptoms, there are also invisible symptoms that people living with MS may find hard to express but can severely impact their overall emotional and social wellbeing, such as pain, fatigue or numbness.[16]

Relapses are defined as new, worsening or recurrent neurological symptoms that last for more than 24 hours with the absence of fever or infections.[17] Relapses may be fully resolved over days or weeks or lead to persistent residual deficits and accumulation of disability.[17]

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.

Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Research & Development, LLC and Janssen Pharmaceutica NV are part of the Janssen Pharmaceutical Companies of 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 ponesimod. 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 Phamaceutica NV and/or 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 January 3, 2021, 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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