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European Commission approves PONVORY™▼ (ponesimod), a Once Daily, Oral Therapy for the Treatment of Adults with Relapsing Forms of Multiple Sclerosis with Active Disease Defined by Clinical or Imaging Features

- *The pivotal Phase 3 OPTIMUM trial showed treatment with ponesimod led to a 30.5 percent reduction in annual relapse rate (p<0.001) vs. treatment with teriflunomide, an active comparator and widely-used first-line oral treatment, in adult patients with relapsing multiple sclerosis, (RMS)*[1]
- *The OPTIMUM trial is the first of its kind to compare head-to-head two oral disease modifying treatments (DMTs) in RMS*
- *Approval follows more than 10 years of cumulative data from Phase 2 and Phase 3 studies demonstrating ponesimod's efficacy and safety*[1,2,3]
- *Approval builds on Janssen's deep-rooted history in neuroscience and reinforces Company commitment to addressing unmet needs for neurological conditions like MS*

BEERSE, BELGIUM, 24 May, 2021 – Janssen, the Pharmaceutical Companies of Johnson & Johnson, announced today that the European Commission (EC) has approved PONVORY▼ (ponesimod) for the treatment of adult patients with

relapsing multiple sclerosis (RMS) with active disease defined by clinical or imaging features.[4]

"Relapsing multiple sclerosis is an unpredictable and complex disease that can present very differently from individual to individual, placing a heavy burden on the patient and their loved ones," said Professor Gavin Giovannoni, MBBCh, PhD, FCP (Neurol., SA), FRCP, FRCPath, Professor of Neurology at Queen Mary University of London. "I welcome the European Commission's approval of ponesimod as an additional treatment option for those living with relapsing multiple sclerosis - it will provide patients with additional choice when making decisions about their treatment."

The EC approval of ponesimod is based on data from the Phase 3 OPTIMUM trial, a multicentre, randomised, double-blind, parallel-group, active-controlled superiority study of 1,133 adult patients (aged 18-55 years) in 28 countries.[1] 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 treatment, in adult patients with RMS.[1] The large, Phase 3 study showed superior efficacy of ponesimod 20mg on the primary endpoint, annualised relapse rate (ARR), with a rate reduction of 30.5 percent ($p<0.001$) compared with teriflunomide.[1] Ponesimod also showed statistically significant superiority on one of the secondary endpoints, combined unique active lesions (CUALs).[1] Ponesimod significantly reduced the number of new inflammatory lesions on brain MRI by 56 percent ($p<0.0001$) at week 108 when compared to teriflunomide.[1]

"The OPTIMUM study is the first Phase 3 study establishing superiority versus another disease modifying treatment for relapsing multiple sclerosis, with ponesimod showing significant reductions in annual relapse rates versus teriflunomide, an active comparator and widely-used first-line oral treatment," said Catherine Taylor, M.D., Vice President, Medical Affairs, Therapeutic Area Strategy, Europe, Middle East and Africa (EMEA), Johnson & Johnson Middle East FZ-LLC. "The approval of ponesimod by the European Commission is a positive

step for people living with relapsing multiple sclerosis, as we work to provide them with an additional treatment option to manage and control their condition."

Within the OPTIMUM study, 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.[1] The most commonly reported adverse events in either 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%), upper respiratory tract infection (10.6% vs. 10.4%) and alopecia (3.2% vs. 12.7%).[1] The safety profile of ponesimod is consistent with the known safety profile of other S1P receptor modulators, although a head-to-head comparison, other than with teriflunomide, is not available.

"At Janssen, our mission is to reduce the burden, disability and devastation caused by diverse diseases of the central nervous system, including multiple sclerosis, for which there remains significant unmet patient need," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. "The approval of ponesimod by the European Commission is a significant milestone as it showcases our continued commitment in neurology, reflecting our deepened focus and commitment to this space."

The EC approval follows the positive CHMP opinion for ponesimod in March 2021[5] and the announcement of the U.S. Food and Drug Administration (FDA) approval of ponesimod for use in adults with relapsing forms of MS.[6] EC approval is valid in all 27 member states of the European Union, and the European Economic Area countries (Norway, Iceland and Liechtenstein).

*Professor Gavin Giovannoni, MBBCh, PhD, FCP (Neurol., SA), FRCP, FRCPath, Professor of Neurology at Queen Mary, University of London is a paid consultant for Janssen. He did not receive any remuneration for his media work.

CP-224441
May 2021

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About Multiple Sclerosis

MS is a chronic autoimmune inflammatory disease of the central nervous system (CNS) in which immune cells attack myelin (the protective casing that insulates nerve cells), damaging or destroying it and causing inflammation.[7] This affects how the CNS processes information and communicates with the rest of the body, causing the neurologic signs and symptoms of MS.[8] Symptoms vary by person, but common symptoms include fatigue, balance and walking problems, numbness or tingling, dizziness and vertigo, vision problems, bladder and bowel problems and weakness.[8,9,10]

About PONVORY (ponesimod)

Ponesimod is an oral, highly selective S1P1 modulator that functionally inhibits S1P1 receptor activity and, in doing so, it is believed to reduce the number of circulating lymphocytes.[11] In patients with multiple sclerosis (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.[12]

One 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.

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 Johnson & Johnson Middle East FZ-LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 Actelion Pharmaceuticals Ltd, 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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