News Release

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Janssen Submits European Marketing Authorisation Application for Ponesimod for Treatment of Adults with Relapsing Multiple Sclerosis

TITUSVILLE, NEW JERSEY, March 4, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) announced today the submission of a marketing authorisation application (MAA) to the European Medicines Agency (EMA) seeking approval for ponesimod for the treatment of adult patients with relapsing multiple sclerosis (MS).

Ponesimod is a selective sphingosine-1-phosphate receptor 1 (S1P1) modulator that inhibits S1P protein activity and in so doing is believed to reduce the number of circulating lymphocytes that can cross the blood-brain barrier.[i] In patients with MS the movement of immune cells into the brain damages myelin, the protective sheath that insulates nerve cells. Damage to myelin slows or halts nerve conduction, producing the neurologic signs and symptoms of MS.[ii]

“More than 2.3 million people worldwide live with MS[iii] – including 700,000 in Europe alone[iv] – and of this population, approximately 85 percent are initially

diagnosed with relapsing MS.[v] Despite continuous advancements in the treatment landscape, a number of unmet needs remain," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. "This submission is an important milestone as we work to bring a new treatment option to those living with relapsing forms of MS."

The MAA is based on the head-to-head OPTIMUM Phase 3 study, which showed superior efficacy of ponesimod 20 mg on the primary endpoint of reduced annualized relapse rate (ARR), as well as most secondary endpoints compared to teriflunomide 14 mg in adults with relapsing MS.

At week 108, a highly statistically significant reduction of 30.5 percent on ARR was observed with ponesimod when compared to teriflunomide. Additionally, a statistically significant reduction of fatigue symptoms and a 56 percent reduction on combined unique active lesions (CUALs) in the brain was observed with ponesimod compared to teriflunomide. The safety profile observed for ponesimod was consistent with previous studies of ponesimod and the known safety profile for other S1P receptor modulators. The most common treatment-emergent adverse events (TEAEs) in the ponesimod 20 mg study arm were alanine aminotransferase (ALT) increased, nasopharyngitis, headache and upper respiratory tract infections.[vi]

"Fatigue remains a challenging, yet invisible, symptom among those living with MS. We are encouraged by the results ponesimod shows in alleviating this symptom, as well as the reduction in new inflammatory lesions and disability accumulation," said Husseini Manji, M.D., F.R.C.P.C., Global Therapeutic Area Head for Neuroscience at Janssen Research & Development, LLC. "We look forward to collaborating closely with the EMA as the application process progresses."

The clinical study data that supports this filing was presented in September 2019 at the 35th Congress of The European Committee for Treatment and Research in

Multiple Sclerosis Conference (ECTRIMS) in Stockholm, Sweden. More information may be found **here**.

About Multiple Sclerosis (MS)

MS is a chronic autoimmune inflammatory disease of the central nervous system affecting 2.3 million people worldwide[iii], with females more impacted than males.[vii] The disease is characterized by demyelination[iii] and axonal loss leading to neurological impairment and severe disability.[viii] Relapsing forms of MS, which make up 85 percent of all MS cases include clinically isolated syndrome, relapsing-remitting MS and active secondary progressive MS.[ix] In addition to the debilitating neurological symptoms of the disease, patients often also suffer from "hidden symptoms," namely fatigue and depression, both of which are major contributors to the reduced quality of life.[x]

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

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. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, 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; 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 29, 2019, 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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