

**News Release**

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**Janssen reports positive top-line Phase 3 results for ponesimod  
in adults with relapsing multiple sclerosis**

*Data are part of the OPTIMUM study comparing the efficacy and safety of  
ponesimod and Aubagio® in adults with relapsing multiple sclerosis*

**TITUSVILLE, NJ, July 25, 2019** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced positive top-line results from the Phase 3 OPTIMUM study, which evaluated the efficacy and safety of ponesimod compared to Aubagio®\* (teriflunomide) in adults with relapsing multiple sclerosis. The study met its primary and most secondary endpoints.

Ponesimod is a selective sphingosine-1-phosphate receptor 1 (S1P1) modulator, a class of drugs that is believed to functionally inhibit S1P activity and reduce the number of circulating lymphocytes by trapping them in the lymph nodes. Therefore, there are less inflammatory cells available to cross into the central nervous system (CNS) where they could damage myelin. Myelin is a protective sheath that insulates nerve cells and is damaged in patients with multiple sclerosis.<sup>1</sup>

The primary endpoint of OPTIMUM was annualized relapse rate (ARR) up to the end of the study. A key secondary endpoint was change from baseline to week

108 in fatigue-related symptoms. Fatigue is considered a significant unmet need from patients' perspective. Additionally, the study evaluated other secondary endpoints: cumulative number of combined unique active lesions (CUALs) using magnetic resonance imaging (MRI), time to first 12-week confirmed disability accumulation (CDA) and time to first 24-week CDA from baseline to end of the study.

The safety profile observed for ponesimod in the OPTIMUM study was consistent with previous studies of ponesimod, and the known safety profile for other S1P receptor modulators.

OPTIMUM was a head-to-head, prospective, multicenter, randomized, double-blind, active controlled, parallel-group, Phase 3 superiority study to compare efficacy, safety and tolerability of ponesimod 20 mg versus teriflunomide 14 mg in adults with relapsing multiple sclerosis. The study included 1,133 participants with the treatment duration of 108 weeks.

Data from the OPTIMUM study have been accepted for presentation at the 35<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 2019.

Data from the OPTIMUM study will serve as the basis of submissions to the U.S. Food and Drug Administration and European Medicines Agency seeking approval of ponesimod as a treatment for relapsing forms of multiple sclerosis, which are anticipated for later this year.

### **About Multiple Sclerosis**

Multiple Sclerosis (MS) is a chronic autoimmune inflammatory disease of the central nervous system affecting 2.3 million people worldwide<sup>2</sup> with females more impacted than males.<sup>3</sup> The disease is characterized by demyelination<sup>1</sup> and axonal loss leading to neurological impairment and severe disability.<sup>4</sup> The main subtype of MS is relapsing forms of MS (RMS), which represents 85% of MS

patients and includes clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS) and active secondary progressive MS (SPMS).<sup>5</sup>

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.<sup>6</sup>

### **About Ponesimod**

Ponesimod is a selective sphingosine-1-phosphate receptor 1 (S1P1) modulator that functionally inhibits S1P activity and reduces the number of circulating lymphocytes. It is thought that in people with relapsing-remitting multiple sclerosis (RRMS), ponesimod prevents immune cells from crossing the blood-brain barrier and damaging myelin. Myelin is a protective sheath that insulates nerve cells and is damaged in patients with multiple sclerosis.

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.

### **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. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal).

\* Aubagio® is a registered trademark of Sanofi Société Anonyme France.

### **Cautions Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding new study data on 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; 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 30, 2018, 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](http://www.sec.gov), [www.jnj.com](http://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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<sup>1</sup> National Multiple Sclerosis Society. What is Myelin? Available at: <https://www.nationalmssociety.org/what-is-MS/Definition-of-MS/Myelin>. Accessed July 22, 2019.

<sup>2</sup> National Multiple Sclerosis Society. Multiple Sclerosis FAQs. Available at: <https://www.nationalmssociety.org/What-is-MS/MS-FAQ-s>. Last accessed April 23, 2019.

<sup>3</sup> National Multiple Sclerosis Society. Who Gets MS. Available at: <https://www.nationalmssociety.org/What-is-MS/Who-Gets-MS>. Last accessed April 24, 2019.

<sup>4</sup> National Multiple Sclerosis Society. Immunology of MS. Available at: <https://www.nationalmssociety.org/What-is-MS/Definition-of-MS/Myelin>. Accessed July 22, 2019.

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<sup>5</sup> National Multiple Sclerosis Society. What is MS? Types of MS. Available at:

<https://www.nationalmssociety.org/What-is-MS/Types-of-MS>. Accessed July 22, 2019.

<sup>6</sup> Multiple Sclerosis Association of America. What is an MS relapse? Available at:

<https://mymsaa.org/publications/ms-relapse-toolkit/what-relapse/>. Accessed July 22, 2019.