News Release

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New Head-to-Head Phase 3 Study Data Show Ponesimod Superiority Versus Aubagio® (teriflunomide) 14 mg in Adults with Relapsing Multiple Sclerosis (MS)

OPTIMUM Phase 3 study data presented for the first time during oral presentation at the 35th Congress of The European Committee for Treatment and Research in Multiple Sclerosis

STOCKHOLM, SWEDEN, September 11, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the results from the Phase 3 OPTIMUM study for ponesimod, an investigational selective S1P1 receptor modulator, showing superior efficacy on the primary endpoint and most secondary endpoints compared to Aubagio® (teriflunomide)* 14 mg in adults with relapsing multiple sclerosis (MS).

In the head-to-head, two-year Phase 3 comparative study, statistically significant reduction of annualized relapse rate (ARR), the study's primary endpoint, was observed with ponesimod when compared to teriflunomide by 30.5% up to week 108 (ARR = 0.202 for ponesimod 20 mg vs. 0.290 for teriflunomide 14 mg, p=0.0003).

The data were presented by Professor Ludwig Kappos**, Chair of the Department of Neurology at University Hospital of Basel, Switzerland, on behalf of the study's investigators, as part of an oral presentation at the 35th Congress of The European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Stockholm, Sweden.

"This is the first large controlled head-to-head study comparing two oral compounds for the treatment of relapsing MS. Notably, we saw superiority of the investigational agent ponesimod when compared to teriflunomide across the primary and most secondary endpoints. These data, in conjunction with the observed safety profile, underline the potential of ponesimod as a new treatment option for MS," said Professor Kappos.

Several pre-specified secondary endpoints were also examined as part of the OPTIMUM trial, including fatigue. Based on results from the Fatigue Symptoms and Impacts Questionnaire - Relapsing Multiple Sclerosis (FSIQ-RMS) at week 108, statistically significant effects on fatigue symptoms were observed with ponesimod compared to teriflunomide (mean difference: -3.57, p=0.0019). FSIQ-RMS is a new MS-specific, 20-item patient-reported outcome measure that comprises symptoms and impacts with an increase from baseline indicating worsening in fatigue symptoms.

"Despite an ever-growing treatment landscape, unmet needs remain in helping patients with MS," said Luc Truyen, M.D., Ph.D., Global Head, Development and External Affairs, Janssen Research & Development, LLC. "We are thrilled to be here at ECTRIMS to present these pivotal findings as they mark the first head-to-head trial of two oral therapies for relapsing MS and demonstrate positive results for ponesimod compared to a leading disease-modifying therapy."

Additional secondary endpoints of note include 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. A 56% reduction ($p<0.0001$) in the number of CUALs was observed with ponesimod compared to teriflunomide. The 12-week CDA was observed in 10.1% and 12.4% of patients in the ponesimod and teriflunomide arms, respectively; however, the result was not statistically significant.

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. The most commonly observed adverse events included nasopharyngitis, headache, upper respiratory tract infections and an increase in alanine amino transferase.

Ponesimod is an investigational agent. Data from the OPTIMUM study will serve as the basis for regulatory submissions to the FDA and European Medicines Agency (EMA) seeking approval of ponesimod as a treatment for relapsing forms of MS.

About Ponesimod

Ponesimod is an investigational 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.[1]

Study Design

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 in adults with relapsing MS. The study enrolled 1,133 participants with the treatment duration of 108 weeks across 162 study site locations worldwide, including the United States, Europe, Canada and Mexico.

Primary Endpoint

The primary endpoint was measured by ARR from baseline to end of study. ARR is defined as the number of confirmed relapses per subject-year. The study met its primary objective.

Secondary Endpoints

Secondary endpoints included fatigue, cumulative number of CUALs, time to first 12-week CDA and time to first 24-week CDA. Fatigue symptoms were measured as change from baseline to week 108 using the FSIQ-RMS, which was developed to evaluate fatigue-related symptoms and the impacts of those symptoms on the lives of people with relapsing MS. CUALs, defined as new gadolinium-enhancing T1 lesions plus new or enlarging T2 lesions (without double-counting of lesions) measured by MRI, were assessed from baseline to week 108. The 12- and 24-week CDAs were defined as increases in the Expanded Disability Status Scale (EDSS) score relative to baseline confirmed after 12 or 24 weeks. The EDSS score quantifies MS-related disability and monitors changes in the level of disability over time and is based on a standardized examination by a neurologist. EDSS ranges from 0 (lowest) to 10 (highest) with 0.5-unit increments.

About Multiple Sclerosis

MS is a chronic autoimmune inflammatory disease of the central nervous system affecting 2.3 million people worldwide[2] with females more impacted than males.[3] The disease is characterized by demyelination[2] and axonal loss leading to neurological impairment and severe disability.[4] The main subtype of MS is relapsing forms of MS, which manifests in 85% of MS patients and includes clinically isolated syndrome, relapsing-remitting MS and active secondary progressive MS.[5]

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.[6]

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. Follow us at www.twitter.com/JanssenGlobal.

*Aubagio® (teriflunomide) is a registered trademark of Sanofi Société Anonyme France.

**Professor Ludwig Kappos is a consultant to Actelion Pharmaceuticals Ltd., a Janssen pharmaceutical company 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 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, 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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[1] National Multiple Sclerosis Society. What is Myelin? Available at: https://www.nationalmssociety.org/What-is-MS/Definition-of-MS/Myelin. Accessed July 22, 2019.

[2] National Multiple Sclerosis Society. Multiple Sclerosis FAQs. Available at: https://www.nationalmssociety.org/What-is-MS/MS-FAQ-s. Accessed April 23, 2019.

[3] National Multiple Sclerosis Society. Who Gets MS. Available at: https://www.nationalmssociety.org/What-is-MS/Who-Gets-MS. Accessed April 24, 2019.

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

[5] 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.

[6] 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.