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Cristiana Maria
Mobile: +32 473 11 28 10
Email: cmaria@its.jnj.com

Investor Relations:
Chris DelOrefice
Office: +1 (732) 524-2955

Jennifer McIntyre
Office: +1 (732) 524-3922

Janssen Highlights Impact of Multiple Sclerosis-Related Fatigue with Real-World Study Data Presentation at MSVirtual2020 and Global Patient Survey

Poster Presentation Shares New Data on the Symptoms and Impacts of Fatigue Using a New Disease-Specific Scale[1]

Global Patient Survey Reveals Approximately Two-Thirds of Multiple Sclerosis Patients Experience Fatigue on a Daily Basis[2]

BEERSE, BELGIUM, 11 September, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from a real-world evidence study demonstrating high levels of fatigue and its impact on patients' lives in the areas of physical, cognitive/emotional and coping activities, among a majority of adult patients with relapsing multiple sclerosis (RMS). These data are being shared online as a poster presentation (#P1004) during MSVirtual2020: 8th Joint ACTRIMS-ECTRIMS Meeting.

The study, which enrolled 200 U.S. patients with RMS measured multiple sclerosis (MS)-related fatigue and its impact on daily life using the Fatigue Symptoms and Impacts Questionnaire – Relapsing Multiple Sclerosis (FSIQ-RMS), a novel disease-specific scale developed using methods consistent with the U.S. Food & Drug Administration guidelines. The FSIQ-RMS is a patient-reported outcome instrument that has demonstrated content and measurement validity for RMS fatigue-related symptom and impact items. The MS symptom with most impact on daily functioning was fatigue (33 percent), followed by walking difficulties (25 percent).[1]

"MS is one of the most common causes of neurological disability in young and middle-aged adults, with over 700,000 people in Europe affected by the condition," said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Janssen Research & Development, LLC. "At Janssen, we approach neurodegenerative conditions holistically, considering both fundamental and secondary – or 'hidden' – symptoms. As such, we developed the FSIQ-RMS to better understand and measure the severity of MS-related fatigue and its impact on daily function, so that these insights can be applied to develop meaningful therapeutic options, as well as educational initiatives to help people with MS, and their healthcare team, better manage this prominent symptom."

Separately, Janssen, in partnership with the National Multiple Sclerosis Society (NMSS), recently conducted a global patient research survey to examine the impact of MS-related fatigue across social and emotional aspects of daily life.[2] The survey included 1,300 adult patients with MS living in the United States, Germany, Canada, France, the United Kingdom and Italy.[2] The survey results show more than 65 percent of patients with MS experience fatigue on a daily basis with 60 percent stating their fatigue has worsened since their diagnosis.[2] Other survey findings reveal:[2]

- More than 75 percent of patients agree it's difficult for others in their life to truly understand how fatigue impacts them.

- Nearly 70 percent of respondents feel they should hide their fatigue from others.

- Over 40 percent of respondents reported feeling lonely as a result of their fatigue.

- Approximately 37 percent stated they had trouble making new friends or had strained friendships because of fatigue.

- Nearly half of patients take breaks throughout the day to manage their fatigue. In the workplace specifically, 85 percent reported their fatigue impacts how they feel and act at work.

- More than one-third of respondents reported they either arrived late or left work early, called in sick (from work) or missed family/social activities because of their fatigue.

- More than 90 percent of patients have discussed their fatigue with their healthcare provider (HCP); however, 56 percent say they don’t feel their HCP fully understands the overall impact fatigue has on their daily lives.

#ENDS#

About Multiple Sclerosis (MS)

MS is a chronic autoimmune inflammatory disease of the central nervous system.[3] It affects more than 700,000 people in Europe, and is one of the most common causes of neurological disability in young and middle-aged adults, with females up to three times more frequently impacted than males.[4,5,6] While prevalence varies worldwide, it is highest in Europe and North America.[7] The disease is characterised by demyelination and axonal loss leading to neurological impairment and severe disability.[8,9] Relapsing forms of MS include clinically isolated syndrome, relapsing-remitting MS (which makes up 85 percent of all MS cases), and secondary progressive MS.[10] 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 reduced quality of life.[11] Fatigue is one of the most common symptoms of MS, occurring in about 80 percent of patients.[12]

Relapses are defined as new, worsening or recurrent neurological symptoms that last for more than 24 hours with the absence of fever or infections. [13] Relapses may be fully resolved over days or weeks or lead to persistent residual deficits and accumulation of disability.[9,13]

About the National Multiple Sclerosis Society (NMSS)

The National Multiple Sclerosis Society exists because there are people with MS. Our vision is a world free of MS. Everything we do is focused so that people affected by MS can live their best lives as we stop MS in its tracks, restore what has been lost and end MS forever.

We are more than an organisation. We are a movement. United in our collective power to do something about MS now and end this disease forever. The gathering place for people with MS, their family and loved ones, healthcare providers, volunteers, donors, fundraisers, advocates, community leaders and all those that seek a world free of MS. A place to connect and take action. In order to change the world, we mobilise all possible human and financial resources to achieve results.

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. 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. 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 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 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 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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