



News Release

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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

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

Titusville, N.J., September 11, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from a real-world evidence study demonstrating high levels of fatigue and impacts on patients’ lives in the areas of physical, cognitive/emotional and coping activities among a majority of adult patients with relapsing multiple sclerosis (RMS). The data are being shared online as an accepted 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).

“At Janssen, we approach diseases holistically, considering both fundamental and secondary – or ‘hidden’ – symptoms that may affect the well-being of people living with neurodegenerative conditions, like MS,” said Bill Martin, Ph.D., Global Therapeutic Area Head, Neuroscience, Janssen Research & Development, LLC. “We developed the FSIQ-RMS to better understand and measure the severity of MS-related fatigue and its impact on daily functioning, 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](#) on social and emotional aspects of daily life. The survey included 1,300 adult patients with MS living in the U.S., Germany, Canada, France, the UK and Italy. Survey results show that 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. Other survey findings include the following:

- 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 that 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 that 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.

About Multiple Sclerosis (MS)

MS is a chronic autoimmune inflammatory disease of the central nervous system affecting 2.3 million people worldwide,ⁱ with females more impacted than males.ⁱⁱ The disease is characterized by demyelinationⁱⁱⁱ and axonal loss leading to neurological impairment and severe disability.ⁱⁱⁱ 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.^{iv} 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.^v Fatigue is one of the most common symptoms of MS, occurring in about 80 percent of patients.^{vi}

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.^{vii}

About the Global Patient Survey

The survey was conducted by Wakefield Research on behalf of Janssen between July 31 and August 13, 2020, among 1,300 adults spanning the U.S., Germany, the UK, France, Italy and Canada who have been treated for multiple sclerosis.

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 organization. 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 mobilize 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. 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. 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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ⁱ National Multiple Sclerosis Society. Multiple Sclerosis FAQs. Available at: <https://www.nationalmssociety.org/What-is-MS/MS-FAQ-s>. Accessed April 23, 2019.

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

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

^{iv} 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.

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- ^v Biernacki T, Sandi D, Kincses ZT, et al. Contributing factors to health-related quality of life in multiple sclerosis. *Brain Behav.* 2019;00:e01466. <https://doi.org/10.1002/brb3.1466>.
- ^{vi} National Multiple Sclerosis Society. Fatigue. Available at: <https://www.nationalmssociety.org/Symptoms-Diagnosis/MS-Symptoms/Fatigue>. Accessed February 25, 2020.
- ^{vii} 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.