Biogen Grows Presence in China with the Approval of TECFIDERA® (dimethyl fumarate) for the Treatment of Relapsing Multiple Sclerosis

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- *TECFIDERA was approved under the National Medical Products Administration priority review process evaluating therapies with urgent clinical needs*
- *More than 500,000 individuals worldwide living with multiple sclerosis (MS) have been treated with TECFIDERA, which has a well-established safety and efficacy profile*
- *Biogen's expansion in China now includes treatment options approved for relapsing MS and spinal muscular atrophy*

CAMBRIDGE, Mass., April 15, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that China's National Medical Products Administration (NMPA) has approved TECFIDERA® (dimethyl fumarate) for the treatment of relapsing multiple sclerosis (MS). First introduced in 2013, TECFIDERA has demonstrated a well-established safety and efficacy profile with more than 10 years of data from clinical trials and real-world experience.[1] It has been used to treat more than 500,000 individuals with MS worldwide.[1] The approval brings a new treatment option to people in China living with relapsing MS and also continues to expand the company's presence in the country.

"It is truly a milestone to bring this well-established treatment to China and be able to help people living with relapsing multiple sclerosis," said Rachid Izzar, President, Intercontinental Region at Biogen. "We thank the NMPA for undertaking priority review to approve TECFIDERA. We are committed to expanding our presence in China and working with the MS community to address unmet medical needs through innovative therapies and solutions."

The NMPA evaluation was based on data from the global, pivotal Phase 3 DEFINE and CONFIRM studies, which enrolled more than 2,600 patients. In DEFINE, TECFIDERA administered twice daily significantly reduced the annualized relapse rate by 53 percent ($p<0.0001$) compared to placebo, at two years. In CONFIRM, twice-daily TECFIDERA significantly reduced the proportion of patients who relapsed by 34 percent ($p=0.0020$) compared to placebo at two years.

"MS is an inflammatory disease that attacks the central nervous system and, if not treated in a timely manner and following standard protocol, can lead to disability due to irreversible neurological damage. Currently in China, a small number of patients are treated according to the standard of care with a disease modifying therapy," said Professor Yongjun Wang, deputy director of the National Clinical Research Center for Neurological Diseases, chairman of the Chinese Society of Neurology and president and chief physician of Beijing Tiantan Hospital, Capital Medical University. "The characteristics, clinical manifestation and disease course varies greatly among patients, which makes personalized treatment essential. Results from clinical trials and more than a decade of real-world evidence have demonstrated the efficacy, safety and tolerability of dimethyl fumarate. The approval and availability of dimethyl fumarate will provide a new option for patients and will help contribute to the clinical evidence on treating MS in China."

The December 2020 General Social Survey on Patients with Multiple Sclerosis in China by the China Alliance for Rare Diseases found that among people with MS who are unemployed or out of school, 90 percent was due to their diagnosis. The report notes the need for the community to work together to help patients and families address the physical and mental challenges that can result from MS.

MS is a life-long, progressive, autoimmune neurologic disease of the central nervous system (CNS). In China, only approximately 10 percent of the population diagnosed with MS is being treated with a disease modifying treatment.[2] It is the second most common cause of non-traumatic neurological disability in young adults.[3] The disease causes damage to the CNS resulting in physical disability as well as neurological dysfunctions involving movement, vision and cognition. The severity and specific symptoms of MS vary from person to person. More than 85 percent of people with MS are diagnosed with relapsing MS, the most common form of the disease.

In May 2018 MS was included on China's First National List of Rare Diseases, which was jointly developed by five national bodies to support diagnosis and treatment of rare conditions. The NMPA initiated a priority review process to evaluate innovative treatments using clinical evidence from trials conducted in major independent review markets. In November 2020 TECFIDERA was included in the list of the *Third Batch of New Overseas Drugs Urgently Needed in Clinical Settings* by the Center for Drug Evaluation under the NMPA.

About TECFIDERA® (dimethyl fumarate)
TECFIDERA, a treatment for relapsing forms of multiple sclerosis (MS) in adults, is the most prescribed oral medication for relapsing MS in the world and has been shown to reduce the rate of MS relapses, slow the progression of disability and impact the number of MS brain lesions, while demonstrating a well-characterized safety profile in people with relapsing forms of MS including clinically isolated syndrome, relapsing-remitting disease and active secondary disease. TECFIDERA is approved in 69 countries, and more than 500,000 patients have been treated with it, representing more than 950,000 patient-years of exposure across clinical trial use and patients prescribed TECFIDERA. Of these, 6,335 patients (14,241 patient-years) were from clinical trials.[3]

TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Serious side effects include anaphylaxis and angioedema, and cases of progressive multifocal leukoencephalopathy, a rare opportunistic viral infection of the brain which has been associated with death or severe disability, have been seen with TECFIDERA patients in the setting of prolonged lymphopenia although the role of lymphopenia in these cases is uncertain. Other serious side effects include a decrease in mean lymphocyte counts during the first year of treatment, herpes zoster and other serious infections, liver injury and flushing. In clinical trials, the most common adverse events associated with TECFIDERA were flushing, abdominal pain, diarrhea and nausea.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for TECFIDERA in the U.S., or visit your respective country's product website.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global

biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential benefits, safety and efficacy of TECFIDERA; the results of certain real-world data; results from the Phase 3 DEFINE study and the Phase 3 CONFIRM study; the identification and treatment of MS; our research and development program for the treatment of MS; and the potential of Biogen's commercial business, including TECFIDERA. These forward-looking statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation the occurrence of adverse safety events; risks of unexpected costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates or expansion of product labeling; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

References:

1. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of December 31, 2020.
2. Chinese Society of Neurology, Chinese Medical Association; China International Exchange and Promotive Association for Medical and Healthcare (2018). China vsMS Report (China MS Patient Status Report).
3. Dimitrov L.G. and Turner B. The British journal of general practice: the journal of the Royal College of General Practitioners volume 64 issue 629 pages 612-613 December 2014.

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