CHMP rekommenderar VUMERITY® (diroximelfumarat) för godkännande i Europeiska unionen som behandling för skovvis förlöpande multipel skleros hos vuxna patienter

- *VUMERITY är en ny fumarat, en oral behandling med väldefinierad effekt- och säkerhetsprofil*
- *Data från fas 3-studien EVOLVE-MS-2 visade att behandling med VUMERITY gav färre gastrointestinala biverkningar och lägre andel behandlingsavbrott, jämfört med Tecfidera*
- *Efter godkännande kommer VUMERITY att vara ett nytt oralt behandlingsalternativ för MS-patienter*

Cambridge, Mass. – September 17, 2021 – Biogen Inc. (Nasdaq: BIIB) today announced that the Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency (EMA), issued a positive opinion and has recommended granting marketing authorization for VUMERITY® (diroximel fumarate) in the European Union (EU). Diroximel fumarate is an oral fumarate for the treatment of adults with relapsing-remitting multiple sclerosis (RRMS). An estimated 2.8 million people live with MS across the globe, with some European countries demonstrating the highest prevalence of MS in the world.[1]

"With MS, finding the right treatment option is as much about managing the clinical aspects of the disease as it is about how treatment fits into a person's life," said Simon Faissner, M.D., PhD, Assistant Professor at the Department of Neurology, Ruhr-University Bochum.

The CHMP's positive opinion will now be referred to the European Commission (EC), which grants marketing authorizations for medicines in Europe.

"We look forward to advancing Biogen's portfolio and continuing to work with the MS community to address critical treatment challenges, including those that affect persistence and adherence to medication for this chronic and life-long disease," said Alfred Sandrock, Jr., M.D., Ph.D., Head of Research and Development at Biogen. "Diroximel fumarate builds on our experience in MS and the established profile of dimethyl fumarate to bring a new oral option at a time when people with MS are making treatment decisions while considering other factors related to their ongoing care during the pandemic."

The positive CHMP opinion was based on data from pharmacokinetic bridging studies comparing diroximel fumarate and TECFIDERA® (dimethyl fumarate) to establish bioequivalent exposure of monomethyl fumarate, the active metabolite, and relied in part on the established long-term safety and efficacy profile of dimethyl fumarate. The CHMP also assessed findings from EVOLVE-MS-2, a large, randomized, double-blind, five-week, multi-center Phase 3 study to evaluate the gastrointestinal (GI) tolerability of diroximel fumarate compared to dimethyl fumarate in patients with RRMS. In EVOLVE-MS-2, the rate of overall treatment discontinuation was lower in participants treated with diroximel fumarate compared to those treated with dimethyl fumarate (1.6% compared to 6%,

respectively). The difference in the discontinuation rates due to GI tolerability was 0.8% for diroximel fumarate compared to 4.8% for dimethyl fumarate.

About VUMERITY® (diroximel fumarate)

Diroximel fumarate is an oral fumarate with a distinct chemical structure from dimethyl fumarate, approved in the U.S. for the treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease (Vumerity® is not approved in Sweden). Once in the body, diroximel fumarate rapidly converts to monomethyl fumarate, the same active metabolite of dimethyl fumarate.

Diroximel fumarate is contraindicated in patients with known hypersensitivity to diroximel fumarate, dimethyl fumarate or any of the excipients of diroximel fumarate; and in patients taking dimethyl fumarate. Serious side effects for diroximel fumarate are based on data from dimethyl fumarate (which has the same active metabolite as diroximel fumarate) and include anaphylaxis and angioedema, progressive multifocal leukoencephalopathy, which is a rare opportunistic viral infection of the brain that has been associated with death or severe disability, a decrease in mean lymphocyte counts during the first year of treatment, herpes zoster and other serious infections, liver injury and flushing. The most common adverse events, obtained using data from dimethyl fumarate (which has the same active metabolite as diroximel fumarate), were flushing, abdominal pain, diarrhea and nausea.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for VUMERITY in the U.S.

Om TECFIDERA® (dimetylfumarat)

Dimetylfumarat är en oral behandling för vuxna patienter med skovvis förlöpande multipel skleros, vilket är den vanligaste formen av multipel skleros. De vanligaste biverkningarna, i kliniska studier, var hudrodnad och gastrointestinala biverkningar. Dimetylfumarat ska inte användas vid misstänkt eller bekräftad progressiv multifokal leukoencefalopati (PML) och rekommenderas inte under graviditet eller till fertila kvinnor som inte använder lämpliga preventivmedel. Sällsynta fall av progressiv multifokal leukoencefalopati (PML) har förekommit.

För information om förskrivningsinformation för TECFIDERA i EU, besök:
https://www.ema.europa.eu/en/medicines/human/EPAR/tecfidera
För information om TECFIDERA i Sverige, besök: www.fass.se

Om Biogen

Biogen upptäcker, utvecklar och tillhandahåller innovativa terapier för människor som lever med allvarliga neurologiska och neurodegenerativa sjukdomar. Företaget grundades 1978 av Charles Weissmann, Heinz Schaller, Kenneth Murray och Nobelpristagarna Walter Gilbert och Phillip Sharp och blev därmed ett av världens första globala bioteknikföretag. Idag har Biogen den ledande portföljen av läkemedel för att behandla multipel skleros, den första godkända behandlingen för spinal muskulär atrofi, marknadsför avancerade biosimilarer och fokuserar på att utveckla forskningsprogram inom multipel skleros och neuroimmunologi, Alzheimers sjukdom och demens, neuromuskulära sjukdomar, neuropsykiatri, immunologi, akut neurologi och neuropatisk smärta.

Vi publicerar rutinmässigt information som kan vara viktig för investerare på vår webbplats www.biogen.com.

Följ oss på sociala medier – 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, about potential regulatory discussions, submissions and approvals and the timing thereof; the potential benefits, safety and efficacy of VUMERITY; the potential benefits, safety and efficacy of TECFIDERA; the results of certain real-world data; and the potential of Biogen's commercial business, including VUMERITY and 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. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. 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 actual timing and content of submissions to and decisions made by the regulatory authorities; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; 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; 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. Walton, Clare. "Rising Prevalence of Multiple SCLEROSIS Worldwide: Insights from the Atlas of Ms, Third Edition." *Multiple Sclerosis (Houndmills, Basingstoke, England)*, U.S. National Library of Medicine, 11 Nov. 2020, pubmed.ncbi.nlm.nih.gov/33174475/.
2. Liseno J, et al. Multiple Sclerosis Patients Treated with Diroximel Fumarate in the Real-World Setting have High Rates of Persistence and Adherence. Neurology. April 13, 2021; 96 (15 Supplement).
3. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of December 31, 2020.

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