**New Data at AAN 2021 from Across Biogen’s MS Portfolio Demonstrate Positive Impact of Treatment on People Living with Relapsing Multiple Sclerosis**

* *New findings from MS PATHS show that treatment with TYSABRI® (natalizumab) can lead to improvements in mental and social health compared to Ocrevus® (ocrelizumab)*
* *Real-world data from VUMERITY® (diroximel fumarate) reinforce the treatment’s gastrointestinal tolerability profile*
* *Biogen including new information on the clinical profile of extended interval dosing with natalizumab*

**Stockholm – April 16, 2021** – [Biogen Inc.](http://www.biogen.com) (Nasdaq: BIIB) announced new data from its portfolio of multiple sclerosis (MS) therapies to be presented at the American Academy of Neurology (AAN) 2021 Virtual Annual Meeting, April 17-22. The presentations include data on quality of life and analyses of extended interval dosing (EID) with NATALIZUMAB as well as new real-world experience data from DIROXIMEL FUMARATE. The research adds to the vast clinical knowledge Biogen as part of its commitment to the care of people living with MS.

**Analyses Demonstrate Improved Quality of Life Outcomes with NATALIZUMABand Further Evaluate Extended Interval Dosing**

To better understand clinically meaningful quality of life parameters following treatment with NATALIZUMAB, MS PATHS (Partners Advancing Technology and Health Solutions) researchers analyzed patient reported data on 12 different domains on the Neuro-QoL (Quality of Life in Neurological Disorders) questionnaire such as sleep disturbance, anxiety, fatigue, depression and participation in daily activities. Results included:

* In people treated with NATALIZUMAB or ocrelizumab with baseline impairment, statistically significant improvements were seen in 10 of 12 and 8 of 12 Neuro-QoL domains, respectively.
* The difference between the two therapies was statistically significant in favor of NATALIZUMAB in three of the domains: satisfaction with social roles and activities (p=0.02), participation in social roles and activities (p=0.0001) and emotional and behavioral dyscontrol (p=0.01).

Neuro-QoL is an independently validated set of patient-reported outcome measurements that assess the physical, mental and social effects of people living with neurological conditions such as MS. Biogen established the MS PATHS network to foster collaboration between leading MS centers in Europe and the U.S. to help transform patient care by generating standardized data from a diverse, real-world patient population.

Additionally, results from two new analyses investigating EID with natalizumab may help further inform the drug’s benefit-risk profile. Biogen continues to evaluate the efficacy, safety and tolerability of natalizumab EID through the prospective NOVA trial ([NCT03689972](https://clinicaltrials.gov/ct2/show/NCT03689972)) with initial results expected in 2021.

* From an analysis of data in MS PATHS, natalizumab patients receiving either EID or Standard Interval Dosing (SID) had comparable real-world effectiveness on quantitative magnetic resonance imaging (MRI) outcomes (p>0.05 for all MRI outcomes).
* An updated analysis of data from the TOUCH Prescribing Program demonstrated in the primary analysis that EID is associated with a significant (P<0.0001) 88% reduction in the risk of progressive multifocal leukoencephalopathy (PML) in comparison to the approved every four-week dose. The data, which included more patients followed for a longer period and with slightly greater exposures, reinforces results from earlier analyses of EID.

**Data Confirm Positive Gastrointestinal Tolerability Profile With DIROXIMEL FUMARATE in Real-World Setting**

New findings on the use of DIROXIMEL FUMARATE in a real-world setting reinforce the benefits of improved gastrointestinal (GI) tolerability and confirm that the experience in clinical trials is consistent with clinical practice. In a retrospective analysis of data from December 2019 to August 2020 of 160 patients with relapsing MS, the treatment discontinuation rate due to GI side effects was 3.8% with 88.6% estimated to still be on therapy at the end of analysis and rate of adherence was 91.4%. In a subgroup of patients who switched from TECFIDERA® (dimethyl fumarate) to DIROXIMEL FUMARATE, the majority of patients switched as a result of gastrointestinal tolerabilty with most remaining on therapy (92.3%).

**Data Presentations Featured at AAN:**

* Impact of Natalizumab on Quality of Life in a Real-World Cohort of Patients with Multiple Sclerosis: Results from MS Partners Advancing Technology and Health Solutions (MS PATHS) – P15.023
* No Difference in Radiologic Outcomes for Natalizumab Patients on Extended Interval Dosing Compared with Standard Interval Dosing in MS PATHS – P15.210
* Natalizumab Extended Interval Dosing (EID) is Associated with a Reduced Risk of Progressive Multifocal Leukoencephalopathy (PML) Compared with Every-4-week (Q4W) Dosing: Updated Analysis of the TOUCH® Prescribing Program Database – P15.201
* Multiple Sclerosis Patients Treated with Diroximel Fumarate in the Real-world Setting have High Rates of Persistence and Adherence – P15.227

**Om TYSABRI® (natalizumab)**

Natalizumab är indicerat i monoterapi hos vuxna med mycket aktiv skovvis förlöpande multipel skleros (MS), för följande patientgrupper: Patienter med mycket aktiv sjukdom trots fullständig och adekvat behandling med minst en sjukdomsmodifierande behandling; eller patienter med snabb utveckling av svår RRMS, definierat som två eller flera funktionsnedsättande skov under ett år eller en eller flera Gd+ lesioner vid MRT eller en avsevärd ökning av T2-lesioner jämfört med nyligen utförd MRT. Natalizumab finns i två beredningsformer, intravenös (IV) och subkutan (SC).

Natalizumab är kontraindicerat hos patienter med: progressiv multifokal leukoencefalopati (PML), förhöjd risk för opportunistiska infektioner (inklusive nedsatt immunförsvar), aktiva maligniteter (undantaget basalcellscancer i huden) samt i kombination med andra sjukdomsmodifierande behandlingar.

Behandling med natalizumab har förknippats med en förhöjd risk för PML (progressiv multifokal leukoencefalopati) som orsakas av JC-virus. Följande riskfaktorer är förknippade med en ökad risk för PML: förekomst av anti-JCV-antikroppar; Behandling efter 2 år; användning av immunosuppressiva medel före behandling med natalizumab. Nyttan och riskerna med natalizmab-behandling ska utvärderas regelbundet. Patienten bör upplysas om tidiga tecken och symtom på PML.

Före start av behandling med natalizumab måste en nyligen genomförd (vanligen inom ca tre månader) undersökning med MRT finnas tillgänglig som en referens och upprepas minst årligen. Mer frekventa MRT-undersökningar ska övervägas för patienter som löper en högre risk att drabbas av PML.

För information om kontraindikationer, varningar och försiktighet, biverkningar, dosering, pris och förpackning se www.fass.se

**About VUMERITY® (diroximel fumarate)**

VUMERITY is an oral fumarate with a distinct chemical structure from TECFIDERA® (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, VUMERITY rapidly converts to monomethyl fumarate, the same active metabolite of dimethyl fumarate.

VUMERITY is contraindicated in patients with known hypersensitivity to diroximel fumarate, dimethyl fumarate or any of the excipients of VUMERITY; and in patients taking dimethyl fumarate. Serious side effects for VUMERITY are based on data from dimethyl fumarate (which has the same active metabolite as VUMERITY) 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 VUMERITY), were flushing, abdominal pain, diarrhea and nausea.

**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 ytterligare information om förpackningar, kontraindikationer, varningar och försiktighet, biverkningar och pris, se www.fass.se.

**Om Biogen**

Biogen är det banbrytande läkemedelsbolaget inom neurologi. Med mod, upptäckarglädje och nobelprisad forskning utmanar vi det omöjliga i vår strävan att ge människor med svåra sjukdomar i centrala nervsystemet hopp och möjligheter till ett friskare liv med hög livskvalitet.

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 Nobelprisvinnarna Walter Gilbert och Phillip Sharp och blev därmed ett av världens första globala bioteknikföretag. Biogen har idag en ledande portfölj av läkemedel för att behandla multipel skleros, den första godkända behandlingen för spinal muskelatrofi, marknadsför avancerade biosimilarer och fokuserar på att utveckla forskningsprogram inom Alzheimers sjukdom, neuroimmunologi, neuromuskulära sjukdomar, oftalmologi, neuropsykiatri, immunologi, akut neurologi och neuropatisk smärta.

Vi publicerar rutinmässigt information för investerare på vår webbplats [www.biogen.com](http://www.biogen.com).

Följ oss på sociala medier –[Twitter](http://www.twitter.com/biogen), [LinkedIn](http://www.linkedin.com/company/biogen-), [Facebook](http://www.facebook.com/Biogen/), [YouTube](http://www.youtube.com/c/biogen).

**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 TYSABRI and VUMERITY; the results of certain real-world data; clinical trials and data readouts and presentations; the identification and treatment of MS; our research and development program for the treatment of MS; and the potential of our commercial business, including TYSABRI and VUMERITY. 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. 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 and/or unexpected concerns that may arise from additional data or analysis; 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; third party collaboration risks; 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.

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