**Nya säkerhets- och effektdata för Biogens MS portfölj presenteras på ACTRIMS-ECTRIMS**

* *Nya data från en pågående fas 3 studie ger en tydligare bild av effekt och förbättrad GI tolerabilitet för Vumerity® (diroximelfumarat)* jämfört med Tecfidera*® (dimetylfumarat)*
* *Utifrån observationsdata utvärderas livskvalitetfördelar för Tysabri® (natalizumab) i jämförelse med Ocrevus®(ocrelizumab*)
* *Baserat på ytterligare observationsdata rapporteras fördelar med Plegridy® (peginterferon beta-1a) och Avonex® (interferon beta-1a) hos äldre personer med skovvis förlöpande multipel skleros*

**Cambridge, Mass. – September TBC, 2020** – [Biogen Inc.](http://www.biogen.com) (Nasdaq: BIIB) today announced new data underscoring the efficacy and safety of its broad, industry-leading portfolio of multiple sclerosis (MS) therapies. These data will be presented during MSVirtual2020, the eighth joint meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS), which will be held virtually September 11-13, 2020.

“We at Biogen are proud of our commitment to addressing both the urgent and long-term challenges facing people living with MS,” said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. “The data we are presenting at ACTRIMS-ECTRIMS highlight the improved outcomes that our broad MS portfolio has continued to provide for people with relapsing forms of MS, regardless of where they are in their treatment journey, as well as our ongoing investment in research and development to identify potentially effective drug candidates.”

**New Phase 3 Data Further Characterize the Effectiveness and Patient-Reported GI Tolerability of Vumerity® (diroximel fumarate)**

New data from the diroximel fumarate Phase 3 clinical program further define the effectiveness and safety profile of Biogen’s latest oral fumarate therapy. Findings from the five-week EVOLVE-MS-2 study reinforce clinically meaningful improvements in patient-assessed gastrointestinal (GI) tolerability associated with diroximel fumarate treatment (n=253) compared to (dimethyl fumarate) (n=251), and support its impact on quality of life for people with relapsing MS. Study participants taking diroximel fumarate reported a lower likelihood of experiencing GI symptoms that interfered with daily activities or were associated with missed work, as well as less concomitant medication use to treat GI symptoms.

An exploratory analysis from the ongoing EVOLVE-MS-1 study assessed the effects of diroximel fumarate on brain volume change and other clinical measures in people with relapsing MS (n=365) treated for up to two years. Separate studies have shown brain volume loss may be associated with cognitive impairment, physical disability and reduced quality of life in people with MS.1,2 Data from EVOLVE-MS-1 show:

* The annual rate of brain volume change in study participants treated with diroximel fumarate for two years was similar to the rate observed in healthy individuals; and
* Approximately 90 percent of people treated with diroximel fumarate remained free from confirmed disability progression and around 84 percent were relapse-free at two years.

Also being presented at the meeting are final data from the Phase 3 ENDORSE study, which further demonstrate the sustained efficacy and well-characterized safety profile of dimetylfumarat in patients followed for up to 13 years.

**Real-World Data From Separate Analyses in the Relapsing MS Population Show Improved Outcomes With Tysabri® (natalizumab), Plegridy® (peginterferon beta-1a) and Avonex® (interferon beta-1a)**

Through MS PATHS (Partners Advancing Technology and Health Solutions), Biogen is collaborating with leading MS centers in Europe and the U.S. to generate standardized, high-quality data from a diverse, real-world MS patient population. To date, more than 17,000 patients have been enrolled in MS PATHS. Data being presented from treatment in the real-world setting support improved outcomes associated with natalizumab, peginterferon beta-1a and interferon beta-1a. Results from separate analyses of MS PATHS data reveal the following:

* In the first comparison of MS PATHS standardized magnetic resonance imaging (MRI) protocols, analyses of changes in brain MRI (occurring over a mean follow-up of 0.8 years) were compared during natalizumab treatment with extended interval dosing (EID; n=85) to the approved every-four-week (Q4W; n=569) dosing. The analysis reported no significant differences in the rates of new T2 lesions, T2 lesion volumes and brain atrophy. Differences in MRI scanners and acquisition protocols in clinical practice have made comparisons of brain MRI outcomes challenging. Multiple real-world studies have suggested the effectiveness of natalizumab EID is similar to the approved Q4W dosing.3-7 Biogen continues to evaluate the efficacy, safety and tolerability of natalizumab EID through the prospective NOVA trial ([NCT03689972](https://www.globenewswire.com/Tracker?data=jAbmQ5yDuHVta3V-xCUfROT0lO4aEjUmnC55P61m9-BuO8AaiL4gAybOThxxexxsSMTzDoAuZRXsAaj-usFmBgMT4iGXlGgIpHsW3nPGtnQYt0Uw5eyHkYsROOxS6vi3VyF856ndfx9VfX8bzElZBejxqHfXTI7HEqIF4ROSqNvTWcthHa-mYCcrw7onNrL24TmMP2eVDDNUTZ7Dt3Q13SejykLdvJIq5JH80m3EkVy7GUB0_tomUkkSeSSGrQ6v)), and recently filed with regulatory authorities for a subcutaneous dosing formulation which, if approved, would allow for more options for natalizumab administration.
* Treatment with natalizumab was associated with greater improvements than ocrelizumab in several quality of life domains according to the Neuro-QoL (Quality of Life in Neurological Disorders) assessment. In a subgroup analysis of matched patients treated with natalizumab or ocrelizumab, significant improvement was observed in nine of 12 Neuro-QoL domains in patients treated with natalizumab (n=144) and in four of 12 domains in patients treated with ocrelizumab (n=502). In patients who had QoL impairments at baseline, annualized rates of improvement were higher with natalizumab than with OCREVUS and significant differences were observed in three domains: positive affect and well-being, satisfaction with social roles and activities and sleep disturbance.
* Clinical outcomes in people with MS aged 60 or older (n=286), compared to those under 60 (n=729), indicate that peginterferon beta-1a and interferon beta-1a may provide real-world treatment benefits over two years in both age groups. Data show functional improvements in processing speed test (PST) and contrast sensitivity test (CST) over one year in both age groups. Additionally, a majority of participants in both age groups remained free from relapse over two years.

**Data from a Phase 1 study of BIIB091 supports continued development for the treatment of MS**

Biogen also presented data from a Phase 1 study of BIIB091, an orally active selective, reversible (noncovalent), small molecule inhibitor of Bruton’s Tyrosine Kinase (BTK).  Data evaluated the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending oral doses in healthy adult participants. Selective BTK inhibition may be beneficial for the treatment of MS by preventing B-cell and myeloid cell activation without immune cell depletion.

**Data Presentations Featured at ACTRIMS-ECTRIMS:**

*Note: All poster presentations from MSVirtual2020 will be made available online at 9 a.m. ET on Friday, September 11, 2020.*

* Improved GI Tolerability With Diroximel Fumarate is Associated With Clinically Meaningful Benefits on Quality of Life Compared With Dimethyl Fumarate in EVOLVE-MS-2 (Poster 0214)
* Effects of Diroximel Fumarate on Brain Volume Change and Disability Progression in Adults With Relapsing-Remitting Multiple Sclerosis From EVOLVE-MS-1 (Poster P0205)
* Safety and Efficacy in Patients Treated With Dimethyl Fumarate and Followed for 13 Years: Final Results of ENDORSE (Platform FC02.05 – Sunday, September 13, 1:48-2:00 p.m. ET)
* No Difference in Radiologic Outcomes for Natalizumab Patients on Extended Interval Dosing Compared With Standard Interval Dosing in MS PATHS (Poster P0360)
* Impact of Natalizumab on Quality of Life in a Real-World Cohort of Patients With Multiple Sclerosis: Results from MS PATHS (Poster P1036)
* Characteristics and Clinical Outcomes of Older Patients With MS Treated With Peginterferon Beta-1a or Intramuscular Interferon Beta-1a in MS PATHS (Poster P0843)
* A Phase 1 Study of BIIB091, a Bruton’s Tyrosine Kinase (BTK) Inhibitor, in Healthy Adult Participants: Preliminary Results (Poster P0186)

**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 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](http://www.fass.se/).

**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 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](http://www.fass.se/)

**Om PLEGRIDY®** *(***peginterferon beta-1a)**

Plegridy är avsett för vuxna patienter för behandling av skovvis förlöpande multipel skleros, vilket är den vanligaste formen av multipel skleros. De vanligaste biverkningarna, i kliniska studier, var erytem vid injektionsstället och influensaliknande symtom. Fertila kvinnor ska använda effektiv preventivmetod. För ytterligare information om förpackningar, kontraindikationer, varningar och försiktighet, biverkningar och pris, se [www.fass.se](http://www.fass.se/)

**Om AVONEX® (interferon beta-1a)**

Avonex är avsett för vuxna patienter för behandling av skovvis förlöpande multipel skleros, vilket är den vanligaste formen av multipel skleros. Den vanligaste biverkningen, i kliniska studier var influensaliknande symtom. Kvinnor i fertil ålder skall använda lämpliga preventivmetoder. För ytterligare information om förpackningar, kontraindikationer, varningar och försiktighet, biverkningar och pris, se [www.fass.se](http://www.fass.se/)

**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, and today 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, neuromuscular disorders, movement disorders, Alzheimer’s disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology, and pain.

**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 VUMERITY, TECFIDERA, TYSABRI, PLEGRIDY and BIIB091; the results of certain real-world data; results from the EVOLVE-MS-2 study, Phase 3 ENDORSE study and the Phase 1 study of BIIB091; the identification and treatment of MS; our research and development program for the treatment of MS; potential regulatory discussions, submissions and approvals and the timing thereof; the potential of Biogen’s commercial business, including VUMERITY, TECFIDERA, TYSABRI, PLEGRIDY and BIIB091; and risks and uncertainties associated with drug development and commercialization. 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 the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis; risks of unexpected costs or delays; unexpected concerns may arise from additional data, analysis or results obtained during clinical trials; 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; failure to obtain regulatory approvals in other jurisdictions; 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.

**References:**

1. Mowry EM, Beheshtian A, Waubant E, et al. Quality of life in multiple sclerosis is associated with lesion burden and brain volume measures. Neurology. 2009;72(20):1760-1765.
2. Lanz M, Hahn HK, Hildebrandt H. Brain atrophy and cognitive impairment in multiple sclerosis: a review [published correction appears in J Neurol. 2008 Feb;255(2):309-10]. J Neurol. 2007;254 Suppl 2:II43-II48.
3. Foley J, Xiong K, Hoyt T, et al. Serum neurofilament light levels in patients with relapsing-remitting multiple sclerosis switching from natalizumab every-4-week dosing to extended interval dosing. AAN 2020; S10.009.
4. Butzkueven, Kappos L, Spelman T, et al. No significant difference in relapse outcomes in patients switching to natalizumab extended interval dosing or remaining on standard interval dosing: propensity score comparative effectiveness analysis of patients in the TYSABRI Observational Program. ECTRIMS 2019; P1033.
5. Yamout B, Sahraian MA, Ayoubi NE, et al. Efficacy and safety of natalizumab extended interval dosing. *Mult Scler Relat Disord.* 2018;24:113-116.
6. Zhovtis Ryerson L, Frohman TC, Foley J, et al. Extended interval dosing of natalizumab in multiple sclerosis. J Neurol Neurosurg Psychiatry. 2016;87:885-889.
7. Bomprezzi R, Pawate S. Extended interval dosing of natalizumab: a two-center, 7-year experience. Ther Adv Neurol Disord. 2014;7:227-231.
8. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of June 30, 2020.
9. Combined post-marketing data based on prescriptions and clinical trials exposure to TYSABRI as of July 31, 2020.
10. Combined post-marketing data based on prescriptions for PLEGRIDY as of March 31, 2020.
11. Combined post-marketing data based on prescriptions for AVONEX as of March 31, 2020.

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