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Ny data publiceras på ECTRIMS i Berlin på TECFIDERA (dimetylfumarat) och TYSABRI (natalizumab)

BIOGEN ADVANCES RESEARCH TO IMPROVE OUTCOMES FOR PATIENTS WITH MULTIPLE SCLEROSIS

- Evidence supports potential of serum neurofilament light (sNfL) as clinically useful biomarker in MS; Biogen and Siemens Healthineers collaborate to develop sNfL blood test
- Real-world data add to the body of evidence establishing the long-term effectiveness of dimethyl fumarate and natalizumab, including in newly diagnosed patients

Stockholm – October 11, 2018 – Through its research initiatives, Biogen Inc. (Nasdaq: BIIB) aims to identify new ways to manage and monitor multiple sclerosis (MS) disease progression and provide physicians with real-world evidence to help inform treatment decisions. Data show serum neurofilament light (sNfL) is a potential biomarker of disease activity and treatment response, and results from MS PATHS (Multiple Sclerosis Partners Advancing Technology and Health Solutions) support the use of technology to broadly monitor for clinically important outcomes, including cognitive changes. New analyses of ongoing studies continue to support the long-term benefits of dimethyl fumarate and natalizumab, particularly when initiating treatment early within the disease course. These findings are being presented at the 34th Congress of the European Committee for Treatment and Research in MS in Berlin, Germany (ECTRIMS; October 10-12).

"Biogen remains committed to investing in MS and pursuing research efforts to advance our understanding of the disease, including aspects that matter most to patients," said Michael Ehlers, executive vice president, research & development at Biogen. "We are generating data that have led to the development of new tools for everyday clinical practice and which inform personalized decisions with the aim of improving patient outcomes."

Biomarker Could Guide MS Treatment Decisions

Biogen is engaged in research to evaluate sNfL, a protein that reflects neuronal damage and is elevated in the blood of people with MS, as a biomarker of disease activity. Results from a retrospective analysis of more than 1,000 patients support the clinical relevance of sNfL levels in the blood to predict disease severity and monitor treatment response in MS patients. Data indicate that sNfL levels above a certain threshold are associated with ongoing disease activity and negative clinical and radiologic outcomes, such as more disability progression and brain atrophy. Researchers

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also found that introducing disease-modifying therapies significantly reduced sNfL levels, and greater reduction was associated with better treatment outcomes.

"There are currently no blood biomarkers for treatment monitoring in MS," said Peter Calabresi, M.D., director of the Division of Neuroimmunology and Neuro-infectious Diseases at the Johns Hopkins University School of Medicine. "These findings confirm sNfL as a clinically useful biomarker to help predict whether a person with MS is likely to have a fast-progressing or milder disease course. They also open the possibility of using a simple blood test to monitor whether a patient is responding to a specific treatment. The strong predictive power of sNfL may ultimately provide physicians with additional information beyond what is currently measured by MRIs to help guide treatment decisions."

Biogen is working to transition these results into a potential resource for clinical practice, and has expanded its collaboration with Siemens Healthineers to develop an sNfL blood test as an additional tool to monitor MS. A highly sensitive, robust and validated assay will allow physicians to measure sNfL levels in the blood of MS patients with the goals of better understanding disease activity and monitoring treatment response.

Real-World Evidence Reinforces Long-Term Effectiveness of Tecfidera and Tysabri

Biogen recognizes the importance of real-world evidence to help guide decisions in clinical practice and optimize patient care. The company continues to evaluate its MS therapies, dimethyl fumarate and natalizumab, to better understand the benefits of using these treatments, including when initiated early within the disease and treatment course.

Results from the ENDORSE study demonstrate that the clinical benefits of dimethyl fumarate in reducing MS relapses and disability progression in newly diagnosed patients were maintained throughout nine years of continuous dimethyl fumarate treatment, with relapse rates remaining stable and more than 90 percent of patients maintaining walking abilities. An analysis from the natalizumab Observational Program (TOP), the largest ongoing, real-world study of natalizumab-treated patients, reinforces the long-term safety and consistent effectiveness of natalizumab over 10 years, especially for patients with minimal or mild disability and those who were previously treated with fewer disease-modifying therapies.

Featured data presentation details:

- Temporal Relationship of Serum Neurofilament Light Levels and Radiological Disease Activity in Patients with Multiple Sclerosis – *Poster P532 – Wednesday, 10 October, 17:00-19:00 CET*
- Serum Neurofilament Light (sNfL) for Disease Prognosis and Treatment Monitoring in Multiple Sclerosis Patients: Is it Ready for Implementation into Clinical Care? – *Platform 5 – Thursday, 11 October, 11:16-11:28 CET*
- Real-world Data from Over 10 years in the TYSABRI® Observational Program: Long-term Safety and Effectiveness of Natalizumab in Relapsing-remitting Multiple Sclerosis Patients – *Poster P908 – Thursday, 11 October, 17:15-19:15 CET*
- Delayed-release Dimethyl Fumarate Demonstrates Sustained Efficacy over Nine Years in Newly Diagnosed Patients with Relapsing-Remitting Multiple Sclerosis – *Poster P920 – Thursday, 11 October, 17:15-19:15 CET*

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

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

Fakta om MS

MS är en kronisk neurologisk sjukdom som ger upphov till inflammationer som angriper det centrala nervsystemet (hjärna och ryggmärg). Sjukdomen är nästan dubbelt så vanlig hos kvinnor som hos män och insjuknandet sker oftast i åldern 20–40 år. I Sverige har omkring 18 000 personer MS och varje år får drygt 1 000 personer diagnosen. I tidiga stadier går sjukdomen oftast i skov, perioder med förvärrade MS-symtom som sedan försvinner helt eller delvis. Senare under sjukdomsprocessen tilltar dock permanenta kroppsliga och kognitiva funktionsnedsättningar.

Om Biogen

Biogen är en pionjär inom neurologisk forskning och gör stora investeringar för att hitta nya behandlingar mot sjukdomar med stora icke tillgodosedda medicinska behov. Vår forskning styrs inte av antalet patienter utan riktar in sig på sjukdomar där det saknas behandling eller där det finns bara ett fåtal behandlingsalternativ.

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