Biogen Data at ECTRIMS 2022 Highlight Innovation in Digital Health Focused on Advancing Treatment and Personalized Care of People Living with MS

October 26, 2022

- Data demonstrate potential of Manual Dexterity Test and Konectom smartphone-based technology in measuring MS disease progression
- Retrospective analysis applying machine learning, artificial intelligence and radiomics identifies brain imaging patterns that may further the understanding of MS disease and lesion heterogeneity
- Two-stage precision medicine models leveraging real-world data from MS PATHS network provide new insights on enabling more individualized predictions of treatment effect

Biogen is working to realize a future where multi-dimensional data are leveraged to better characterize and monitor MS disease progression and to predict therapy response at an individual level,” said Shibeshih Belachew, M.D., Ph.D., Head of Science, Biogen Digital Health. “This year’s ECTRIMS presentations represent our ongoing digital health research and highlight progress in developing advanced measurement methods that aim to enhance drug development and personalized care for better patient outcomes.”

Developing Digital Tools for More Precise MS Disease Measurement

Multiple presentations at ECTRIMS highlight the potential for technology to provide new opportunities in disease measurement through digital health technology tools. A poster investigating the relationship between novel measures from a technology-enabled nine-hole peg test called the Manual Dexterity Test (MDT) included 3,525 patients and 44,394 MDT observations. Results suggest that overall MDT time is a reliable measure that correlates with changes in disability progression and quality of life in MS patients and that a new metric of MDT speed yields superior predictive models of disease progression relative to overall MDT time.

Two additional posters analyzed interim data from the DigiToms study [NCT04756700] evaluating a smartphone-based Cognitive Processing Speed (CPS) Test from Konectom®, a mobile application that is intended to be used as a self-assessment tool to objectively quantify motor and cognitive functions. Data demonstrate that CPS score and response time features are sensitive to cognitive impairment and show discriminative validity between people with MS and healthy participants. A second poster outlines differences in three outcome measures of the CPS test when performed with a fixed reference key versus a dynamic reference key, an important element of test design. MDT and Konectom are currently only used in limited research settings.

Applying Machine Learning, Artificial Intelligence and Radiomics to Generate MS Disease Progression Insights

Three presentations at ECTRIMS feature the most recent research from Biogen’s collaboration with TheraPanacea, which aims to develop computer-aided diagnosis software solutions to accelerate drug development and improve patient care using machine learning (ML), artificial intelligence (AI) and radiomics. One poster demonstrates that machine learning and radiomics may extract more information about the heterogeneity observed in MS lesions than is currently possible from a visual read. Nearly 2,400 MRI scans from the ADVANCE and ASCEND Phase 3 clinical trials were retrospectively analyzed, and clusters of acute MS lesions were identified with specific spatial, geometric, and textural patterns. Two additional posters focus on advancing technical capabilities of conventional MRI by using novel ML-AI-based algorithms for MS lesion segmentation.

Advancing Precision Medicine Models Toward Predicting Individual Treatment Response

The ability to more precisely predict how individuals will respond to treatment is needed to advance personalized care and improve patient outcomes. One poster at ECTRIMS highlights analyses using real-world data from 1,600 patients in the MS PATHS (Partners Advancing Technology and Health Solutions) network. Researchers were able to replicate findings from published two-stage precision medicine models that were applied to clinical trial data, providing proof of concept for this analytical methodology using real-world data. The use of two-stage precision medicine models may eventually offer a pathway for predicting and choosing specific treatments in actual practice based on an individual’s own presentation of disease.

Title and Times of Biogen Digital Health Data Presentations at ECTRIMS:

- Unsupervised Clustering of Acute Multiple Sclerosis Lesions across Spatial, Geometric and Textural Domains – EP0978 – October 26, 8 a.m. CET / 2 a.m. ET
- Moving Beyond the Number of Correct Responses as an Outcome Measure in Symbol-digit Substitution Testing using Konectom Smartphone-based Cognitive Processing Speed Test – EP1159– October 26, 8 a.m. CET / 2 a.m. ET
- Glial Fibrillary Acidic Protein and Multiple Sclerosis Progression Independent of Acute Inflammation – EP1019 – October 26, 8 a.m. CET / 2 a.m. ET
- Machine Learning Parcellation of Multiple Sclerosis Lesions into Texturally Consistent Super-Voxels for Lesion Classification – EP1008 – October 26, 8 a.m. CET / 2 a.m. ET
- Longitudinal Association of Intra-Task Measures Derived from a Technology-Enabled 9-Hole Peg Test with Disease Progression and Quality of Life in Multiple Sclerosis – P093 – October 26, 8 a.m. CET / 2 a.m. ET
• Performance Differences Observed with Fixed Versus Dynamic Reference Keys within Konectom Smartphone-based Cognitive Processing Speed Test – P042 – October 26, 8 a.m. CET / 2 a.m. ET

• Proof of Concept for 2-stage Models of Heterogeneous Treatment Effects Derived from the Real-World MS PATHS Research Network – P372 – October 26, 8 a.m. CET / 2 a.m. ET

• A Novel Deep Learning Algorithm for Multi-Modal Multiple Sclerosis Lesion Segmentation – P227 - October 26, 8 a.m. CET / 2 a.m. ET

• Motion Capture of the Manual Dexterity Test to Categorize Hand Function in Multiple Sclerosis – P499 – October 26, 8 a.m. CET / 2 a.m. ET

• Assessment of Candidate MRI Biomarkers of Ongoing MS Disease in the Absence of Acute Inflammation – P618 – October 26, 8 a.m. CET / 2 a.m. ET

About Biogen Digital Health
Biogen Digital Health is a global unit of Biogen dedicated to pioneering personalized and digital medicine in neuroscience. We aspire to transform patients’ lives by making personalized and digital medicine in neuroscience a reality. Powered by data-science and digital technologies, we drive solutions to advance research, clinical care, and patient empowerment. We believe that now, more than ever, biology and technology should go hand-in-hand to better meet patient needs, while enabling a shift towards more prevention-focused, affordable, and equitable care.

About Biogen
As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological 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, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer’s disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry’s most diversified pipelines in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company’s operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

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 digital tools; 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 Biogen Digital Health and digital tools. 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.