Biogen, Beckman Coulter and Fujirebio to Collaborate on Blood-Based Biomarkers and Test for Tau Pathology in Alzheimer's Disease

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- The collaboration aims to identify and develop accessible, minimally invasive blood-based biomarkers specific for tau pathology in the brain
- These tools have the potential to be used to stratify patients or monitor treatment response for a new generation of future therapies impacting tau pathology in Alzheimer's disease

CAMBRIDGE, Mass. and BREA, Calif. and TOKYO, July 30, 2024 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB), Beckman Coulter, Inc. and Fujirebio announced a collaboration to potentially identify and develop blood-based biomarkers for tau pathology in the brain and to potentially clinically advance and potentially commercialize new tests for tau pathology in Alzheimer's disease (AD). The development of tau-specific blood-based biomarkers that can measure a patient's tau burden could provide critical insights into the underlying pathological processes of AD and may help advance the development of a new generation of therapies impacting tau pathology.

Through this collaboration, the companies will work to identify new blood-based biomarkers and advance known blood-based biomarkers for tau pathology in AD. The collaboration aims to develop and clinically advance new tools that measure brain tau pathology to potentially stratify patients or monitor treatment response in AD clinical trials. The collaboration has the potential to advance tau-specific blood-based biomarkers and diagnostic tools that could be used not only in clinical trials, but also in clinical practice to enable adoption of future therapies impacting tau pathology.

"Stratifying and monitoring patients for tau pathology is a growing need for the next generation of Alzheimer's therapies, such as our pipeline of investigational tau-targeting therapies, including tau-directed ASO," said Jane Grogan, Ph.D., Head of Research at Biogen. "Through this collaboration, we plan to leverage our deep scientific expertise in the development and use of biomarkers, combined with our partners' capabilities in diagnostics, to potentially accelerate the development timeline for blood-based diagnostics that can measure a patient's levels of tau pathology."

"Collaborative efforts between Biogen, Beckman Coulter and Fujirebio combine the strength of leading edge biomarker development with innovative potential treatments focused on the tauopathy aspect of neurodegeneration, driving us closer to effective solutions," said Kathleen Orland, Senior Vice President, General Manager, Chemistry, and Immunoassay for Beckman Coulter Diagnostics. "Ensuring high quality neurological tests are broadly available through our global installed-base of analyzers, this collaboration with Biogen and Fujirebio underscores our commitment to working with leaders in neurodegenerative disease areas to bring fully automated, high throughput, blood-based Alzheimer's disease testing to the millions of patients who suffer from dementia worldwide."

"Blood-based biomarkers for tau pathology could advance the development and implementation of disease-modifying therapies for neurodegenerative disorders such as AD," said Monte Wiltse, President & CEO of Fujirebio Diagnostics, Inc. "This partnership will further help us accelerate our efforts to develop novel neurodegenerative disease diagnostics and deliver them to laboratories and clinicians around the world via our global diagnostics partners, addressing the unmet medical need for blood-based biomarkers."

Under the terms of the collaboration, Biogen will provide Alzheimer's clinical study data and expertise in biomarker research to prioritize markers for tau pathology. Fujirebio and Beckman Coulter will be responsible for providing diagnostic development, manufacturing and commercialization.

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

About Beckman Coulter. Inc.
A global leader in advanced diagnostics, Beckman Coulter has challenged convention to elevate the diagnostic laboratory's role in improving patient health for more than 80 years. Our mission is to Relentlessly Reimagine Healthcare, One Diagnosis at a Time – and we do this by applying the power of science, technology and the passion and creativity of our teams. Our diagnostic solutions are used in complex clinical testing, and are found in hospitals, reference laboratories and physician office settings around the globe. We exist to deliver smarter, faster diagnostic solutions that move the needle forward from what's now to what's next. We do this by accelerating care with an extensive clinical menu, scalable lab automation technologies, insightful clinical informatics, and lab performance services. Headquartered in Brea, Calif., Beckman Coulter has more than 11,000 global team members. 2024-13330.

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About Fujirebio
Fujirebio, a member of H.U. Group Holdings Inc., is a global leader in the field of high-quality in vitro diagnostics (IVD) testing. It has more than 50 years' accumulated experience in the conception, development, production, and worldwide commercialization of robust IVD products. Fujirebio supplies new technology and novel diagnostic markers to the global Diagnostics industry through material supply, contract development and manufacturing.

Fujirebio was the first company to develop and market CSF biomarkers under the Innogenetics brand over 25 years ago. Fujirebio remains the only company with such a comprehensive line-up of manual and fully automated neurodegenerative disease assays and consistently partners with organizations and clinical experts across the world to develop new pathways for earlier, easier and more complete neurodegenerative diagnostic tools. More information can be found at www.fujirebio.com/alzheimer.

Biogen Safe Harbor

This press release contains forward-looking statements, relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; the potential for blood based AD biomarker tests; regulatory discussions, submissions, filings, and approvals; the potential benefits, safety, and efficacy of our and our collaboration with Beckman Coulter Diagnostics and Fujirebio;. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "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.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology failures or breaches; problems with our manufacturing processes; risks relating to management, personnel and other organizational changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media and artificial intelligence based software for our business; results of operations, and financial condition; fluctuations in our operating results; risks related to investment in properties; risks relating to access to capital and credit markets; risks related to indebtedness; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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