Biogen Completes Acquisition of Human Immunology Biosciences

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CAMBRIDGE, Mass., July 02, 2024 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) has completed the acquisition of Human Immunology Biosciences (HI-Bio™), a privately-held clinical-stage biotechnology company focused on targeted therapies for patients with severe immune-mediated diseases (IMDs).

“We are very excited about the addition of felzartamab into our pipeline, further strengthening our presence in immunology with a promising late-stage therapeutic candidate being studied in multiple indications,” said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. “With the transaction now complete, we will begin working together with our colleagues from HI-Bio on plans to advance felzartamab to phase 3 and ultimately deliver innovative treatments to patients with unmet needs across a range of rare diseases.”

“I’m looking forward to the important progress HI-Bio will make as part of Biogen, and the power of combining our talented HI-Bio team with Biogen’s global infrastructure to support the development of felzartamab and accelerate Biogen’s expanding immunology portfolio,” said Travis Murdoch, M.D., CEO of HI-Bio. “It’s clear from our engagement over many months – as we considered how HI-Bio programs could progress in the best possible way – that our teams share many of the same values, including being science-led and execution-focused, and a core mission to positively impact patients with severe diseases.”

Felzartamab demonstrated positive interim results from the Phase 2 IgA nephropathy (IgAN) study and from the completed Phase 2 antibody-mediated rejection (AMR) study. These data were presented at the recent European Renal Association Congress in Stockholm. The AMR study data were also published in the New England Journal of Medicine. Felzartamab has also demonstrated proof-of-concept in a Phase 2 study in primary membranous nephropathy (PMN) and there are plans to advance felzartamab to Phase 3 in AMR, IgAN, and PMN.

About Felzartamab
Felzartamab is an investigational therapeutic human monoclonal antibody directed against CD38, a protein expressed on mature plasma cells. Felzartamab has been shown in clinical studies to selectively deplete CD38+ plasma cells, which may allow applications that ultimately improve clinical outcomes in a broad range of diseases driven by pathogenic antibodies. Felzartamab was originally developed by MorphoSys AG for multiple myeloma. HI-Bio exclusively licensed the rights to develop and commercialize felzartamab across all indications in all countries and territories excluding China (including Macau and Hong Kong and Taiwan).

Felzartamab is an investigational therapeutic candidate that has not yet been approved by any regulatory authority and its safety and effectiveness have not been established.

About Antibody-Mediated Rejection (AMR) in Kidney Transplant Recipients
Antibody-mediated rejection (AMR) is a major cause of kidney transplant failure, with chronic AMR affecting ~12% of patients that receive kidney transplants annually in the U.S.[1] AMR has emerged as the leading cause of late graft loss in kidney transplant recipients. Effective treatment options for chronic AMR are currently limited.[2]

About Primary Membranous Nephropathy (PMN)
Primary membranous nephropathy (PMN) is a rare IMD affecting the kidneys, with an estimated incidence rate of ~1/100K per year in the United States.[3] There are currently no therapies specifically approved for PMN. Standard of care comprises off-label use of a variety of agents, including immunosuppressive therapies like cyclophosphamide, and CD20-targeted B-cell depleting agents such as rituximab.[4] Even with these strategies, approximately one third of patients do not achieve remission.[4]

About IgA Nephropathy (IgAN)
Immunoglobulin A nephropathy (IgAN) is the most common primary glomerulonephritis worldwide. It is a leading cause of chronic kidney disease with up to 40% of IgAN patients progressing to end stage kidney disease about 20 years after diagnosis. IgAN accounts for about 40% of all native-kidney biopsies in Japan, 25% in Europe, 12% in the United States, but less than 5% in central Africa.[5]

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.

Biogen Safe Harbor
This press release contains forward-looking statements, relating to: the anticipated and potential benefits of the acquisition of HI-Bio; including with respect to retention; the potential of, and relating to, the felzartamab program and HI-Bio’s other pipeline programs; expected financing of the proposed acquisition; costs and other anticipated financial impacts of the proposed transaction; our strategy and plans; clinical development programs, clinical trials, and data readouts and presentations; regulatory discussions, submissions, filings, and approvals; the potential benefits, safety, and efficacy of products and investigational therapies; actions to augment our pipeline, collaborations, and business development activities; and our future financial and operating results. 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. All forward-looking statements contained in this press release speak only as of the date made and, except to the extent required by law, we undertake no obligation to publicly update or revise any forward-looking statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: the impact of the announcement and pendency of the acquisition on HI-Bio's business, including on relationships with its employees, business partners and government entities; uncertainties as to the timing and completion of the merger; the risk that required regulatory approval or other condition to closing may not be satisfied; the diversion of management time on transaction-related issues; costs and potential litigation, settlements and investigations relating to the proposed merger; the ability to retain management and other personnel; 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 the acquisition or 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 the ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, or that regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our or HI-Bio's 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.

References:

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