Biogen Bolsters Late-Stage Pipeline, Expands Immunology Portfolio with Agreement to Acquire Human Immunology Biosciences

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- Transaction to include felzartamab, a potential first-in-class therapeutic candidate with promise as a pipeline-in-a-product across a range of immune-mediated diseases
- Felzartamab is an investigational anti-CD38 monoclonal antibody that, through its cell depletion approach, has demonstrated clinical proof of concept in rare immune-mediated indications, with plans to advance to Phase 3
- Proposed acquisition builds on Biogen capabilities in immunology with plans to combine Human Immunology Biosciences expertise in immune-mediated indications with Biogen's global development and commercial experience in rare diseases

CAMBRIDGE, Mass. and SOUTH SAN FRANCISCO, Calif., May 22, 2024 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Human Immunology Biosciences (HI-Bio™), a privately-held clinical-stage biotechnology company focused on targeted therapies for patients with severe immune-mediated diseases (IMDs), today announced the companies have entered into a definitive agreement under which Biogen has agreed to acquire HI-Bio for $1.15 billion upfront and up to $650 million in potential milestone payments.

HI-Bio's lead asset, felzartamab, is a fully human anti-CD38 monoclonal antibody that has been shown in clinical studies to selectively deplete CD38+ cells including plasma cells and natural killer, or NK, cells which may allow for additional applications that improve clinical outcomes in a broad range of immune-mediated diseases.

Felzartamab has received Breakthrough Therapy Designation (BTD) and Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for development in the treatment of primary membranous nephropathy (PMN) and has received ODD in the treatment of antibody-mediated rejection (AMR) in kidney transplant recipients. Phase 2 studies have been completed in PMN and AMR and remain ongoing in IgA nephropathy (IgAN), and HI-Bio has plans to advance each indication to Phase 3. HI-Bio plans to present two abstracts at the upcoming European Renal Association (ERA) Congress in Stockholm, including the complete Phase 2 data from the AMR study in kidney transplant patients and interim data from the Phase 2 IgAN study. Felzartamab has clinical data in AMR, PMN and IgAN indications.

"We believe this late-stage asset, which has demonstrated impact on key biomarkers and clinical endpoints in three renal diseases with serious unmet needs, is a strategic addition to the Biogen portfolio as we continue to augment our pipeline and build on our expertise in immunology," said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. "We look forward to welcoming HI-Bio employees into Biogen and, together, working to advance potential therapies for patients with rare immune diseases with high unmet need."

"With its deep development and commercialization capabilities, Biogen is in a position to accelerate the development of new medicines, including felzartamab, for patients with severe immune-mediated diseases," said Travis Murdoch, M.D., Chief Executive Officer of HI-Bio. "We are excited to combine the HI-Bio team's expertise with Biogen's global footprint."

Biogen plans to leverage its existing global development and commercialization capabilities in rare disease and its strong scientific expertise in immunology to support the advancement of felzartamab and the HI-Bio pipeline. Biogen seeks to retain expertise and talent from HI-Bio and establish a San Francisco Bay Area team focused on expanding our efforts in immune-mediated diseases.

In addition to lead program felzartamab, the HI-Bio pipeline includes izastobart/HIB210, an anti-C5aR1 antibody currently in a Phase 1 trial and with potential for continued development in a range of complement-mediated diseases. HI-Bio also has discovery stage mast cell programs with potential in a range of immune-mediated diseases.

Financial Details and Terms of the Transaction
Under the terms of the agreement, Biogen will make an upfront payment to HI-Bio of $1.15 billion. HI-Bio's stockholders would also be eligible for payments of up to an additional $650 million, for a total potential deal value of up to $1.8 billion, should the felzartamab programs achieve certain development milestones. The acquisition of HI-Bio is not expected to impact Biogen's previously issued 2024 guidance. Biogen expects to finance the acquisition with cash and may also draw on its revolving credit agreement. The transaction is subject to customary closing conditions, including receipt of necessary regulatory approvals and is currently anticipated to close in the third quarter of 2024.

Advisors
Covington & Burling LLP acted as legal advisor to Biogen. Goldman Sachs & Co. LLC and BofA Securities, Inc. acted as financial advisors to HI-Bio and Goodwin Procter LLP acted as its legal advisor.

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.

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
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.

About HI-Bio
Human Immunology Biosciences, Inc. (HI-Bio™), was incubated by ARCH Venture Partners and Monograph Capital to develop precision therapies for immune-mediated diseases and to bring clinical immunology into its next chapter. Inspired by the rise of targeted therapies in clinical oncology, the company pursues a therapeutic strategy of targeting and depleting the immune cell types that drive IMDs. The company's most advanced candidate, felzartamab, is a CD38-targeted antibody shown in clinical studies to deplete CD38+ cells, including plasma and natural killer (NK) cells, which are implicated in a range of indications including antibody-mediated rejection (AMR), IgA nephropathy (IgAN), lupus nephritis (LN) and primary membranous nephropathy (PMN). Other investors include Alpha Wave Global, Arkin Bio Capital, Jeito Capital and Viking Global Investors.

To learn more about HI-Bio, visit www.hibio.com or follow the company on LinkedIn and X.

Biogen Safe Harbor
This press release contains forward-looking statements, relating to: our and HI-Bio's ability to complete the proposed transaction, and the expected timing of such completion; 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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MEDIA CONTACTS:
Biogen
Jack Cox
+ 1 781 464 3260
public.affairs@biogen.com

HI-Bio
Morgan Warners
morgan.warners@fgsglobal.com

Rich Allan
rich.allan@fgsglobal.com

INVESTOR CONTACT:
Biogen
Chuck Triano
+1 781 464 2442
IR@biogen.com