Biogen and Innocare Announce License and Collaboration Agreement For Orelabrutinib, an Innovative CNS Penetrant BTK Inhibitor For the Potential Treatment of Multiple Sclerosis

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- *Orelabrutinib is a Phase 2 oral small molecule Bruton's tyrosine kinase inhibitor with high selectivity and the ability to cross the blood-brain barrier*
- *InnoCare to receive a $125 million upfront payment and is eligible to receive potential development and commercial milestone payments*

CAMBRIDGE, Mass. and BEIJING, July 12, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and InnoCare Pharma Limited (HKEX: 09969) today announced that they have entered into a license and collaboration agreement for orelabrutinib, an oral small molecule Bruton's tyrosine kinase inhibitor (BTKi) for the potential treatment of multiple sclerosis (MS). Orelabrutinib is a covalent BTKi with high selectivity and the ability to cross the blood-brain barrier, and is currently being studied in a multi-country, placebo-controlled Phase 2 trial in relapsing-remitting MS.

Orelabrutinib inhibits BTK, which is a key enzyme that is part of the signaling cascade of immune cells including B cells and myeloid cells. With the ability to cross the blood brain barrier, orelabrutinib has the potential to inhibit B cell and myeloid cell effector functions in the central nervous system (CNS), and may provide a clinically meaningful benefit on progression in all forms of MS. By addressing the progressive biology of the disease, orelabrutinib may offer people living with MS an additional treatment option and the possibility to slow disease progression.

"Given the complex and chronic nature of MS, we believe the unique characteristics of orelabrutinib, combining high selectivity and CNS penetrance, may translate to potential clinical advantages relative to other BTKi programs," said Alfred Sandrock, Jr., M.D., Ph.D., Head of Research and Development at Biogen. "For over 30 years, Biogen has led in MS research and today has a leading portfolio of MS products. We are focused on developing next-generation approaches that we hope will improve outcomes for those living with progressive and relapsing forms of MS."

"Biogen is a recognized leader in neuroscience and we believe this transaction will help advance the development of orelabrutinib in MS," said Jasmine Cui, Ph.D., Co-Founder, Chairwoman and Chief Executive Officer at InnoCare. "We are excited about the potential of orelabrutinib for the treatment of patients with all forms of MS given the potential efficacy and safety profile, plus a promising level of blood-brain barrier penetration. BTK inhibitors may have the potential to transform the treatment paradigm of autoimmune diseases, in particular MS."

Under the terms of the agreement, Biogen will have exclusive rights to orelabrutinib in the field of MS worldwide and certain autoimmune diseases outside of China (including Hong Kong, Macau and Taiwan), while InnoCare will retain exclusive worldwide rights to orelabrutinib in the field of oncology and certain autoimmune diseases in China (including Hong Kong, Macau and Taiwan). InnoCare will receive a $125 million upfront payment and is eligible to receive up to $812.5 million in potential development milestones and potential commercial payments should the collaboration achieve certain development, commercial milestones and sales thresholds. InnoCare is also eligible to receive tiered royalties in the low to high teens on potential future net sales of any product resulting from the collaboration. Closing of the collaboration is contingent on completion of review under antitrust laws, including the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 in the U.S., and other customary closing conditions.

About Orelabrutinib
Orelabrutinib is a small molecule Bruton's tyrosine kinase inhibitor (BTKi) developed for the treatment of cancer and in development for the potential treatment of autoimmune diseases.

In the field of multiple sclerosis, orelabrutinib is a BTKi with high selectivity and ability to cross the blood-brain barrier and could achieve high-target occupancy in the central nervous system. It is currently being investigated in a global Phase 2 study in RRMS patients.

In the field of oncology, InnoCare received approval for orelabrutinib from the China National Medical Products Administration (NMPA) in two indications: the treatment of patients with relapsed/refractory chronic lymphocytic leukemia (R/R CLL)/small lymphocytic lymphoma (R/R SLL), and the treatment of patients with relapsed/refractory mantle cell lymphoma (R/R MCL).

About Bruton's Tyrosine Kinase Inhibitors
Bruton's tyrosine kinase (BTK) is a tyrosine kinase that is encoded by the BTK gene in humans. BTK plays a crucial role in B-cell receptor signaling cascade in B cells leading to B cell proliferation, survival, differentiation and cytokine production. BTK also plays a key function in myeloid cell signaling. Central nervous system (CNS) penetrant BTK small molecule inhibitors work by inhibiting B cells and myeloid cells in the periphery and in the CNS. Among myeloid cells expressing BTK, microglia, which reside in the CNS, have been shown to express high level of BTK in multiple sclerosis.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative 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, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

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.

About InnoCare Pharma
InnoCare Pharma (HKEX:09969) is a commercial-stage biopharmaceutical company committed to discovering, developing, and commercializing first-in-class and/or best-in-class drugs for the treatment of cancer and autoimmune diseases with high unmet medical needs in China and worldwide.

InnoCare was founded in 2015 by Dr. Jasmine Cui, who has extensive experience in new drug development and business management and the world-renowned structural biologist Dr. Yigong Shi. InnoCare has branches in Beijing, Nanjing, Guangzhou, Shanghai, New Jersey and Boston.

InnoCare has strong in-house innovation capabilities, holding multiple foreign and domestic patents with a rich product pipeline targeting liquid tumors, solid tumors, and autoimmune diseases. On March 23, 2020, InnoCare was successfully listed on Hong Kong Stock Exchange.

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 and results that may be achieved through Biogen's proposed collaboration with InnoCare; the anticipated completion of the proposed collaboration; the potential benefit, safety and efficacy of orelabrutinib; the potential clinical effects of orelabrutinib; the clinical development program for orelabrutinib; the potential treatment of MS and other autoimmune diseases; the potential of Biogen's commercial business and pipeline programs; Biogen's strategy and plans; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "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 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, risks that the proposed collaboration will not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed collaboration will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed collaboration can be achieved; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of orelabrutinib, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce 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 Biogen's 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 Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

InnoCare Forward-looking Statements
This news release contains the disclosure of some forward-looking statements. Except for statements of facts, all other statements can be regarded as forward-looking statements, that is, about our or our management's intentions, plans, beliefs, or expectations that will or may occur in the future. Such statements are assumptions and estimates made by our management based on its experience and knowledge of historical trends, current conditions, expected future development and other related factors. This forward-looking statement does not guarantee future performance, and actual results, developments and business decisions may not match the expectations of the forward-looking statement. Our forward-looking statements are also subject to a large number of risks and uncertainties, which may affect our short-term and long-term performance.

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