Jasper Therapeutics Announces Health Canada Clearance of Clinical Trial Application for Phase 1b/2a Study of Briquilimab in Asthma

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REDWOOD CITY, Calif., Sept. 10, 2024 (GLOBE NEWSWIRE) -- Jasper Therapeutics, Inc. (Nasdaq: JSPR) (Jasper), a clinical stage biotechnology company focused on development of briquilimab, a novel antibody therapy targeting c-Kit (CD117) to address mast cell driven diseases such as chronic spontaneous urticaria (CSU), chronic inducible urticaria (CIndU) and asthma, today announced that Health Canada has cleared the Company's Clinical Trial Application (CTA) for a Phase 1b/2a asthma challenge study evaluating briquilimab in asthma.

"We are excited to announce that Health Canada has issued a no objection letter allowing us to move forward with our first clinical trial evaluating briquilimab in asthma, and we look forward to commencing patient enrollment shortly," said Edwin Tucker, M.D., Chief Medical Officer. "Our clinical development plan follows an established and efficient pathway beginning with a challenge study in patients with allergic asthma to enable rapid advancement of the program. We aim to demonstrate proof of concept for the depletion of mast cells with briquilimab as an effective mechanism of action in asthma and to inform potential future studies in the broader asthma population."

The Phase 1b/2a study in asthma is a single dose double-blind, placebo-controlled study that is expected to enroll 30 patients across as many as 10 sites in Canada and the EU with a key objective of demonstrating proof-of-concept in asthma utilizing a therapeutic dose to inform future trials in the broader asthma population. The study will be conducted utilizing a single 180mg dose of subcutaneous briquilimab and key assessments will be both early and late asthmatic response, changes in airway hyperresponsiveness, mast cell depletion and recovery and safety. Jasper expects to commence dosing patients in the fourth quarter of 2024 and to report initial data in the second half of 2025.

"Clearance of the CTA for the asthma study is an important milestone for Jasper as we continue to build out our pipeline of programs evaluating briquilimab in mast cell driven diseases," said Ronald Martell, President and Chief Executive Officer of Jasper. "Being able to move directly to a 180mg dose in this study as a result of the dose escalation in the BEACON study is an excellent outcome as we believe that driving deep depletion of mast cells in the airways with a higher dose of briquilimab will be key to demonstrating durable clinical benefit in asthma patients."

Trademark Allowed for Jasper c-Kit Mouse ™Model

Jasper also announced that a registered trademark has been allowed by the U.S. Patent and Trademark Office for the proprietary Jasper c-Kit Mouse™ model. The Jasper c-Kit Mouse™ model was developed to enable direct testing of c-Kit inhibitors across numerous diseases, overcoming the limitations of standard models which do not bind antibodies directed at the human c-Kit receptor.

"We are pleased that the U.S. Patent and Trademark Office has allowed registration of a trademark for the Jasper c-Kit Mouse™ model," said Wendy Pang, M.D., Ph.D., Senior Vice President, Research and Translational Medicine. "Briquilimab was shown to reduce asthmatic response to allergen in the Jasper c-Kit Mouse™ model, supporting the launch of our clinical program in asthma. We believe that our ability to conduct preclinical studies with superior clinical translatability via the Jasper c-Kit Mouse™ model provides a strategic advantage as we continue to expand development into additional indications."

About Briquilimab

Briquilimab (formerly JSP191) is a targeted aglycosylated monoclonal antibody that blocks stem cell factor from binding to the cell-surface receptor c-Kit, also known as CD117, thereby inhibiting signaling through the receptor. This inhibition disrupts the critical survival signal, leading to the depletion of the mast cells via apoptosis which removes the underlying source of the inflammatory response in mast cell driven diseases such as chronic urticaria. Jasper is currently conducting clinical studies of briquilimab as a treatment in patients with CSU or with CIndU and is planning to initiate a clinical study in patients with asthma. Briquilimab is also currently in clinical studies as a treatment for patients with LR-MDS and as a conditioning agent for cell therapies for rare diseases. To date, briquilimab has a demonstrated efficacy and safety profile in more than 145 dosed participants and healthy volunteers, with clinical outcomes as a conditioning agent in severe combined immunodeficiency (SCID), acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), Fanconi anemia (FA), and sickle cell disease (SCD).

About Jasper

Jasper is a clinical-stage biotechnology company developing briquilimab, a monoclonal antibody targeting c-Kit (CD117) as a therapeutic for chronic mast and stem cell diseases such as chronic urticaria, asthma and lower to intermediate risk MDS and as a conditioning agent for stem cell transplants for rare diseases such as SCD, FA and SCID. To date, briquilimab has a demonstrated efficacy and safety profile in more than 145 dosed participants and healthy volunteers, with clinical outcomes as a conditioning agent in SCID, AML, MDS, FA, and SCD. For more information, please visit us at www.jaspertherapeutics.com.

Forward-Looking Statements

Certain statements included in this press release that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are sometimes accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding briquilimab's potential, including with respect to its potential in mast cell driven diseases such as CSU, CIndU, and asthma, the potential for the depletion of mast cells with briquilimab to be an effective mechanism of action in asthma and its potential durable clinical benefits; Jasper's expectations regarding the Phase 1b/2a asthma challenge study evaluating briquilimab in

asthma, including protocols and expected patient enrollment and timing thereof, expected site locations, expected key objectives, expected timing to commence dosing and expected timing to report initial data; and Jasper's expectations regarding building out its pipeline of programs evaluating briquilimab in mast cell driven diseases. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of Jasper and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, an assurance, a prediction or a definitive statement of fact or probability. Many actual events and circumstances are beyond the control of Jasper. These forward-looking statements are subject to a number of risks and uncertainties, including general economic, political and business conditions; the risk that the potential product candidates that Jasper develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; the risk that clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release; the risk that Jasper will be unable to successfully market or gain market acceptance of its product candidates; the risk that prior study results may not be replicated; the risk that Jasper's product candidates may not be beneficial to patients or successfully commercialized; patients' willingness to try new therapies and the willingness of physicians to prescribe these therapies; the effects of competition on Jasper's business; the risk that third parties on which Jasper depends for laboratory, clinical development, manufacturing and other critical services will fail to perform satisfactorily; the risk that Jasper's business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of health epidemics; the risk that Jasper will be unable to obtain and maintain sufficient intellectual property protection for its investigational products or will infringe the intellectual property protection of others; and other risks and uncertainties indicated from time to time in Jasper's filings with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q. If any of these risks materialize or Jasper's assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. While Jasper may elect to update these forward-looking statements at some point in the future, Jasper specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Jasper's assessments of any date subsequent to the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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