Jasper Therapeutics Announces IND Clearance for Phase 1b/2a Study of Subcutaneous Briquilimab in Chronic Spontaneous Urticaria

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First Patient Expected to be Dosed by Year-end 2023; Early Data Expected by Mid-2024

Clinical Study in Chronic Inducible Urticaria Planned to Commence in Early 2024

REDWOOD CITY, Calif., Oct. 09, 2023 (GLOBE NEWSWIRE) -- Jasper Therapeutics, Inc. (Nasdaq: JSPR) (Jasper), a biotechnology company focused on the development of briquilimab, a novel antibody therapy targeting c-Kit (CD117) to address mast cell driven diseases such as chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU), as well as lower to intermediate risk myelodysplastic syndromes (LR-MDS) and novel stem cell transplant conditioning regimens, today announced that its investigational new drug (IND) application for a Phase 1b/2a repeat dose clinical study of subcutaneous briquilimab in the treatment of CSU has been cleared by the U.S. Food and Drug Administration (FDA).

“We’re very excited to be advancing briquilimab into clinical studies for chronic urticaria patients,” said Edwin Tucker, Chief Medical Officer of Jasper. “The clearance to proceed by the FDA for our IND allows us to move quickly to commence our CSU study in patients who are ineligible for, or refractory to, omalizumab, which is a patient population of high unmet need. We expect this dose escalation study to provide proof of concept for the depletion of mast cells by briquilimab as a differentiated mechanism of action in CSU and to help identify optimal doses and dosing regimens for future registrational studies in the broader CSU patient population.”

The Phase 1b/2a study in CSU is a dose escalation study evaluating repeat doses of subcutaneous briquilimab in adult CSU patients who remain symptomatic after treatment with, or who cannot tolerate omalizumab. The study is expected to enroll approximately 40 patients across 6 cohorts and the primary endpoints will be safety and tolerability of briquilimab with secondary endpoints focused on efficacy measures and pharmacokinetics. The study will be conducted at sites in the US and EU and Jasper is expecting to enroll the first patient by the end of 2023 and to be able to report data from early cohorts by mid-2024.

“Clearance of the IND for the CSU study is a critical milestone for Jasper, which represents the first step in building out our pipeline with a focus on treating mast cell diseases with briquilimab,” said Ronald Martell, President and Chief Executive Officer of Jasper. “In parallel with our preparations for the CSU study, the team was also developing a proof of concept study in CIndU to further expand our mast cell franchise. A clinical trial application for the CIndU study has now been filed with the European Medicines Agency and we expect to commence the study in the first quarter of 2024, with an initial data read out targeted as early as year-end 2024.”

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 disease such as chronic urticaria. Jasper intends to start clinical studies of briquilimab as a primary treatment in Chronic Spontaneous Urticaria as well as in Chronic Inducible Urticaria. Briquilimab is also currently in clinical studies as a treatment for patients with Low to Intermediate Risk myelodysplastic syndromes (MDS) and as a conditioning agent for cell and gene 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), 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 and lower to intermediate risk myelodysplastic syndromes (MDS) and as a conditioning agent for stem cell transplants for rare diseases such as sickle cell disease (SCD), Fanconi anemia (FA) and severe combined immunodeficiency (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, acute myeloid leukemia (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, the development of briquilimab for CSU, LR-MDS and stem cell transplant conditioning; the Phase 1b/2a repeat dose clinical study of subcutaneous briquilimab in the treatment of CSU, including the expected number of patients to be dosed, the cohorts, the site locations and the primary and secondary endpoints; Jasper’s expectations regarding the results of the study, including the potential to provide proof of concept and help identify optimal doses and dosing regimens for future registrational studies; Jasper’s plans to commence a proof of concept study in CIndU, including the expected timing for commencing the study and the expected timing for the initial data read out; briquilimab’s further development and the strategic direction for briquilimab. 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 studies or 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, 2022 and any 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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