Jasper Therapeutics Highlights Recent Accomplishments and Key Upcoming Milestones

January 5, 2024

- EU Clinical Trials authorized for Phase 1b/2a SPOTLIGHT and BEACON studies of briquilimab in CIndU and CSU, respectively

- Patient enrollment in Phase 1b/2a SPOTLIGHT study of briquilimab in CIndU expected to commence in first quarter of 2024, initial data readout in second half of 2024

- Initial data from Phase 1b/2a BEACON study in CSU expected in mid-2024

REDWOOD CITY, Calif., Jan. 05, 2024 (GLOBE NEWSWIRE) -- Jasper Therapeutics, Inc. (Nasdaq: JSPR) (Jasper), a biotechnology company focused on development of briquilimab, a novel antibody therapy targeting c-Kit (CD117) in 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 its recent accomplishments, including the authorization by the European Medicines Agency (EMA) of the Company's Clinical Trial Applications (CTA) for its Phase 1b/2a trials of briquilimab in CIndU and CSU, and outlined its corporate priorities and anticipated milestones for 2024. Called SPOTLIGHT – "**S**tudy (**P**hase 1b/2a) **O**f subcu**T**aneous br**I**quilimab in patients dia**G**nosed with c**H**ronic inducible ur**T**icaria" – the CIndU study will evaluate single doses of subcutaneous briquilimab in adult patients with cold urticaria or symptomatic dermographism.

"2023 was a strategically important year for Jasper," said Ronald Martell, President and Chief Executive Officer of Jasper. "We secured IND clearance and CTA authorization for the Phase 1b/2a BEACON study of briquilimab in CSU and successfully dosed the first patient. Additionally, we reported positive data from the Phase 1/2 trial of briquilimab in patients with Fanconi Anemia (FA) along with the final Phase 1 results in patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS) undergoing hematopoietic cell transplant, initiated the LR-MDS Phase 1b trial, and strengthened our leadership team.

Our achievements in 2023 set the stage for a transformational year ahead with multiple key clinical milestones on the horizon across multiple indications. Specifically, we expect to present initial data from the Phase 1b/2a BEACON study in mid-2024, which will provide valuable insight into the therapeutic potential of briquilimab. We also anticipate initiating our Phase 1b/2a SPOTLIGHT study in CIndU following our recently obtained CTA authorization from the EMA, with initial data expected in the second half of the year. Finally, we expect to present data from our Phase 1b LR-MDS study in the first half of 2024."

Key Recent and Upcoming Milestones

- Obtained IND clearance and CTA authorization for initiation of its Phase 1b/2a BEACON study of subcutaneous briquilimab in CSU. The BEACON study is a dose escalation trial evaluating repeat doses of subcutaneous briquilimab in adult CSU patients who remain symptomatic after treatment with, or who cannot tolerate, omalizumab, and is currently enrolling approximately 40 patients at sites in the US and EU. Jasper expects to report initial data on multiple cohorts from the study of briquilimab in CSU in mid-2024.
- Obtained CTA authorization for initiation of its Phase 1b/2a SPOTLIGHT study of subcutaneous briquilimab in CIndU. The SPOTLIGHT study is evaluating single doses of subcutaneous briquilimab in adult CIndU patients and is expected to enroll approximately 15 patients at sites in the EU. Patient enrollment is expected to commence in early 2024 and initial data is expected in the second half of 2024.
- Hosted a key opinion leader webinar on the potential of briquilimab as a therapeutic in chronic urticaria, as well as the current treatment landscape and unmet medical needs for patients with CSU. A replay of the webinar is available at this link.
- Initiated a Phase 1 trial of briquilimab as second-line therapy in subjects with LR-MDS. Data readout from the Phase 1 trial evaluating the safety and tolerability of briquilimab as a second-line therapy in subjects with LR-MDS is anticipated in the first half of 2024.
- Presented positive final results from the Phase 1 study of briquilimab in combination with fludarabine and low-dose irradiation (Flu/TBI) conditioning in older adults with AML in complete remission (CR) or MDS undergoing allogeneic hematopoietic cell transplant at the *America Society of Hematology (ASH) 2023 Annual Meeting.*
- Announced European Union Orphan Drug Designation for briquilimab as a conditioning treatment for patients prior to receiving a stem cell transplant.
- Strengthened the organization with key leadership appointments including Thomas Wiggans as Chairperson of the Board of Directors, Scott Brun, M.D. as a Director, Herb Cross as Chief Financial Officer, Edwin J. Tucker, M.D. as Chief Medical Officer, and Patricia Carlos as SVP, Regulatory Affairs & Quality.

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. Briquilimab is also currently in clinical studies as a treatment for patients with LR-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), AML, MDS, 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 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 LR-MDS, as well as novel stem cell transplant conditioning regimens and its potential as an important treatment option for patients suffering from CSU and CIndU; Jasper's expectations regarding its Phase 1b/2a study of briquilimab in CSU, including the number of patients to be dosed, the site locations, expected enrollment and expected timing for reporting initial data; Jasper's expectations regarding its Phase 1b/2a study of briquilimab in CIndU, including the expected timing of initiating the study, expected timing of patient enrollment, expected timing for reporting initial data, the number of patients to be dosed and site locations; Jasper's expectations regarding timing of data readout for its Phase 1 trial of briquilimab as second-line therapy in subjects with LR-MDS; and Jasper's expectations regarding the advancement of its briquilimab programs across a range of indications. 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, 2022 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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