



Jasper Therapeutics Reports Positive Data from SPOTLIGHT Study of Briquilimab in Chronic Inducible Urticaria

October 14, 2024

14 of 15 participants enrolled achieved a clinical response

10 of 12 participants in the 120mg cohort achieved a complete response

No serious adverse events; no grade 3 or higher adverse events reported

Initial data from BEACON study expected week of January 6th, 2025, including 180mg Q8W cohort

Company to host conference call and webinar today at 8:00 a.m. EDT

REDWOOD CITY, Calif., Oct. 14, 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 reported preliminary data from the Company's ongoing SPOTLIGHT Phase 1b/2a study of subcutaneous briquilimab in adult participants with cold urticaria (ColdU) or symptomatic dermographism (SD), the two most prevalent sub types of CIndU. 14 of 15 participants (93%) enrolled in both dose cohorts of the study (n=15) achieved a clinical response within the 6-week preliminary analysis period following administration. In the 120mg dose cohort, 10 of 12 participants (83%) experienced a complete response (CR), and 1 participant experienced a partial response (PR). Briquilimab was well tolerated in the study, with no serious adverse events (SAEs) and no grade 3 or higher adverse events (AEs) reported. In alignment with the Company's clinical development plan, Jasper has obtained regulatory clearance to enroll a 180mg dose cohort (n=12) in the SPOTLIGHT study. Jasper expects to present full data from the SPOTLIGHT study in the first half of 2025.

Jasper also announced that it expects to report initial data from all cohorts of the BEACON study in CSU during the week of January 6th, 2025, including the recently added 180mg Q8W dose cohort.

"We are very excited to report positive data from the SPOTLIGHT study, our first readout from a clinical trial evaluating briquilimab in chronic urticaria, with briquilimab driving rapid complete responses in over 80% of CIndU patients enrolled in the 120mg cohort," said Ronald Martell, President and Chief Executive Officer of Jasper. "In addition to the responses observed, we are pleased that briquilimab was well tolerated in the study. These results demonstrate the ability of briquilimab to support optimal biologic dosing by rapidly delivering robust and durable clinical benefit along with a potentially differentiated safety profile. Additionally, we look forward to presenting initial data from all cohorts of the BEACON study in CSU in early January of next year. On behalf of the entire Jasper team, I'd like to thank both the investigators and the patients who participated in both studies, along with their families and caregivers."

SPOTLIGHT Study Design and Data Summary:

The SPOTLIGHT study is a Phase 1b/2a open label clinical trial evaluating a single dose of subcutaneous briquilimab in adult patients with ColdU or SD who are refractory to antihistamines. The study will enroll 27 patients across three dose cohorts, 40mg (n=3), 120mg (n=12), and 180mg (n=12). The primary endpoints are safety and tolerability of briquilimab and secondary endpoints are focused on clinical activity and PK/PD, including measurement of serum tryptase and mast cells in skin. To assess clinical activity, participants' symptoms are induced via provocation testing prior to dosing with briquilimab and at defined time points through 12 weeks post-dosing.

As of the data cut date of October 10th, 2024, 15 participants have been enrolled in the study and received a single dose of subcutaneous briquilimab (n=3 at 40mg, n=12 at 120mg), with all participants having at least 6 weeks of follow-up post-dosing. 12 participants (n=4 ColdU, n=8 SD) were enrolled in the 120mg dose cohort. Participants had high disease burden as assessed by provocation threshold testing. In the 120mg cohort, mean baseline TempTest® threshold was 20.8°C (range: 15-27°C) for ColdU patients, and mean baseline FricTest® threshold was 3.9 of 4 (range: 3-4) for SD patients.

14 of 15 participants (93%) enrolled in both dose cohorts of the study (n=15) achieved a clinical response to provocation testing within the 6-week preliminary analysis period following treatment. 10 of 12 participants (83%) treated in the 120mg cohort achieved a CR with either their critical temperature threshold improving to at least 4°C for ColdU patients or their FricTest® score improving to 0 for SD patients, and 1 of 12 participants enrolled in the 120mg cohort achieved a PR as their best response. 1 of 3 participants treated in the 40mg cohort achieved a CR and the other two participants achieved a PR as their best response. Complete responses in TempTest® or FricTest® were observed as early as 1 week following dosing. All patients will continue to be assessed for response through week 12, and Jasper expects to present full study results, including the 180mg cohort, in the first half of 2025.

Mean baseline serum tryptase for participants in the 120mg cohort was 7.6 ng/ml (range: 3.6-25.7 ng/ml). Significant reductions in tryptase were observed as early as the week 1 assessment and were correlated with the onset of clinical responses. The greatest reduction in mean tryptase of 66% was observed at 2 weeks following treatment in the 120mg cohort. At the week 6 assessment, mean tryptase reduction observed was 31% below baseline and 7 of 12 participants (58%) enrolled in the 120mg cohort continued to maintain a clinical response (CR=6, PR=1).

Briquilimab was well tolerated in the study. No SAEs or AEs grade 3 were reported. Furthermore, there were no reported AEs related to hair or skin color changes, hypersensitivity, or anemia. Mild decreases in neutrophil counts were observed, with no participants experiencing neutrophil counts below 1500.

"It is very exciting to see initial clinical data showing that treatment with briquilimab can lead to deep clinical benefit shortly after administration, particularly given the difficult-to-treat patient population in antihistamine refractory CIndU," said Martin Metz, M.D., Professor of Dermatology and Allergy Charité – Universitätsmedizin Berlin. "I am also encouraged by the safety and tolerability profile observed in the SPOTLIGHT study thus far, particularly the lack of hypopigmentation or hair color changes. Patients with CIndU currently have very few treatment options, and I look forward to continuing to support the development of briquilimab in chronic urticarias."

Conference Call / Webinar

Jasper will host a conference call and webinar today at 8:00 a.m. EDT. A live question and answer session with management will follow the formal presentations. A link to the webinar, including presentation slides, can be found [here](#). To access the live conference call via phone, dial 1-844-826-3033 or 1-412-317-5185, or click [here](#).

The presentation slides and a link to the live and archived webcast will also be available on the [Events & News – Events](#) page of Jasper's Investor Relations website.

About Briquilimab

Briquilimab 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 initiating 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 160 dosed participants and healthy volunteers, with clinical outcomes in CIndU, and 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 160 dosed participants and healthy volunteers, with clinical outcomes in CIndU and 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 and its potential to support optimal biologic dosing by rapidly delivering robust and durable clinical benefit along with a potentially differentiated safety profile; the expected number of participants in the SPOTLIGHT study; Jasper's expected timing for presenting full study results for all cohorts of the SPOTLIGHT study; and Jasper's expected timing for presenting initial data from all cohorts of the BEACON study. 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 prior test, study and trial results, including preliminary results for the SPOTLIGHT study reported in this press release, may not be replicated in continuing or future studies and trials; 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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