Jasper Therapeutics Reports Clinical Data Update from Briquilimab Studies in Chronic Spontaneous Urticaria

July 7, 2025

8 of 9 participants (89%) treated in the 240mg and 360mg single dose cohorts achieved a complete response

8 of 11 participants (73%) enrolled in the 180mg Q8W open label extension study achieved a complete response at 12 weeks

Results from the 240mg Q8W and the 240mg followed by 180mg Q8W cohorts appear to be confounded by issues with one drug product lot

ETESIAN study in asthma to be stopped due to same drug product lot issue

No grade 3 or higher treatment related adverse events reported

Company to host conference call and webinar today, Monday, July 7, at 8:30 a.m. EDT

REDWOOD CITY, Calif., July 07, 2025 (GLOBE NEWSWIRE) -- Jasper Therapeutics, Inc. (Nasdaq: JSPR) (Jasper), a clinical stage biotechnology company focused on development of briquilimab, a novel antibody therapy targeting KIT (CD117) to address mast cell driven diseases such as chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU), is reporting updated data from Company's BEACON Phase 1b/2a study of subcutaneous briquilimab in adult participants with CSU and providing an update on the program. Briquilimab administration resulted in deep and rapid disease control in the 240mg and 360mg single-dose cohorts, with 8 of 9 (89%) of participants enrolled across both cohorts achieving a complete response, and with 7 of 9 (78%) achieving a clinical response by week 2. In addition, BEACON participants who rolled over into the open-label extension study dosing at 180mg Q8W demonstrated robust clinical efficacy with 8 of 11 (73%) participants achieving a complete response at 12 weeks.

Results from the 240mg Q8W and the 240mg followed by 180mg Q8W dose cohorts appear to be confounded by an issue with one drug product lot used in those cohorts, with 10 of the 13 patients dosed with drug from the lot in question. The Company is investigating the drug product lot in question and expects to have the results of that investigation in the coming weeks. Key observations noted in those 10 patients were lower than expected drops in mean tryptase levels and no discernable impact on UAS7 scores. The 2 participants enrolled in the cohorts that have been confirmed as being dosed with drug product from a different lot both achieved complete response.

New drug product is being provided to clinical sites to transition the 10 patients who were initially dosed with drug from the lot in question to drug product for their next administration that has demonstrated efficacy in earlier and ongoing cohorts. The Company also plans to enroll an additional 10-12 patients in total across the 240mg Q8W and the 240mg followed by 180mg Q8W cohorts to ensure a robust data set to inform the Phase 2b CSU study. Data from the additional BEACON patients is expected in 4Q 2025 and commencement of the Phase 2b study is now expected in mid-2026.

The Company has also determined that the drug product lot in question was used to treat participants enrolled in the ETESIAN trial evaluating briquilimab in asthma. As a result, and in order to focus resources on advancing briquilimab in CSU, the Company is halting the study and pausing development in asthma. In addition, the Company is halting development in SCID and will be implementing a number of other cost cutting measures, including a potential restructuring, to extend runway and reduce expenses.

"We were pleased that results from the 240mg and 360mg single dose cohorts continue to indicate that briquilimab treatment can lead to deep and durable disease control in patients with CSU," said Ronald Martell, President and Chief Executive Officer of Jasper. "We are also very excited by the performance of the 180mg Q8W dose in the open label extension study with the strong efficacy observed, in combination with the encouraging safety data, supporting a differentiated profile. While we are very disappointed by the confounded results seen in the two multi-dose cohorts of the BEACON study, we are currently investigating the cause and are taking steps to ensure that drug product from the lot in question is returned to the Company and that sites have drug product from other lots to continue dosing. We plan to enroll an additional 10-12 patients across the two impacted cohorts to inform final dose selection for the Phase 2b study, and will be implementing a number of cost cutting measures to reduce burn and extend our cash runway in light of this delay."

BEACON and Open-Label Extension Study Design and Data Summary:

The BEACON study is a randomized, double-blind, and placebo-controlled Phase 1b/2a trial evaluating multiple ascending doses of subcutaneous briquilimab as a therapy for adult patients with moderate to severe CSU despite treatment with high dose antihistamines. 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. Primary measurements used to assess clinical activity were the sum of the Hives Severity Score and the daily Itch Severity Score (ISS), as measured via the Urticaria Activity Score over 7 days (UAS7) on a 0 to 42-point scale.

The open-label extension study in chronic urticarias is enrolling participants from the BEACON study as well as the SPOTLIGHT study in CIndU upon completion of their initial follow up period. Participants in the open-label extension are treated with 180mg of briquilimab on a Q8W dosing schedule.

The updated data, as of July 3, 2025, includes the results from 20 additional patients treated with briquilimab in the BEACON study, including 2 additional participants at 240mg single dose (in addition to 3 previously enrolled participants), 6 at 240mg Q8W, 7 at 240mg followed by 180mg Q8W, and 5 at 360mg single dose (N=4 evaluable for efficacy), as well as from 11 participants enrolled in the open label extension study at 180mg Q8W, all of whom completed at least 12 weeks of follow-up following initial dosing with investigational product.

Substantial reductions in UAS7 scores were reported with a mean change from baseline at 4 weeks of 28.3 points in the 240mg single-dose cohort and 22.9 points in the 360mg single-dose cohort. Complete responses (UAS7 = 0) were achieved by 5 of 5 (100%) of participants treated in the 240mg single-dose cohort and 3 of 4 (75%) participants treated in the 360mg single dose cohort and 7 of 9 (78%) maintained well controlled disease through 8 weeks.

Briquilimab treatment also resulted in deep and durable disease control in the open label extension study evaluating briquilimab at 180mg Q8W, with 8 of 11 participants (73%) achieving complete response at the week 12 assessment.

Substantial reductions in tryptase were observed as early as the week 1 assessment and were correlated with the onset of clinical responses. Tryptase levels below the lower limit of quantification were reported for 8 of 10 (80%) participants across the 240mg and 360mg single dose cohorts.

Briquilimab continued to be well tolerated in the BEACON study, as well as the open label extension, with no dose limiting toxicities observed. Safety observations potentially related to KIT blockade were infrequent and generally limited to low grade events, none of which resulted in discontinuations or dose delays and the majority of which resolved during repeat dosing. Mild and predictable decreases in neutrophil counts were observed upon dosing, with counts generally recovering prior to subsequent dose and no association to fever or infection. All cases of neutrophil count reduction observed in the 240mg and 360mg single dose cohorts resolved while on study with a median time to resolution of 42 days.

Conference Call / Webinar

Jasper will host a conference call and webinar on Monday, July 7, 2025, at 8:30 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 844-826-3033 from the US or 412-317-5185 from outside the US, or click here. The conference ID is 10201355, and the conference call passcode is 6702622.

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

About Jasper

Jasper is a clinical-stage biotechnology company focused on developing briquilimab as a therapeutic for chronic mast cell diseases. Briquilimab is a targeted aglycosylated monoclonal antibody that blocks stem cell factor from binding to the cell-surface receptor KIT, 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 and asthma. Jasper is currently conducting clinical studies of briquilimab as a treatment in patients with CSU and CIndU. Briquilimab has a demonstrated efficacy and safety profile in patients and healthy volunteers, with positive clinical outcomes in CSU and CIndU. For more information, please visit us at www.jaspertx.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 that briquilimab treatment can lead to deep and durable disease control in patients with CSU; Jasper's planned investigation of drug product lot and expected timing for the results of such investigation; the expected provision of new drug product to transition patients who were initially dosed with drug from the lot in question and the expected results of any such transition; Jasper's plans to enroll additional patients in the 240mg Q8W and the 240mg followed by 180mg Q8W cohorts and the expected number of patients to be enrolled in such cohorts; the expected timing of announcing data from additional BEACON study patients and the expected timing for commencing any Phase 2b study; potential cost cutting measures that may be implemented, including a potential restructuring, and the potential effects thereof, including on Jasper's cash runway and expenses; and briquilimab's safety profile. 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 may not be replicated in continuing or future studies and trials; the risk that Jasper's investigation into the drug product lot may be inconclusive or may not lead to the anticipated conclusion; the risk that Jasper may be unable to raise capital to continue its operations and continue the BEACON study; 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, 2024 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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