Jasper Therapeutics Reports Positive Data from BEACON Study of Briquilimab in Chronic Spontaneous Urticaria

January 8, 2025

Rapid onset of deep and durable clinical responses observed across multiple dosing cohorts with a favorable safety profile

Mean change in UAS7 from baseline of -26.6 observed in the 240mg single dose cohort at 8 weeks, multiple dosing regimens ≥120mg demonstrated UAS7 change of more than -25 points

100% (N=3) Complete Responses (UAS7 = 0) observed in the 240mg single dose cohort at 8 weeks and 66% maintained Well Controlled disease at 12 weeks

Serum tryptase reductions below the lower limit of quantification observed at multiple dose levels

Data supports commencement of CSU registrational program expected to commence second half of 2025

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

REDWOOD CITY, Calif., Jan. 08, 2025 (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 positive preliminary data from Jasper's ongoing BEACON Phase 1b/2a study of subcutaneous briquilimab in adult participants with CSU. Substantial reductions in UAS7 were reported, with a mean change from baseline at 8 weeks of -26.6 in the 240mg single-dose cohort and multiple dosing regimens at or above 120mg demonstrating UAS7 changes of more than -25 points. Clinical responses were observed as early as 1-week post-first dose, and Complete Responses (UAS7 = 0) were achieved by patients at each therapeutic dose level (80mg, 120mg, 180mg and 240mg), most notably, all patients in the 240mg single-dose cohort (N=3) maintained Complete Responses through the 8-week time-point. Durability of response was generally dose dependent and reductions in serum tryptase to levels below the lower limit of quantification were observed at multiple dose levels. Briquilimab was well tolerated in the study with a favorable safety profile.

"I am excited to see the preliminary clinical data which demonstrated that treatment with briquilimab led to rapid and durable symptom control in patients with CSU, especially given the omalizumab-experienced population enrolled in the BEACON study," said Thomas B. Casale, M.D., Professor of Medicine and Pediatrics, University of South Florida Morsani College of Medicine. "I am also very encouraged by the safety and tolerability profile observed thus far in both the BEACON and SPOTLIGHT studies. I believe these data support advancing briquilimab into a registrational program following the completion of BEACON, and I look forward to participating in additional studies of briquilimab in chronic urticaria."

"We are very pleased to present the positive preliminary data from the BEACON study, which demonstrates the potential of briquilimab as a leading therapeutic for CSU patients," said Edwin Tucker, Chief Medical Officer of Jasper. "The profound reduction in UAS7 from baseline in multiple cohorts, the dose dependent durability of response and the significant and prolonged drops in mean serum tryptase from baseline demonstrate the potential for deep and durable efficacy of briquilimab in CSU. Combined with the favorable safety profile enabled by our optimal biologic dosing approach, we believe briquilimab has demonstrated the potential to be a leading therapeutic option for patients with CSU. On behalf of the entire Jasper team, I'd like to thank the investigators and the patients who are participating in the study, along with their families and caregivers."

BEACON 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 treatment for adult patients with moderate to severe CSU despite high dose antihistamines and treatment with, or who cannot tolerate, omalizumab. 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 preliminary data, as of December 31, 2024, include the results from 49 participants (N=3 at 10mg, N=3 at 40mg, N=6 at 80mg, N=8 at 120mg, N=14 at 180mg, N=3 at 240mg, and N=12 placebo) who completed at least 12 weeks of follow-up following initial dosing with investigational product. Participants had high disease burden as assessed by UAS7 score with mean baseline score of 27.9 in the 120mg dose group, 25.9 in the 180mg dose group, 26.6 in the 240mg dose group, and 28.6 in the placebo group.

Substantial reductions in UAS7 score were reported with multiple dosing regimens at or above 120mg demonstrating mean change from baseline of greater than -25 points at 12 weeks, as well as a mean change from baseline at 8 weeks of -26.6 points in the 240mg single-dose cohort. Complete responses (UAS7 = 0) were achieved by patients treated at each therapeutic dose level (80mg, 120mg, 180mg and 240mg), and all patients in the 240mg single-dose cohort (N=3) maintained Complete Responses through the 8-week time-point. In general, clinical responses following first dose at the 120mg and 180mg dose levels showed durability out to 4-6 weeks, while clinical responses at the 240mg level showed durability out to 8-12 weeks. These data demonstrate that treatment with briquilimab leads to rapid onset of durable and dose-dependent symptom control in patients with CSU.

Single-Dose Clinical Activity Assessments Summary at Week 8

	240 mg Single-Dose	Placebo

	(N=3)	(N=12)
UAS7 Changes		
Baseline mean UAS7 (SD)	26.6 (10.9)	28.6 (9.4)
Mean change at Week 8	-26.6	-12.4
Mean difference from placebo	-14.2	-
Clinical Responses		
UAS7≤6 (Well Controlled)	100%	25%
UAS7=0 (Complete Response)	100%	17%

Q8W Dose Clinical Activity Assessments Summary at Week 12

	80mg Q8W (N=6)	120 mg Q8W (N=4)	180mg Q8W (N=7)	Placebo (N=12)
UAS7 Changes				
Baseline mean UAS7 (SD)	31.0 (7.9)	27.0 (7.5)	26.5 (8.0)	28.6 (9.4)
Mean change at Week 12	-9.3	-27.2	-13.2	-9.2
Mean difference from placebo	-0.1	-18.0	-4.0	-
Clinical Responses				
UAS7≤6 (Well Controlled)	33%	75%	43%	8%
UAS7=0 (Complete Response)	17%	50%	29%	8%

Q12W Dose Clinical Activity Assessments Summary at Week 16

	120 mg Q12W (N=4)	180mg Q12W (N=7)	Placebo (N=12)
UAS7 Changes			
Baseline mean UAS7 (SD)	28.8 (10.6)	27.8 (7.8)	28.6 (9.4)
Mean change at Week 16	-29.8	-21.7	-10.1
Mean difference from placebo	-19.7	-11.6	-
Clinical Responses			
UAS7≤6 (Well Controlled)	75%	57%	25%
UAS7=0 (Complete Response)	50%	57%	17%

Mean baseline serum tryptase for participants in the enrolled in the study was within the normal range in all cohorts. 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 86% (6 of 7) of participants in the 180mg Q8W cohort at week 2, and for 100% (3 of 3) of participants in 240mg single dose cohort at week 1.

Briquilimab was well tolerated in the study, with no dose limiting toxicities observed. Safety observations potentially related to c-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. Predictable decreases in neutrophil counts were observed upon dosing, with counts generally recovering prior to subsequent dose and no association to fever or infection. A single Grade 3 neutropenia event was reported in a participant with prior history of idiopathic neutropenia and thrombocytopenia.

Patients enrolled in the study will continue to be dosed and assessed for safety/tolerability and clinical activity, and Jasper has commenced an open-label extension study in chronic urticarias that will roll over patients from the BEACON to a 180mg Q8W dose upon completion of their initial follow up period. Consistent with the Company's clinical development plan, Jasper submitted for regulatory review of two additional BEACON cohorts, 240mg Q8W (N=8) and 180mg Q8W following a 240mg induction dose (N=8).

Jasper expects to begin a registrational program in CSU with a Phase 2b study expected to commence in the second half of 2025. Final selection of doses for the Phase 2b study will be further informed by additional data at 180mg Q8W from the open-label extension study, as well as by further data from BEACON cohorts evaluating a 360mg single dose, a 240mg Q8W dose and a 180mg Q8W dose following a 240mg loading dose. Data from these additional cohorts are expected to be presented by mid-2025.

"We are very happy to report preliminary data from the BEACON study," said Ronald Martell, President and Chief Executive Officer of Jasper. "The favorable safety profile, rapid onset of durable responses, the pharmacokinetic profile, and the depth and durability of tryptase reductions observed, all support advancing a 240mg dosing regimen into the Phase 2b portion of a CSU registrational program that we plan to commence in the second half of 2025. With positive data in both SPOTLIGHT and BEACON studies and preliminary data on the ETESIAN study in asthma expected in the second half of 2025, we continue to rapidly advance our briquilimab franchise in mast cell driven diseases."

Conference Call / Webinar

Jasper will host a conference call and webinar today at 8:00 a.m. EST, including remarks from Dr. Thomas B. Casale, M.D., the lead US investigator for the BEACON study. 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.

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

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 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 and asthma. Jasper is currently conducting clinical studies of briquilimab as a treatment in patients with CSU, CIndU or asthma. 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 as a leading therapeutic for CSU patients; the potential for deep and durable efficacy of briquilimab in CSU; briquilimab's safety profile; the advancement of briquilimab into a registrational program; additional studies of briquilimab in chronic urticaria; patient enrollment in an open-label extension study in chronic urticarias that will roll over patients from the BEACON to a 180mg Q8W dose; regulatory review of two additional BEACON cohorts, 240mg Q8W (N=8) and 180mg Q8W following a 240mg induction dose (N=8); Jasper's expectations regarding a registrational program in CSU, including the expected timing of the Phase 2b study and dose selection; Jasper's expected timing for presenting data from additional BEACON cohorts; and Jasper's expectations regarding rapidly advancing its briquilimab franchise 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 prior test, study and trial results, including preliminary results for the BEACON 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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