Jasper Therapeutics Presents Positive Final Results from Phase 1 Study of Briquilimab in Patients with AML or MDS Undergoing Hematopoietic Cell Transplant in Oral Presentation at ASH 2023

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Stanford Medicine Presents Additional Positive Data from Investigator-Sponsored Phase 1b/2a Study of Briquilimab in Patients with Fanconi Anemia

REDWOOD CITY, Calif., Dec. 10, 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 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 acute myeloid leukemia (AML) in complete remission (CR) or myelodysplastic syndromes (MDS) undergoing allogeneic hematopoietic cell transplant (HCT). The results were presented by Dr. Arpita Gandhi, M.D., M.S., Assistant Professor of Medicine in the Division of Hematology/Medical Oncology at the Oregon Health & Science University School of Medicine during an oral session at the America Society of Hematology (ASH) 2023 Annual Meeting & Exposition, being held December 9-12, 2023 in San Diego, CA and virtually.

The study enrolled 32 adult patients (62 to 79 years) with AML in CR (n=13), MDS (n=16), or AML not in CR (n=3). Following a 0.6 mg/kg infusion of briquilimab, serum levels were assessed to determine start of Flu at 30 mg/m 2/day on Transplant Day (TD) -4, -3, -2, and TBI 2-3 Gy on TD0. Peripheral blood grafts were infused on TD0 (10-14 days after briquilimab). Primary endpoints were safety, tolerability, and briquilimab pharmacokinetics, and secondary endpoints included engraftment, chimerism, measurable residual disease (MRD) clearance, acute graft-versus-host-disease (GVHD), chronic GVHD, non-relapse mortality (NRM), regression-free survival (RFS), and overall survival (OS) at 1 year. Results from the study demonstrated that a regimen of briquilimab plus Flu/TBI led to successful engraftment of donor blood stem cell without the associated short and long-term toxicities that accompany busulfan-based regimens commonly used in transplant of donor or gene-corrected cells, and led to promising early minimal residual disease clearance. Further, briquilimab dosing resulted in predictable pharmacokinetics and allowed donor cell infusion 9-14 days after administration, and all patients who engrafted achieved neutrophil recovery before TD +26.

Also at ASH, Dr. Rajni Agarwal, Professor of Pediatrics in the Division of Stem Cell Transplantation at the Stanford Medicine presented new positive results from the investigator-sponsored Phase 1b/2a study evaluating briquilimab as a conditioning agent in the treatment of Fanconi Anemia (FA). Data from the study show that briquilimab infusion appears to be safe and well tolerated in patients with FA, that it is feasible to generate adequate hematopoietic stem cell grafts from haplo donors with resulting safe and well tolerated graft infusions, and that all patients enrolled engrafted promptly within 2 weeks of transplant with stable donor chimerism of > 95% in all lineages. The 2a portion of the study is ongoing and continues to enroll patients.

“We are pleased with the results from both studies presented at ASH, demonstrating the potential of briquilimab to serve as a crucial component of non-toxic conditioning regimens for stem cell transplant to treat AML/MDS and FA,” said Edwin Tucker, M.D., Chief Medical Officer of Jasper. “We continue to enroll patients in our Phase 1b trial evaluating briquilimab as a second-line therapy in subjects with LR-MDS and look forward to presenting data from that study next year, in addition to data from our core mast cell disease programs.”

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 is evaluating briquilimab as a treatment in patients with Chronic Spontaneous Urticaria, and will begin clinical development in Chronic Inducible Urticaria as well. 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 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 MDS and as a conditioning agent for stem cell transplants for rare diseases such as SCID, 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 SCID. 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 its promising safety profile, its clinical potential in a variety of indications and patient types, the feasibility that it can generate adequate hematopoietic stem cell grafts from haplo donors with resulting
safe and well tolerated graft infusions and its potential to serve as a crucial component of non-toxic conditioning regimens for stem-cell transplants to treat AML/MDS and FA, the development of briquilimab for CSU, CIndU, LR-MDS and novel stem cell transplant conditioning regimens, and Jasper's expectations regarding its Phase 1b trial evaluating briquilimab as a second-line therapy in subjects with LR-MDS, including its continued enrollment and the expected timing for presenting data for the trial. 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 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.

Contacts:

John Mullaly (investors)
LifeSci Advisors
617-429-3548
jmullaly@lifesciadvisors.com

Alex Gray (investors)
Jasper Therapeutics
650-549-1454
agray@jaspertherapeutics.com

Lauren Barbiero (media)
Real Chemistry
646-564-2156
lbarbiero@realchemistry.com

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