Jasper Therapeutics Announces FDA Fast Track Designation for JSP191, a novel monoclonal antibody targeting CD117, in the treatment of patients with severe combined immunodeficiency (SCID) undergoing allogeneic hematopoietic stem cell transplant

September 15, 2022

- *JSP191 is currently being evaluated in four ongoing clinical studies in allogeneic hematopoietic stem cell transplant in patients with Acute Myeloid Leukemia (AML) / Myelodysplastic Syndromes (MDS), SCID, Fanconi anemia and Sickle Cell Disease*

- *On track to initiate a new study of JSP191 as a therapeutic in second-line therapy for patients with lower-risk MDS later this year*

REDWOOD CITY, Calif., Sept. 15, 2022 (GLOBE NEWSWIRE) -- Jasper Therapeutics, Inc. (Nasdaq: JSPR), a biotechnology company focused on developing multiple new therapies for the field of stem and cellular medicine, today announced that JSP191, an anti-CD117 monoclonal antibody, has received fast track designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with severe combined immunodeficiency (SCID) undergoing allogeneic hematopoietic stem cell transplant. To date, JSP191 has been studied in 14 SCID patients in an ongoing multicenter clinical trial with clinical outcome data presented at academic medical conferences.

“Patients born with SCID have a severely compromised immune system and need to rely on an allogeneic hematopoietic stem cell transplant to create the immune cells needed to fight infection,” said Ronald Martell, President and Chief Executive Officer of Jasper Therapeutics. “Unfortunately many patients are too fragile to tolerate the toxic chemotherapy doses typically used in transplant, and may suffer severe side effects or fail transplant. Along with the FDA’s previous designations of Orphan and Rare Pediatric Disease for JSP191, this new Fast Track designation recognizes the potential role of JSP191 in improving clinical outcomes for these patients and will allow us to more closely work with the FDA in the upcoming months to determine a path toward a Biologics License Application (BLA) submission.”

The FDA’s Fast Track designation is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill unmet medical needs. The purpose is to accelerate the development of important new drugs for patients. Drugs granted Fast Track designation are eligible for more frequent meetings with the FDA to discuss the drug’s development plan and ensure the collection of appropriate data needed to support approval, as well as eligibility for Accelerated Approval, Priority Review and Rolling Review if relevant criteria are met.

About JSP191

JSP191 is a humanized monoclonal antibody that blocks stem cell factor receptor signaling leading to the clearance of hematopoietic stem and progenitor cells from the bone marrow. JSP191 is in clinical development as a stem cell transplant conditioning agent where it helps create an empty space for donor or gene-corrected transplanted stem cells to engraft. While hematopoietic cell transplantation can be curative for patients, its use is limited because standard high-dose myeloablative conditioning is associated with severe toxicities and standard low-dose conditioning has limited efficacy. To date, JSP191 has been evaluated in more than 110 healthy volunteers and patients. Four clinical trials for myelodysplastic syndromes (MDS)/ acute myeloid leukemia (AML), severe combined immunodeficiency (SCID), Fanconi anemia (FA) and Sickle Cell Disease undergoing allogeneic transplant are currently ongoing. JSP191 is also planned to enter clinical development as a second-line therapeutic in transfusion-dependent, lower-risk MDS patients to preferentially drive recovery of healthy hematopoietic stem cells in order to help restore normal hematopoiesis.

About Jasper Therapeutics

Jasper Therapeutics is a biotechnology company focused on the development of novel curative therapies based on the biology of the hematopoietic stem cell. The company is advancing two potentially groundbreaking programs. JSP191, an anti-CD117 monoclonal antibody, is in clinical development as a conditioning agent that clears hematopoietic stem cells from bone marrow in patients undergoing hematopoietic cell transplantation. It is designed to enable safer and more effective curative allogeneic hematopoietic cell transplants and gene therapies. Clinical study of JSP191 as a novel, disease-modifying, therapeutic for patients with lower risk MDS is also planned to begin in 2022. In parallel, Jasper Therapeutics is advancing its preclinical mRNA hematopoietic stem cell grafts platform, which is designed to overcome key limitations of allogeneic and autologous gene-edited stem cell grafts. Both innovative programs have the potential to transform the field and expand hematopoietic stem cell therapy cures to a greater number of patients with life-threatening cancers, genetic diseases and autoimmune diseases than is possible today. For more information, please visit us at 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 any potential benefits of the Fast Track Designation for JSP191, the potential for JSP191 to significantly improve clinical outcomes, the potential for JSP191 to address the limitations of transplant conditioning, the potential plans to

initiate clinical development of JSP191 and any potential Biologics License Application for JSP191 and the expected timing for initiating clinical studies and trials. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of Jasper Therapeutics 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. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of Jasper Therapeutics. 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 Therapeutics develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; risks relating to uncertainty regarding the regulatory pathway for Jasper Therapeutics' product candidates; 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 Therapeutics 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 final study data may not be consistent with preliminary study data; the risk that Jasper Therapeutics' product candidates may not be beneficial to patients or successfully commercialized; the risk that Jasper Therapeutics has overestimated the size of the target patient population, their willingness to try new therapies and the willingness of physicians to prescribe these therapies; the effects of competition on Jasper Therapeutics' business; the risk that third parties on which Jasper Therapeutics depends for laboratory, clinical development, manufacturing and other critical services will fail to perform satisfactorily; the risk that Jasper Therapeutics' business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic; the risk that Jasper Therapeutics 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 Therapeutics' public filings with the SEC, including its Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent Quarterly Reports on Form 10-Q. If any of these risks materialize or Jasper Therapeutics' assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Jasper Therapeutics does not presently know, or that Jasper Therapeutics currently believes are immaterial, that could also cause actual results to differ from those contained in the forward-looking statements. While Jasper Therapeutics may elect to update these forward-looking statements at some point in the future, Jasper Therapeutics specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Jasper Therapeutics' 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

Jeet Mahal (investors)
Jasper Therapeutics
650-549-1403
jmahal@jaspertherapeutics.com

Source: Jasper Therapeutics