



Jasper Therapeutics Announces Positive Data from Phase 1 Clinical Trial of JSP191 as Targeted Stem Cell Conditioning Agent in Patients with Myelodysplastic Syndromes or Acute Myeloid Leukemia Undergoing Hematopoietic Cell Transplantation

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First targeted stem cell factor receptor (anti-CD117) antibody evaluated as a conditioning agent prior to blood stem cell transplantation in patients with hematologic malignancies

Data presented as late-breaking abstract at 2021 TCT

REDWOOD CITY, Calif.--([BUSINESS WIRE](#))--Jasper Therapeutics, Inc., a biotechnology company focused on hematopoietic cell transplant therapies, today announced positive preliminary findings from its ongoing multicenter Phase 1 clinical trial of JSP191, a first-in-class anti-CD117 (stem cell factor receptor) monoclonal antibody, as a conditioning agent in older patients with myelodysplastic syndromes (MDS) or acute myeloid leukemia (AML) undergoing hematopoietic (blood) cell transplantation.

Data from the first six patients who received a single dose of JSP191 prior to transplantation showed successful engraftment in all six patients. Complete donor myeloid chimerism (equal or greater than 95%) was observed in five of six evaluable patients at 28 days, and all three evaluable patients had total donor chimerism equal or greater than 95% observed at day 90. In addition, at 28 days, three of five evaluable patients showed complete eradication of measurable residual disease (MRD) as measured by next-generation sequencing. Two of the five evaluable patients showed substantial reductions in MRD. No treatment-related serious adverse events were reported.

The findings were presented by lead investigator Lori Muffy, M.D., M.S., Assistant Professor of Medicine (Blood and Bone Marrow Transplantation) at Stanford Medicine, as a late-breaking abstract at the 2021 Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR).

"These early clinical results are the first to demonstrate that JSP191 administered in combination with a standard non-myeloablative regimen of low-dose radiation and fludarabine is well tolerated and can clear measurable residual disease in older adults with MDS or AML undergoing hematopoietic cell transplantation – a patient population with historically few options," said Kevin N. Heller, M.D., Executive Vice President, Research and Development, of Jasper Therapeutics. "These patients could be cured by hematopoietic cell transplantation, but the standard-of-care myeloablative conditioning regimens used today are highly toxic and associated with high rates of morbidity and mortality particularly in older adults. Traditional lower intensity transplant conditioning regimens are better tolerated in older adults, but are associated with higher rates of relapse in MDS/AML patients with measurable residual disease. JSP191, a well-tolerated biologic conditioning agent that targets and depletes both normal hematopoietic stem cells and those that initiate MDS and AML, has the potential to be a curative option for these patients."

The open-label, multicenter Phase 1 study (JSP-CP-003) is evaluating the safety, tolerability and efficacy of adding JSP191 to the standard conditioning regimen of low-dose radiation and fludarabine among patients age 65 to 74 years with MDS or AML undergoing hematopoietic cell transplantation. Patients were ineligible for full myeloablative conditioning. The primary outcome measure of the study is the safety and tolerability of JSP191 as a conditioning regimen up to one year following a donor cell transplant.

"We designed JSP191 to be given as outpatient conditioning and to have both the efficacy and safety profile required for use in newborn patients and older patients for successful outcomes," said Wendy Pang, M.D., Ph.D. Executive Director, Research and Translational Medicine, of Jasper Therapeutics. "We are enthusiastic about the reduction of measurable residual disease seen in these patients, especially given that it is associated with improved relapse-free survival. We are excited to continue our research in MDS/AML, with plans for an expanded study. We are evaluating JSP191, the only antibody of its kind, in two ongoing clinical studies and are encouraged by the positive clinical data seen to date."

About MDS and AML

Myelodysplastic syndromes (MDS) are a group of disorders in which immature blood-forming cells in the bone marrow become abnormal and do not make new blood cells or make defective blood cells, leading to low numbers of normal blood cells, especially red blood cells.¹ In about one in three patients, MDS can progress to acute myeloid leukemia (AML), a rapidly progressing cancer of the bone marrow cells.¹ Both are diseases of the elderly with high mortality. Each year, about 5,000 patients with MDS and 8,000 people with AML in the G7 countries receive hematopoietic cell transplants. These transplants are curative but are underused due to the toxicity of the current high-intensity conditioning regimen, which includes the chemotherapy agents busulfan and fludarabine.

About JSP191

JSP191 (formerly AMG 191) is a first-in-class humanized monoclonal antibody in clinical development as a conditioning agent that clears hematopoietic stem cells from bone marrow. JSP191 binds to human CD117, a receptor for stem cell factor (SCF) that is expressed on the surface of hematopoietic stem and progenitor cells. The interaction of SCF and CD117 is required for stem cells to survive. JSP191 blocks SCF from binding to CD117 and disrupts critical survival signals, causing the stem cells to undergo cell death and creating an empty space in the bone marrow for donor or gene-corrected transplanted stem cells to engraft.

Preclinical studies have shown that JSP191 as a single agent safely depletes normal and diseased hematopoietic stem cells, including in animal models of SCID, myelodysplastic syndromes (MDS) and sickle cell disease (SCD). Treatment with JSP191 creates the space needed for transplanted normal donor or gene-corrected hematopoietic stem cells to successfully engraft in the host bone marrow. To date, JSP191 has been evaluated in more than 90 healthy volunteers and patients.

JSP191 is currently being evaluated in two separate clinical studies in hematopoietic cell transplantation. A Phase 1/2 dose-escalation and expansion trial is evaluating JSP191 as a sole conditioning agent to achieve donor stem cell engraftment in patients undergoing hematopoietic cell transplantation for severe combined immunodeficiency (SCID), which is potentially curable only by this type of treatment. Data presented at the 62nd American Society of Hematology (ASH) Annual Meeting showed that a single dose of JSP191 administered prior to stem cell transplantation in a 6-month-old infant was effective in establishing sustained donor chimerism followed by development of B, T and NK immune cells. No treatment-related adverse events were reported. A Phase 1 clinical study is evaluating JSP191 in combination with another low-intensity conditioning regimen in patients with MDS or AML undergoing hematopoietic cell transplantation. For more information about the design of these two ongoing clinical trials, visit www.clinicaltrials.gov (NCT02963064 and NCT04429191).

Additional studies are planned to advance JSP191 as a conditioning agent for patients with other rare and ultra-rare monogenic disorders and autoimmune diseases.

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's lead compound, JSP191, is in clinical development as a conditioning antibody that clears hematopoietic stem cells from bone marrow in patients undergoing a hematopoietic cell transplant. This first-in-class conditioning antibody is designed to enable safer and more effective curative hematopoietic cell transplants and gene therapies. For more information, please visit us at jaspertherapeutics.com.

¹ <https://www.cancer.org/cancer/myelodysplastic-syndrome/about/what-is-mds.html>

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