Jasper Therapeutics Announces Updated 90-day Data from Phase 1 Clinical Trial of JSP191 as Targeted Stem Cell Conditioning Agent in Older Patients with Myelodysplastic Syndromes or Acute Myeloid Leukemia Undergoing Hematopoietic Cell Transplantation

May 19, 2021

New efficacy, safety and pharmacokinetic data in first six subjects to be presented in poster session at 2021 ASCO Annual Meeting

At 90 days after transplant, measurable residual disease (MRD) as measured by cytogenetics, flow cytometry and next-generation sequencing was negative (undetected) in five patients and reduced in one patient

At 90 days after transplant, full chimerism (greater than 95%) was observed in five of the six patients

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jasper Therapeutics, Inc., a biotechnology company focused on hematopoietic cell transplant therapies, today announced updated 90-day efficacy, safety and pharmacokinetic data from its ongoing multicenter Phase 1 clinical trial of JSP191, the company’s first-in-class anti-CD117 monoclonal antibody, as a targeted, non-toxic conditioning regimen in older patients with myelodysplastic syndromes (MDS) or acute myeloid leukemia (AML) undergoing allogeneic hematopoietic (blood) cell transplantation. Data from the dose-finding part of the study showed that conditioning with a single dose of JSP191 0.6 mg/kg prior to low dose radiation and fludarabine in preparation for transplantation was well tolerated in all six patients and led to successful transplant as evidenced by full chimerism and elimination of measurable residual disease (MRD) in five of six patients. The findings will be presented by lead investigator Lori Muffly, M.D., M.S., Assistant Professor of Medicine (Blood and Bone Marrow Transplantation) at Stanford Medicine, in a poster session at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held online from June 4-8. The abstract is available now on the ASCO Annual Meeting website.

“We are very encouraged by the updated efficacy and safety results from this Phase 1 clinical study, which is the first to evaluate JSP191 in combination with non-myeloablative conditioning for older patients with MDS or AML. These data are consistent with pre-clinical work that demonstrated the capacity of JSP191 to target myelodysplastic cells and synergize with low doses of radiation. While hematopoietic cell transplantation is curative in these patients, its use is limited in older and frail patients because of the toxicity associated with standard-of-care myeloablative conditioning agents,” said Kevin N. Heller, M.D., Executive Vice President, Research and Development, of Jasper Therapeutics. “Based on this data and feedback from the FDA, we have now opened the dose-expansion phase of the study at the recommended Phase 2 dose. We anticipate announcing topline data in the first half of next year. We continue to evaluate JSP191 as a conditioning agent in multiple additional diseases, including our ongoing clinical trial in severe combined immunodeficiency (SCID), our upcoming study in refractory autoimmune disease and with our partnerships with the NIH and Stanford in sickle cell disease and Fanconi anemia. We believe that JSP191 addresses key limitations of current conditioning regimens and potentially may expand the number of patients with devastating diseases who could be cured with hematopoietic stem cell therapy.”

At 90 days after transplant, MRD as measured by cytogenetics, karyotype and next-generation sequencing was negative (undetected) in five patients and reduced in one patient, and full chimerism (greater than 95%) was observed in five of the six patients. One patient had secondary graft failure with no evidence of relapse at 90 days. JSP191, when added to low-dose radiation and fludarabine, was well tolerated in all six patients; the protocol allows for subjects to receive the conditioning regimen in an outpatient setting. No infusion reactions, treatment-related toxicities such as oral mucositis or evidence of acute graft versus host disease were reported. Pharmacokinetic data showed that serum levels of the JSP191 0.6 mg/kg dose were consistent among study participants as evaluated up to 14 days post-infusion.

Phase 1 Study Design

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. Secondary endpoints include engraftment and donor chimerism, MRD clearance, non-relapse mortality, event-free survival and overall survival.

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 29,000 patients are diagnosed with MDS and approximately 42,000 patients are diagnosed with AML in the G7 countries for which approximately 2,500 patients with MDS and approximately 8,000 people with AML receive hematopoietic stem 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 is a first-in-class humanized monoclonal antibody in clinical development as a conditioning agent that blocks stem cell factor receptor signaling leading to clearance of hematopoietic stem cells from bone marrow, creating an empty space for donor or gene-corrected transplanted stem cells to engraft. To date, JSP191 has been evaluated in more than 90 healthy volunteers and patients. Jasper is currently enrolling in two clinical trials for acute myeloid leukemia (AML)/myelodysplastic syndromes (MDS) and severe combined immunodeficiency (SCID) and expects to begin enrollment in three additional studies in 2021 for severe autoimmune disease, sickle cell disease and Fanconi anemia patients undergoing hematopoietic cell transplantation.

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, a first-in-class anti-CD117 monoclonal antibody, is in clinical development as a conditioning agent that clears hematopoietic stem cells from bone marrow in patients undergoing a hematopoietic cell transplantation. It is designed to enable safer and more effective curative allogeneic and autologous hematopoietic cell transplants and gene therapies. In parallel, Jasper Therapeutics is advancing its preclinical engineered hematopoietic stem cell (eHSC) 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.


Contacts

Lily Eng
Real Chemistry
206-661-8627
leng@realchemistry.com

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