



Jasper Therapeutics Announces Orphan Drug and Rare Pediatric Disease Designations for JSP191 for Conditioning Treatment Prior to Stem Cell Transplant

REDWOOD CITY, Calif. – June 14, 2021 – Jasper Therapeutics, Inc., a biotechnology company focused on hematopoietic cell transplant therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to JSP191, a monoclonal antibody targeting the CD117 (stem cell factor) receptor, for conditioning treatment prior to hematopoietic stem cell transplantation. In addition, the FDA granted rare pediatric disease designation to JSP191 as a conditioning treatment for patients with severe combined immunodeficiency (SCID), a life-threatening genetic illness that is typically fatal within two years without hematopoietic cell transplantation.

“The FDA’s decision to grant orphan drug designation to JSP191, and rare pediatric disease designation in SCID, underscores the critical need for innovative conditioning agents for patients undergoing hematopoietic cell transplant, in an indication where currently there is no FDA approved or consensus guidelines recommended conditioning agent,” said William Lis, Executive Chairman and CEO of Jasper Therapeutics. “Hematopoietic cell transplant is a potentially life-saving cure for multiple diseases such as SCID, acute myeloid leukemia, myelodysplastic syndromes, sickle cell disease, auto immune disease and others. However, the genotoxic mechanism of action of current conditioning agents limits the use of curative transplants due to severe adverse safety events or lack of efficacy due to the use of a reduced dose or no conditioning prior to transplant. We believe JSP191 has the potential to safely and effectively expand lifesaving, curative stem cell transplant across multiple diseases. The orphan drug and rare pediatric designations from the FDA provide additional momentum and validation for JSP191, and we are committed to advancing its use across multiple indications to improve patient care.”

Jasper is currently conducting clinical studies of JSP191 as a conditioning agent prior to hematopoietic stem cell transplant in patients with SCID and separately in patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS). SCID is a rare, life-threatening, pediatric disorder affecting an estimated 1/58,000 births in the general population. The ongoing SCID clinical trial is evaluating JSP191 as a conditioning agent to enable stem cell transplantation in patients who are either transplant-naive or who received a prior stem cell transplant with a poor outcome. Jasper has presented data from this study at multiple scientific conferences, which demonstrated that JSP191 has been well tolerated with no treatment-related adverse events across multiple patients ranging from 3 months to 38 years old. Successful engraftment and immune reconstitution has also been observed. Given the preliminary safety, tolerability and evidence of efficacy, Jasper intends to continue enrolling evaluating previously transplanted and newly diagnosed SCID patients to support additional filings with FDA.

About Orphan Drug Designation and Rare Pediatric Disease Designation

The FDA Orphan Drug Designation program provides orphan status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States. Among the benefits of orphan designation are seven years of market exclusivity following FDA approval, waiver or partial payment of application fees, and tax credits for clinical testing expenses conducted after orphan designation is received.

The FDA defines a rare pediatric disease as a serious or life-threatening disease primarily affecting individuals age 18 years or younger that impacts fewer than 200,000 people in the United States. The FDA Rare Pediatric Disease designation and voucher program is intended to facilitate development of new drugs and biologics for the prevention and treatment of rare pediatric diseases. Under this program, the FDA awards priority review vouchers to sponsors of product applications that meet certain criteria. The voucher can be used to receive a priority review of a subsequent marketing application for a different product or sold or transferred to another company.

About SCID

Severe combined immune deficiency (SCID) is a group of rare disorders caused by mutations in genes involved in the development and function of infection-fighting immune cells. Infants with SCID appear healthy at birth but are highly susceptible to severe infections. The condition is fatal, usually within the first year or two of life, unless infants receive immune-restoring treatments, such as transplants of blood-forming stem cells, gene therapy or enzyme therapy.

About JSP191

JSP191 is a 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. It is currently enrolling in two clinical trials for myelodysplastic syndromes (MDS)/acute myeloid leukemia (AML) and severe combined immunodeficiency (SCID) and expects to begin enrollment in four additional studies in 2021 for severe autoimmune disease, sickle cell disease, chronic granulomatous 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, an 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.

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Important Information and Where to Find It

In connection with the proposed transaction between Amplitude Healthcare Acquisition Corporation (“Amplitude”) and Jasper Therapeutics, Inc. (“Jasper Therapeutics”), Amplitude intends to file relevant materials with the SEC, including a registration statement on Form S-4, which will include a proxy statement/prospectus. Promptly after the registration statement is declared effective by the SEC, Amplitude will mail the definitive proxy statement/prospectus and a proxy card to each stockholder as of a record date for the meeting of Amplitude stockholders to be established for voting on the proposed business combination. **Investors and security holders of Amplitude are urged to read these materials (including any amendments or supplements thereto) and any other relevant documents in connection with the transaction that Amplitude will file with the SEC when they become available because they will contain important information about Amplitude, Jasper Therapeutics and the transaction.** The preliminary proxy statement/prospectus, the definitive proxy statement/prospectus and other relevant materials in connection with the transaction (when they become available), and any other documents filed by Amplitude with the SEC, may be obtained free of charge at the SEC’s website (www.sec.gov). The documents filed by Amplitude with the SEC also may be obtained free of charge upon written request to 1177 Avenue of the Americas, Fl 40, New York, New York 10036.

Participants in the Solicitation

Amplitude and its directors and executive officers may be deemed participants in the solicitation of proxies from Amplitude’s stockholders with respect to the business combination. Information about Amplitude’s directors and executive officers and a description of their interests in Amplitude will be included in the proxy statement/prospectus for the proposed transaction and be available at the SEC’s website (www.sec.gov). Additional information regarding the interests of such participants will be contained in the proxy statement/prospectus for the proposed transaction when available.

Jasper Therapeutics and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the stockholders of Amplitude in connection with the proposed business combination. Information about Jasper Therapeutics’ directors and executive officers and information regarding their interests in the proposed transaction will be included in the proxy statement/prospectus for the proposed transaction.

Non-Solicitation

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of Amplitude, the combined company or Jasper Therapeutics, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

Special Note Regarding Forward-Looking Statements

Certain statements made herein that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are 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 future events and other statements that are not historical facts. These statements are based on the current expectations of Amplitude's and Jasper’s management 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 any 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 Amplitude and Jasper. These statements are subject to a number of risks and uncertainties and actual results may differ materially. If any of these risks materialize or if assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that Amplitude and Jasper presently do not know or that Amplitude and Jasper currently believe are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements provide Amplitude's and Jasper’s expectations, plans or forecasts of future events and views as of the date of this communication. Amplitude and Jasper anticipate that subsequent events and developments will cause Amplitude's and Jasper’s assessments to change. However, while Amplitude and Jasper may elect to update these forward-looking statements at some point in the future, Amplitude and Jasper specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing Amplitude’s and Jasper’s assessments as of any date subsequent to the date of this communication. Accordingly, undue reliance should not be placed upon the forward-looking statements.
