Adicet Opens Enrollment for ADI-001 Phase 1 Clinical Trial in Autoimmune Diseases

September 30, 2024

Activated clinical sites for Phase 1 trial of ADI-001 in autoimmune diseases, including lupus nephritis (LN), systemic lupus erythematosus (SLE), systemic sclerosis (SSc) and anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV)

Enrollment open for patients with LN; enrollment in SLE, SSC, and AAV expected to open in the fourth quarter of 2024

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Sep. 30, 2024-- Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer, today announced the opening of enrollment for the Phase 1 clinical trial evaluating ADI-001 in autoimmune diseases.

"The favorable safety profile, cellular kinetics and B cell depletion in peripheral blood and secondary lymphoid tissue demonstrated with ADI-001 clinical experience to date, positions ADI-001 to potentially bring a paradigm shift in the treatment of autoimmune diseases," said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet Bio. "We expect to have several additional sites open for enrollment by the end of the fourth quarter of 2024, and further increase the number of active sites during the first quarter of 2025. At this time, our sites are open to enroll patients with LN, and we plan to initiate enrollment of patients with SLE, SSc, and AAV in the fourth quarter of this year. We look forward to reporting preliminary clinical data from this trial of ADI-001 in LN as well as SLE, SSc, and AAV in the first half of 2025."

This announcement follows the U.S. Food and Drug Administration's (FDA) decision to grant Fast Track Designation to ADI-001 for the treatment of relapsed/refractory class III or class IV LN and clearance from the FDA to develop ADI-001 in four autoimmune indications, including LN, SLE, SSc, and AAV.

The Phase 1 study has three separate arms, enrolling LN and SLE patients into one arm, SSc patients into a second arm and AAV patients into a third arm. Enrolled patients will receive a single dose of ADI-001. The dose-limiting toxicity window is 28 days with response and safety assessments conducted on Day 28 and during the follow up period on months 3, 6, 9, 12, 18 and 24. The primary objectives of the study are to evaluate the safety and tolerability of ADI-001. Secondary objectives include measuring cellular kinetics, pharmacodynamics, changes in autoantibody titers, and appropriate disease activity scores in each indication.

About ADI-001

ADI-001 is an investigational allogeneic gamma delta CAR T cell therapy targeting B-cells via an anti-CD20 CAR. ADI-001 was granted Fast Track Designation by the FDA for the potential treatment of relapsed/refractory class III or class IV lupus nephritis and relapsed or refractory B-cell NHL.

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. Adicet is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients. For more information, please visit our website at https://www.adicetbio.com.

Forward-Looking Statements

This press release contains "forward-looking statements" of Adicet within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the business and operations of Adicet. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: clinical development of Adicet's product candidates, including future plans or expectations for ADI-001 and the potential safety, tolerability and efficacy for the treatment of autoimmune diseases; expectations for ADI-0001 to bring a paradigm shift in treatment of autoimmune diseases; and the expected progress, timing and success of the Phase 1 clinical study of ADI-001 in LN, SLE, SSc, and AAV, including timing and expectations for site activation, enrollment, future data releases and Adicet's ability to demonstrate proof-of-concept.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including without limitation, the effect of global economic conditions and public health emergencies on Adicet's business and financial results, including with respect to disruptions to our preclinical and clinical studies, business operations, employee hiring and retention, and ability to raise additional capital; Adicet's ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; that positive results, including interim results, from a preclinical or clinical study may not necessarily be predictive of the results of future or ongoing studies; clinical studies may fail to demonstrate adequate safety and efficacy of Adicet's product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; and regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; and Adicet's ability to meet production and product release expectations. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Adicet's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Adicet's most recent annual report on Form 10-Q and subsequent filings with the U.S. Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in Adicet's other filings with the SEC. All information in this press release is as of the date of the release, and Adicet undertakes no duty to update this information unless required by law.

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