Adicet Bio Announces First Lupus Nephritis Patient Dosed in Phase 1 Clinical Trial of ADI-001 in Autoimmune Diseases

November 18, 2024

Enrollment underway for lupus nephritis (LN) patients

Preliminary clinical data in LN anticipated in 1H25

Initiation of patient enrollment in systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM) and stiff person syndrome (SPS) expected in 1Q25; patient enrollment in anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV) expected in 2H25

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Nov. 18, 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 that the first LN patient has been dosed in the Phase 1 clinical trial evaluating ADI-001 in autoimmune diseases.

“Dosing the first lupus nephritis patient in our Phase 1 trial of ADI-001 marks an important step forward in our mission of improving the lives of patients affected by autoimmune diseases, particularly lupus nephritis,” said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet Bio. “With clinical biomarker data from our study in non-Hodgkin’s lymphoma demonstrating robust tissue trafficking and complete CD19+ B cell depletion in peripheral blood and secondary lymphoid tissue, ADI-001 has the potential to be a transformative off-the-shelf treatment option for several autoimmune diseases. Additionally, the FDA’s Fast Track Designation to ADI-001 in relapsed/refractory class III or class IV LN and the clearance of our investigational IND amendment application of ADI-001 for the treatment of SPS and IIM further serves to emphasize the broad and urgent unmet need for approved therapies to address autoimmune diseases.”

Dr. Galimi continued, “With clinical sites open for enrollment and additional sites that are expected to open in the near future, we anticipate sharing preliminary clinical data from the trial in the first half of 2025. In addition, we look forward to initiating enrollment for SLE, SSc, IIM, and SPS patients in the first quarter of 2025 and for AAV patients in the second half of 2025."

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.

About the Phase 1 Trial

The Phase 1 study has four separate arms, enrolling LN and SLE patients into one arm, SSc patients into a second arm, IIM and SPS patients in a third arm and AAV patients into a fourth 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.

For more information about becoming a study site, please email clinicaltrials@adicetbio.com or visit https://www.adicetbio.com/hcp/autoimmune/.

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; ADI-001’s potential to be a transformational off-the-shelf treatment option for several autoimmune diseases; timing and success of the Phase 1 clinical study of ADI-001 in LN, SLE, SSc, AAV, IIM and SPS, including timing and expectations for site activation, enrollment, future data releases and Adicet’s ability to demonstrate proof-of-concept; and the potential benefits of fast track designation for ADI-001 for the treatment of LN.

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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Source: Adicet Bio, Inc.