Adicet Bio Announces First Patient Dosed in Phase 1 Clinical Trial of ADI-001 in Treatment-Refractory Rheumatoid Arthritis (RA)

October 16, 2025

Preliminary clinical data from the Phase 1 trial expected in 2H/2026

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Oct. 16, 2025-- 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 patient has been dosed in its Phase 1 clinical trial evaluating ADI-001 in treatment-refractory RA.

“Dosing the first patient in our clinical study of ADI-001 in treatment-refractory RA marks an important milestone in our Phase 1 program, which is now enrolling across seven autoimmune conditions,” said Julie Maltzman, M.D., Chief Medical Officer of Adicet Bio. “In this study we are evaluating two conditioning regimens, cyclophosphamide alone and in combination with fludarabine, to explore how different conditioning regimens may impact the overall therapeutic experience. Following the recent promising safety and efficacy results of ADI-001 in lupus nephritis and systemic lupus erythematosus, we are further encouraged about the potential of ADI-001 to transform outcomes across a range of autoimmune conditions.”

About the Phase 1 Trial in RA

The Phase 1 study is designed to evaluate the safety, tolerability and preliminary efficacy of ADI-001 in patients with treatment-refractory RA. The study will evaluate two conditioning regimens: cyclophosphamide alone and cyclophosphamide with fludarabine. The primary objectives of the study are to evaluate the safety and tolerability of ADI-001. Secondary objectives include measuring cellular kinetics, pharmacodynamics, and disease activity scores.

About Adicet’s Autoimmune Disease Phase 1 Program

The Phase 1 program is evaluating ADI-001 across seven different autoimmune diseases including: lupus nephritis (LN), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS), anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV) and RA. ADI-001 was granted Fast Track Designation by the U.S. Food and Drug Administration for the potential treatment of relapsed/refractory class III or class IV LN, refractory SLE with extrarenal involvement, and SSc.

The Phase 1 study in RA testing ADI-001 using two different conditioning regimens is in the context of a broader initiative at Adicet that seeks to deliver a best-in-class portfolio of therapies for autoimmune patients. This initiative includes additional ongoing preclinical programs, including gene-edited CAR T and in vivo CAR T programs targeting B cells with the potential for reducing or eliminating the need for conditioning.

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 ADI-001, including the potential safety, tolerability and efficacy of ADI-001 for the treatment of autoimmune indications, including RA; the expected progress, timing and success of the Phase 1 clinical trial of ADI-001 in RA, including site activation, continued enrollment and expectations around the timing of future data releases; ADI-001’s potential safety profile, availability as an off-the-shelf therapy and outpatient administration; and expectations regarding the Phase 1 program and ADI-001’s potential to be a best-in-class therapy for autoimmune diseases.

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-K, quarterly reports 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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