



Adicet Bio Announces First Systemic Sclerosis (SSc) Patient Dosed in Ongoing Phase 1 Clinical Trial of ADI-001 in Autoimmune Diseases

July 24, 2025

Phase 1 clinical trial of ADI-001 in autoimmune diseases actively enrolling patients with lupus nephritis (LN), systemic lupus erythematosus (SLE) and SSc

Preliminary clinical data from Phase 1 trial of ADI-001 in autoimmune diseases expected in 2H/2025

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Jul. 24, 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 systemic sclerosis (SSc) patient has been dosed in the second cohort of the Phase 1 clinical trial evaluating ADI-001 in autoimmune diseases.

"We are pleased with the continued momentum of our Phase 1 trial of ADI-001 in autoimmune diseases as we announce the dosing of the first SSc patient, a key development milestone for Adicet," said Julie Maltzman, M.D., Chief Medical Officer of Adicet Bio. "There remains a critical unmet need for safe and effective treatment options to combat debilitating autoimmune diseases, including SSc, for which we believe ADI-001 has the potential to offer transformative benefits. We are pleased with the enrollment in our LN and SLE cohort and look forward to sharing preliminary clinical data from the trial in the second half of 2025."

About ADI-001

ADI-001 is an investigational allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapy targeting B-cells via an anti-CD20 CAR. ADI-001 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed/refractory class III or class IV lupus nephritis (LN), refractory systemic lupus erythematosus (SLE) with extrarenal involvement and systemic sclerosis (SSc).

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, including SSc; ADI-001's potential to offer transformative benefits for several autoimmune diseases; and 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.

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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250724025385/en/): <https://www.businesswire.com/news/home/20250724025385/en/>

Adicet Bio, Inc.

Investor and Media Contacts

Anne Bowdidge

abowdidge@adicetbio.com

Penelope Belnap

Precision AQ

212-362-1200

Penelope.belnap@precisionaq.com

Source: Adicet Bio, Inc.