Adicet Bio Provides Corporate Update and Highlights Expected 2025 Milestones

January 8, 2025

Adicet made significant progress in 2024 and is well-positioned for success in 2025: Advancing Phase 1 clinical trial evaluating ADI-001 across six autoimmune diseases; preliminary data in lupus nephritis (LN) patients anticipated in 1H25, data from other patient cohorts expected in 2H25

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

First patient dosed and enrollment ongoing in Phase 1 clinical trial of ADI-270 in metastatic/advanced clear cell renal cell carcinoma (ccRCC); preliminary data expected in 1H25

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Jan. 8, 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 provided corporate updates and highlighted upcoming milestones for 2025.

“2024 was a momentous year for Adicet as we amplified our efforts in autoimmune diseases and solid tumors. We dosed our first patients in our clinical trials evaluating our gamma delta 1 chimeric antigen receptor (CAR) T cell candidates, ADI-001 in LN and ADI-270 in ccRCC. Notably, ADI-270 is the first gamma delta CAR T cell therapy to enter clinical development for solid tumors, underscoring our commitment to pioneering innovative treatments. In the first half of 2025, we look forward to reporting preliminary data for both programs,” said Chen Schor, President and Chief Executive Officer at Adicet Bio. “Within our autoimmune portfolio, the successful expansion of our Phase 1 trial of ADI-001 into six autoimmune indications, building upon clinical biomarker data demonstrating ADI-001’s robust tissue trafficking and complete CD19+ B cell depletion in secondary lymphoid tissue, further reinforces ADI-001’s potential as an off-the-shelf treatment option.

Mr. Schor continued: “In our oncology pipeline, the initiation of our Phase 1 trial of ADI-270 in ccRCC patients marked a crucial achievement as the first gamma delta 1 CAR T cell product candidate for the treatment of solid tumors. As we look ahead to 2025, we believe we are well positioned to build on this momentum to advance our product candidates to patients living with autoimmune diseases and cancer.”

Clinical Program Progress and Upcoming Milestones:

Autoimmune Diseases Clinical Programs

- In June 2024, the Company announced that the Food and Drug Administration (FDA) had granted Fast Track Designation to ADI-001 for the potential treatment of relapsed/refractory class III or class IV LN.
- In September 2024, Adicet presented clinical biomarker data from the Phase 1 GLEAN trial of ADI-001 at the 9th Annual CAR-TCR Summit demonstrating robust tissue trafficking resulting in high levels of ADI-001, significant CAR T cell activation, and complete CD19+ B cell depletion in secondary lymphoid tissue.
- In October 2024, the Company received FDA clearance for an amendment to its Investigational New Drug (IND) application to evaluate ADI-001 in IIM and SPS as part of the Phase 1 trial of ADI-001 in autoimmune diseases. This followed the clearance of an IND amendment in August 2024 to expand clinical development of ADI-001 in the Phase 1 trial beyond LN to include SLE, SSc and AAV.
- In November 2024, Adicet announced the dosing of the first LN patient in the Phase 1 trial of ADI-001 in autoimmune diseases. The Company expects to initiate enrollment for patients with SLE, SSc, IIM, and SPS in the first quarter of 2025, and for patients with AAV in the second half of 2025.
- Preliminary clinical data from the Phase 1 trial of ADI-001’s LN patient cohort are anticipated in the first half of 2025. Preliminary data from the Phase 1 trial’s other patient cohorts are expected in the second half of 2025.

Hematologic Malignancies and Solid Tumor Clinical Programs

- In April 2024, Adicet presented preclinical data for ADI-270 at the American Society of Gene and Cell Therapy (ASGCT) showing robust anti-tumor activity in an in vivo model of ccRCC, including tumor infiltration, resistance to the immunosuppressive tumor microenvironment, and potent activity via CAR and innate-mediated targeting.
- In July 2024, the Company announced that FDA Fast Track Designation had been granted to ADI-270 for the potential treatment of patients with metastatic/advanced ccRCC who have been treated with an immune checkpoint inhibitor and a vascular endothelial growth factor inhibitor.
- In December 2024, Adicet announced the dosing of the first patient in the Phase 1 clinical trial evaluating ADI-270 in

patients with metastatic/advanced ccRCC.

- Preliminary clinical data from the ADI-270 Phase 1 trial in ccRCC are expected in the first half of 2025.

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 ADI-270 and the potential safety, tolerability and efficacy for the treatment of autoimmune diseases and cancer; ADI-001’s potential to be an off-the-shelf treatment option for autoimmune indications; ADI-270’s potential to be the first gamma delta CAR T cell therapy to address solid tumors; timing and success of the Phase 1 clinical trial of ADI-001 in LN, SLE, SSc, AAV, IIM and SPS, including timing and expectations for enrollment and future data releases; timing and success of the Phase 1 clinical trial of ADI-270 in ccRCC, including expectations for future data releases; and expectations regarding Adicet’s uses of capital, expenses and financial results, including the expected cash runway.

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 titled “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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