Adicet Bio Receives FDA Fast Track Designation for ADI-001 for the Treatment of Systemic Sclerosis (SSc)

February 27, 2025

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Feb. 27, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to ADI-001 for the potential treatment of adult patients with systemic sclerosis (SSc).

Fast Track Designation is a process designed to facilitate development and expedite the review of drugs intended to treat serious conditions and fill an unmet medical need.

About ADI-001

ADI-001 is an investigational allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapy targeting CD20 for the treatment of autoimmune diseases. ADI-001 has been granted Fast Track Designation by the FDA for the treatment of relapsed/refractory class III or class IV lupus nephritis (LN), systemic lupus erythematosus (SLE) with extrarenal involvement and systemic sclerosis (SSc). The Company is advancing ADI-001 across six autoimmune indications. Patient enrollment is ongoing in the Phase 1 study evaluating ADI-001 for the treatment of LN. Patient enrollment in SLE, SSc, idiopathic inflammatory myopathy (IIM, or myositis), and stiff person syndrome (SPS) is expected to be initiated in the second quarter of 2025. Initiation of enrollment in anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV) is expected in the second half of 2025. In the Phase 1 GLEAN trial, ADI-001 was shown to target B-cells via an anti-CD20 CAR and demonstrated robust exposure and complete CD19+ B-cell depletion both in blood and secondary lymphoid tissue.

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 the initiation of patient enrollment for the Phase 1 trial of ADI-001 in SLE, SSc, IIM, SPS and ANCA AAV and potential benefits resulting from the Fast Track Designation.

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 geopolitical conflicts and economic conditions on Adicet’s business and financial results, including with respect to disruptions to Adicet’s 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 FDA 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 and periodic and current reports on Form 10-Q and Form 8-K filed 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.