Adicet Bio Presents Clinical Biomarker Data for Off-the-Shelf CAR T Cell Therapy in an Oral Session at the American College of Rheumatology (ACR) Convergence 2024

November 16, 2024

-Data demonstrate characteristics essential for treatment of autoimmune diseases, including robust tissue homing and complete CD19+ B cell depletion in secondary lymphoid tissue

-Results highlight the potential benefits unique to gamma delta 1 CAR T cell therapy and ADI-001's potential as a best-in-class off-the-shelf cell therapy for autoimmune diseases

-The company is pursuing ADI-001 in a basket study across six indications including lupus nephritis (LN), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS) and anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV)

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Nov. 16, 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 clinical biomarker data from the ADI-001 Phase 1 GLEAN trial which demonstrates robust tissue homing, significant CAR T cell activation, and complete CD19+ B cell depletion in secondary lymphoid tissue will be featured in an oral session at ACR Convergence 2024 in Washington, D.C., November 14-19.

"We believe the key to advancing care for autoimmune patients is to develop a therapeutic candidate that demonstrates robust tissue homing, complete CD19+ B cell depletion in tissue, and superior drug exposure in secondary lymphoid tissue with a positive safety profile. We are proud to share data and analyses, including clinical biomarker data, at ACR that support the potential of ADI-001 in autoimmune diseases," said Francesco Galimi, M.D., Ph.D., Chief Medical Officer. "After activating clinical trial sites for LN and receiving investigational new drug application (IND) clearances to pursue additional autoimmune indications, we are committed to advancing ADI-001 in a basket study across six autoimmune indications. This strategy highlights our focus on addressing the significant unmet medical needs of patients who urgently require innovative and effective new treatment options."

A summary of the results is reported below:

- ADI-001 demonstrated significant levels of CAR T cell activation and tissue exposure in lymph node biopsies in the GLEAN trial, representing a range of 27-64% of total cellular material detected by ddPCR in evaluable biopsies at the 1E9 dose, and exceeding levels previously reported for patients who received autologous alpha-beta CAR T therapies. CAR T cells detected in tissues also demonstrated a robust activation profile, based on in situ levels of granzyme B.
    - Recently published studies have demonstrated depletion of CD19+ plasmablasts, memory B cells and naïve B cells in peripheral blood using anti-CD20 targeted antibodies, however, these CD20-targeted antibody modalities failed to fully deplete B cells within secondary lymphoid tissue.
- Concurrent with ADI-001 tissue trafficking and activation, complete depletion of CD19+ B cells within analyzed lymph node tissue was also observed. These results support ADI-001's potential for achieving complete B-cell depletion in peripheral blood and within tissues.

Details of the oral presentation

Title: ADI-001: An Allogeneic CD20-targeted γδ CAR T Cell Therapy with Potential for Improved Tissue Homing in Autoimmune Indications
Session Name: Abstracts: Miscellaneous Rheumatic & Inflammatory Diseases II
Abstract Number: 1866169
Presenting Author: Monica Moreno, Ph.D.
Date and Time: November 19, 2024; 12:00 p.m. – 12:15 p.m. ET

About ADI-001 in Autoimmune Diseases

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 (LN). Adicet is exploring the potential of ADI-001 in a basket study across six indications including lupus nephritis (LN), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS) and anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV).

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

About the Phase 1 Clinical 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.

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 potential safety, tolerability and efficacy of ADI- 001 in multiple autoimmune indications; the potential for ADI-001 to be best-in-class allogenic cell therapy for autoimmune diseases; and the clinical development of ADI-001 in LN, SLE, SSc, IIM, SPS and AAV.

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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