Adicet Announces FDA Clearance of IND Application for First-in-Class Allogeneic CAR Gamma-Delta T Cell Therapy

October 22, 2020

Phase 1 Clinical Study will Evaluate ADI-001 Safety and Efficacy in Patients with B-cell non-Hodgkin's lymphoma

MENLO PARK, Calif. and BOSTON, Oct. 22, 2020 (GLOBE NEWSWIRE) -- Adicet Bio, Inc. (Nasdaq: ACET), a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for ADI-001, an allogeneic gamma delta (γδ) T cell therapy expressing a chimeric antigen receptor (CAR) targeting CD20 for treatment of non-Hodgkin's lymphoma (NHL). The active IND enables the Company to initiate the first-in-human clinical trial to assess safety and efficacy of ADI-001 in NHL patients.

"The clearance of the IND for ADI-001 by the FDA is a significant milestone in the development of CAR γδ T cell therapies by Adicet, and marks the beginning of clinical development of a deep pipeline of "off-the-shelf" γδ T cell products," said Chen Schor, President and Chief Executive Officer of Adicet. "We are particularly excited to advance on our goal to exploit the therapeutic potential of our first in class engineered CAR γδ T cell therapy in NHL patients. We believe that ADI-001 offers the opportunity for on demand treatment, selective tumor targeting, innate and adaptive anti-tumor immune response, and durable activity in patients. We look forward to advancing our product pipeline to address additional solid and hematologic tumors."

The Phase 1 study for ADI-001 will enroll up to 80 late-stage non-Hodgkin's lymphoma patients at a number of cancer centers across the U.S. The study includes a dose finding portion followed by dose expansion cohorts to explore the activity of ADI-001 in multiple subtypes of NHL. Site initiation activities are underway and interim clinical data from this study are expected in 2021.

About ADI-001

ADI-001 is an investigational allogeneic gamma delta T cell therapy being developed as a treatment for B-cell non-Hodgkin's lymphoma (NHL). ADI-001 targets malignant B-cells via an anti-CD20 CAR and via the gamma delta T cell endogenous cytotoxicity receptors. Gamma delta T cells engineered with an anti-CD20 CAR have demonstrated highly potent antitumor activity in preclinical models, leading to effective long-term control of tumor growth.

About Adicet

Adicet is a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases. Adicet is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors and T cell receptor-like antibodies to enhance selective tumor targeting, facilitate innate and adaptive anti-tumor immune response, and improve persistence for durable activity in patients. For more information, please visit our website at http://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 business and operations of Adicet including, but not limited to preclinical and clinical development of Adicet's product candidates, including future plans or expectations for ADI-001 and potential therapeutic effects of ADI-001, the timing and outcome of discussions with FDA and other regulatory agencies, expectations regarding the design, implementation, timing, and success of its future clinical studies of ADI-001, including whether they are pivotal or would support registration, and expectations regarding its other CAR γδ T cell therapy development activities. 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 COVID-19 on our business and financial results, including with respect to disruptions to our clinical trials, business operations, and ability to raise additional capital; Adicet's ability to execute on its strategy; that positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; future clinical studies may fail to demonstrate adequate safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; regulatory developments in the United States and foreign countries; the company's estimates regarding expenses, future revenue, and capital requirements; as well as those risks and uncertainties set forth in the company's most recent annual report on Form 10-K and subsequent filings with the Securities and Exchange Commission. 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 our periodic reports on Form 10-Q and Form 8-K filed with the 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.

Adicet Bio, Inc.
Investor and Media Contacts
Anne Bowdidge
abowdidge@adicetbio.com

Janhavi Mohite
Stern Investor Relations, Inc.
212-362-1200

janhavi.mohite@sternir.com

Source: Adicet Bio, Inc.