Adicet Bio Reports Positive Clinical Update from ADI-001 Phase 1 Trial in Relapsed/Refractory Non-Hodgkin's Lymphoma (NHL)

May 26, 2022

As of the February 14, 2022 ASCO abstract data-cut date, ADI-001 demonstrated a 67% complete response rate with positive preliminary durability data and a favorable safety and tolerability profile

Updated data from a May 31, 2022 data-cut date will be presented during oral presentation at ASCO Annual Meeting on June 6, 2022, at 6:00am PT / 9:00am ET

Company to host webcast on June 6, 2022, at 1:30pm PT / 4:30pm ET

MENLO PARK, Calif. & BOSTON--(BUSINESS WIRE)--May 26, 2022-- Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing first-in-class allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapies for cancer, today announced that an abstract detailing updated safety and efficacy data from the Company's Phase 1 study of ADI-001 for the potential treatment of relapsed or refractory B-cell Non-Hodgkin's Lymphoma (NHL) was made available as part of the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, to be held June 3-7, 2022. The abstract provides a summary of clinical data as of a February 14, 2022, data-cut date.

"We are very pleased to see the continued positive data resulting from our ongoing Phase 1 clinical trial evaluating ADI-001 in relapsed/refractory NHL. We believe that our allogeneic gamma delta CAR T cell therapy approach may improve complete response rate and durability by the complementary innate, adaptive and CAR-mediated anti-tumor response," said Chen Schor, President and Chief Executive Officer of Adicet. "We look forward to presenting updated data on safety, efficacy, pharmacokinetics and longer follow up, including available data from patients enrolled in dose level 3, at the upcoming 2022 ASCO Annual Meeting with a coinciding press release as well as a company webcast later that afternoon."

Data highlights as of the February 14, 2022 data-cut date included in the ASCO abstract were as follows:

- Six evaluable patients were enrolled in dose level 1 (DL1; 30 million CAR+ cells) and dose level 2 (DL2; 100 million CAR+ cells), 33% (2/6) were female and the median age was 62 years (range 45-75). There were five patients with large B-cell lymphoma and one with mantle cell lymphoma. Indolent lymphomas, such as follicular lymphoma, are currently not enrolled in the study.
- Overall, the patients were heavily pretreated with a median number of prior therapies of 3.5 (range 2-5) and had a poor prognostic outlook as indicated by the median International Prognostic Index (IPI) score of 3.5 (range 2-4). One patient previously progressed following two prior treatments with autologous anti-CD19 CAR T cell therapy (lisocabtagene maraleucel) prior to receiving ADI-001.
- At Day 28, the overall response rate (ORR) and the complete response (CR) rate based upon independent central reading by PET/CT were 67% (4/6 patients).
- As of the February 14, 2022 data-cut date, of the four patients who achieved CR after treatment with ADI-001:
  - Two patients remained in CR with ≥ three months post-treatment follow-up, including a triple-hit large B-cell lymphoma patient who had previously progressed following two administrations of autologous anti-CD19 CAR-T and a total of five lines of prior therapy.
  - As previously disclosed, one patient, a 66-year-old female who had responded to ADI-001, developed COVID-19 related pneumonia approximately two and a half months after ADI-001 administration and later died of complications from it, unrelated to ADI-001. This patient was previously reported as a partial response (PR) by local radiological assessment and has been assessed as a CR by independent central reading.
  - One patient with a CR had not reached the three-month assessment date as of the data-cut date for the ASCO abstract submission.
- Safety data from the trial at the February 14, 2022 data-cut date were consistent with the previously reported well tolerated profile, with no occurrence of Grade ≥ 3 Cytokine Release Syndrome (CRS), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) or Graft vs Host Disease. No dose-limiting toxicities were documented.
- All response data have been determined per protocol by independent central reading of PET/CT per Lugano (2014) criteria.

The full abstract is available online on the ASCO website.

Updated data from a May 31, 2022 data-cut date will be presented during an oral presentation by Sattva Neelapu, M.D. Professor in the Department of Lymphoma/Myeloma at The University of Texas MD Anderson Cancer Center, at the ASCO Annual Meeting on June 6, 2022. Adicet will summarize

the data from the May 31, 2022 data-cut date in a press release and provide additional information in a company webcast on June 6, 2022.

Details of the oral presentation are as follows:

Abstract Number: 7509
Abstract Title: A Phase 1 Study of ADI-001: Anti-CD20 CAR-engineered Allogeneic Gamma Delta (γδ) T cells in Adults with B-cell malignancies
Presenting Author: Sattva Neelapu, M.D., The University of Texas MD Anderson Cancer Center
Session Type/Title: Clinical Science Symposium/ Beating Bad Blood: The Power of Immunotherapy in Hematologic Malignancies
Date: Monday, June 6, 2022
Time: 8:00 AM-9:30 AM CDT

Adicet Investor Webcast/ Conference Call Information

The Company will host a conference call and webcast on June 6, 2022, at 4:30 p.m. ET to discuss the results. The live webcast of the presentation can be accessed under “Presentations & Events” in the investors section of the Company's website at www.adicetbio.com or by dialing (877) 800-3802 (domestic) or +1 (615) 622-8057 (international) and reference the conference ID 5466375. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About ADI-001

ADI-001 is an investigational allogeneic gamma delta CAR T cell therapy being developed as a potential treatment for relapsed or refractory B-cell NHL. ADI-001 targets malignant B-cells via an anti-CD20 CAR and via the gamma delta innate and T cell endogenous cytotoxicity receptors. Gamma delta T cells engineered with an anti-CD20 CAR have demonstrated potent antitumor activity in preclinical models, leading to long-term control of tumor growth. In April 2022, ADI-001 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed or refractory B-cell NHL.

About the GLEAN Study

This Phase 1 study is an open-label, multi-center study of ADI-001 enrolling adults diagnosed with B-cell malignancies who have either relapsed, or are refractory to at least two prior regimens. The primary objectives of the study are to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of ADI-001, and to determine optimal dosing as a monotherapy. The study is expected to enroll approximately 75 patients. For more information about the clinical study design, please visit www.clinicaltrials.gov (NCT04735471).

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer. Adicet is advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with CAR and T cell receptor-like targeting moieties 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 www.adicetbio.com.

Available Information

Adicet announces material information to the public about the Company, its product candidates and clinical trials, and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission (SEC), press releases, public conference calls, webcasts, the investor relations section of the Company website at investor.adicetbio.com and the Company’s Twitter account (@AdicetBio), in order to achieve broad, non-exclusionary distribution of information to the public and for complying with its disclosure obligations under Regulation FD.

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. These forward-looking statements include, but are not limited to, express or implied statements regarding the potential safety, durability, tolerability and therapeutic effects of ADI-001 and the expectations around the upcoming release of interim clinical data from Adicet’s Phase 1 trial of ADI-001 in NHL patients at the ASCO Annual Meeting.

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 Adicet’s business and financial results, including with respect to disruptions to Adicet’s clinical trials, business operations 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 from a clinical study may not necessarily be predictive of the results of future or ongoing clinical 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. 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-K for the year ended December 31, 2021 and subsequent 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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