Adicet Bio Reports Emerging Data from ADI-001 Phase 1 Trial at the American Society of Clinical Oncology Annual Meeting

June 6, 2022

ADI-001 demonstrated 75% CR and ORR rate across all dose levels with favorable safety and tolerability profile in patients with relapsed/refractory high grade aggressive Non-Hodgkin's Lymphoma (NHL) , as of May 31, 2022 data-cut date

80% ORR and CR rate at dose levels 2 and 3 combined

100% ORR and CR rate in three anti-CD19 CAR-T relapsed patients

50% of evaluable patients with at least six months follow-up remain cancer free

Dose-related increase of ADI-001 exposure observed in blood

Company expects to identify recommended Phase 2 dose in second half of 2022 and initiate at least one potentially pivotal study in first half of 2023

Company to host webcast today at 1:30pm PT / 4:30pm ET

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Jun. 6, 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 emerging positive 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) in an oral presentation at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting on June 6, 2022. The presentation outlines a summary of clinical data as of a May 31, 2022, data-cut date.

"Adicet is a pioneer in the field of gamma delta CAR T cell therapies and it is gratifying to see the highly encouraging clinical data for ADI-001 unfold as a potential best-in-class therapy for NHL," said Chen Schor, President and Chief Executive Officer of Adicet Bio. "Notably, with a favorable safety and tolerability profile, treatment to date with ADI-001 demonstrated an impressive CR rate, including 100% in CAR-T relapsed patients, and very encouraging durability of response. We look forward to discussing the data in more detail and outlining next steps in our webcast this afternoon."

"It is impressive to see 50 percent of six-month evaluable patients cancer free beyond seven months. One of these patients had previously relapsed after two treatments with autologous anti-CD19 CAR T and now remains cancer free seven and a half months following administration of ADI-001, suggesting the patient has had major clinical benefit from ADI-001. This is particularly notable because patients who relapse after autologous anti-CD19 CAR T have dismal outcomes with a median survival of approximately six months," said Sattva Neelapu, M.D., Professor in the Department of Lymphoma/Myeloma at The University of Texas MD Anderson Cancer Center. "When we look at the totality of these early data, we have an indicator that allogeneic gamma-delta CAR T cell therapy like ADI-001 could be a significant advance."

"NHL remains a disease that is very difficult to treat, especially in high-risk patients with aggressive disease. Our study is enrolling patients with aggressive B-cell lymphoma, including patients with double-hit and triple-hit high-grade B cell lymphoma and patients who had a prior relapse to autologous anti-CD19 CAR T therapy," said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet Bio. "We are encouraged by the CRs observed to date in the Phase 1 study and are committed to rapidly advancing ADI-001 into a potential pivotal program."

Data highlights as of the May 31, 2022 data-cut date included in the ASCO presentation are as follows:

- Of the eight evaluable patients, three received ADI-001 at dose level 1 (30 million CAR+ cells), three received ADI-001 at dose level 2 (100 million CAR+ cells) and two received ADI-001 at dose level 3 (300 million CAR+ cells). There are currently no patients with indolent lymphoma, such as follicular lymphoma, enrolled in the study.
- Patients were heavily pretreated with a median number of prior therapies of 4 (range 2-5) and had a poor prognostic outlook as indicated by the median International Prognostic Index (IPI) score of 4 (range 2-5).
- ADI-001 treatment demonstrated a 75% overall response rate (ORR) and complete response (CR) in the study across all dose levels. In dose levels 2 and 3 combined, ADI-001 demonstrated an 80% ORR and CR rate.
- In three patients that previously relapsed after prior autologous anti-CD19 CAR T therapy, treatment with ADI-001 demonstrated 100% ORR and CR rate. These patients included a triple-hit high grade B-cell lymphoma patient with prior exposure to Liso-cel, as well as a DLBCL patient and a double-hit high grade B-cell lymphoma patient who had previously achieved a PR to Axi-cel.
- Early data indicate encouraging durable anti-tumor responses with potential for dose related increase in durability. 50% (2 of 4) of evaluable patients with at least six months follow up remain cancer free.
- Detection of circulating ADI-001 in the blood by flow cytometry indicated in vivo expansion and dose-related increase of ADI-001 exposure in patients.

- ADI-001 was well tolerated in the study to date. There were no occurrences of dose-limiting toxicities, graft vs host disease (GvHD), or Grade 3 or higher Cytokine Release Syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) reported. There were no infections associated with enhanced lymphodepletion (eLD).

Table 1: Summary of ADI-001 interim data from three dosing cohorts: *

Dose Level	Age/Sex	B-cell lymphoma subtypes	# prior lines of therapies	Time since ADI-001 initial dosing (months)	Prior CAR T?	BOR by Lugano Criteria 2014
DL 1 30 million CAR+ cells	62/F	Transformed DLBCL (from chronic lymphocytic leukemia)	5 prior lines	>6	No	PD
	66/F	Transformed high grade B-cell lymphoma (from follicular lymphoma)	4 prior lines	>6	No	CR
	75/M	Triple-hit high grade B-cell lymphoma	5 prior lines	>6	Yes	CR
DL 2 100 million CAR+ cells	62/M	Mantle cell lymphoma	5 prior lines	>6	No	CR
	45/M	Diffuse large B-cell lymphoma	3 prior lines	3-6	No	PD
	61/M	Diffuse large B-cell lymphoma	2 prior lines	3-6	No	CR
DL 3 300 million CAR+ cells	62/M	Double-hit high grade B-cell lymphoma	4 prior lines	3-6	Yes	CR
	64/F	Diffuse large B-cell lymphoma	4 prior lines	1-3	Yes	CR

*Efficacy-evaluable patients as of the May 31, 2022 data-cut date. Data are subject to further review and verification. BOR= best overall response. PD=progressive disease.

Table 2: ADI-001 Preliminary Efficacy Data:
(Per protocol analysis, independent radiographic assessment using Lugano 2014)

	DL1 (3E7) (N=3)	DL2 (1E8) (N=3)	DL3 (3E8) (N=2)	Total (N=8)	Prior CD19 CAR-T (N=3)
ORR / BOR	67% (2/3)	67% (2/3)	100% (2/2)	75% (6/8)	100% (3/3)
CR, % (N)	67% (2/3)	67% (2/3)	100% (2/2)	75% (6/8)	100% (3/3)

*Efficacy-evaluable patients as of the May 31, 2022, data-cut date. Data are subject to further review and verification.

As of the May 31, 2022, data-cut date, of the six patients who achieved CR:

Dose level 1:

As previously disclosed, one patient administered ADI-001 in dose level 1, a 66-year-old female who had achieved a CR, 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 triple-hit high grade B-cell lymphoma in dose level 1 who had relapsed following two prior treatments with autologous anti-CD19 CAR T therapy, had a CR after treatment with ADI-001. The patient developed a local skin relapse at four months, and was administered local radiotherapy. The skin lesion resolved with no systemic therapy provided to the patient. The patient continues to be cancer free seven and a half months following administration of ADI-001, as measured by a negative PET/CT scan.

Dose level 2:

Both patients administered ADI-001 in dose level 2 have ongoing CR. One patient has a CR beyond seven months and one patient has a CR beyond four and a half months.

Dose level 3:

Both patients administered ADI-001 in dose level 3 have ongoing CR with follow-up beyond three and one month, respectively.

In summary, 50% of evaluable patients with at least six months follow up (2 of 4) remain cancer free.

Table 3: ADI-001 Preliminary Safety Data in Efficacy-Evaluable Patients+

	DL1 (3E7) N=3		DL2 (1E8) N=3		DL3 (3E8) N=2		Total N=8	
Adverse Event Types	All Grade N (%)	Gr ≥3 N (%)	All Grade N (%)	Gr ≥3 N (%)	All Grade N (%)	Gr ≥3 N (%)	All Grade N (%)	Gr ≥3 N (%)
CRS	2 (67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (25)	0 (0)
ICANS	0 (0%)	0 (0%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)	1 (13)	0 (0)
GvHD	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0)	0 (0)
DLTs	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0)	0 (0)
Infection*	1(33%)	1(33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (13)	1 (13)
SAE - TEAE	1(33%)	1(33%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)	2 (25)	1 (13)

+Safety assessment was performed using the Common Terminology Criteria for Adverse Events (v5) and the American Society for Transplantation and Cellular Therapy criteria. The two ADI-001-related adverse events of special interest (AESI) were a Grade 1 CRS at DL1 and a Grade 1 ICANS at sDL2, which resolved within 24 hours without medical intervention; No DLTs or GvHD; No treatment discontinuations due to AEs; two patient administered standard lymphodepletion (sLD) and six patients eLD; There were no eLD-associated clinical infection.

*One patient in DL 1 who received sLD developed COVID-19 pneumonia later died of complications of it, unrelated to ADI-001.

Given the safety profile to date, the protocol was amended to include a new DL 4 (1E9 CAR+ cells) and a potential ADI-001 consolidation dosing at DL3 to finalize the recommended Phase 2 dose in the second half of 2022. The Company expects to provide at least one additional clinical update for the ADI-001 Phase 1 study in the second half of 2022. The Company will discuss with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) the design of two pivotal intent studies and a potential path to support a Biologics License Application (BLA) and Marketing Authorization Application (MAA) for ADI-001 and initiate at least one potentially pivotal study in the first half of 2023.

Details of the ASCO Oral Presentation:

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

Webcast/ Conference Call information

The Company will host a conference call and webcast today, June 6, 2022, at 4:30pm 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 referencing 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 anti-tumor 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, including the expected design, implementation, timing and success of ADI-001, plans and timing for the release of additional clinical data from Adicet's Phase 1 trial of ADI-001 in relapsed/refractory NHL patients. Future progress of the GLEAN study, including ongoing patient enrollment; and timing of a dose selection for the Phase 2 trial in the second half of 2022 and initiation of a potentially pivotal program in the first half of 2023.

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, including interim 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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