

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 10, 2022

Adicet Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38359
(Commission File Number)

81-3305277
(IRS Employer
Identification No.)

200 Berkeley Street, 19th Floor
Boston, Massachusetts
(Address of Principal Executive Offices)

02116
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 503-9095

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ACET	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On December 10, 2022, Adicet Bio, Inc. (Adicet or the Company) issued a press release titled “Adicet Bio Reports Positive Data from Ongoing ADI-001 Phase 1 Trial in Patients with Relapsed or Refractory Aggressive B-Cell Non-Hodgkin’s Lymphoma (NHL),” a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

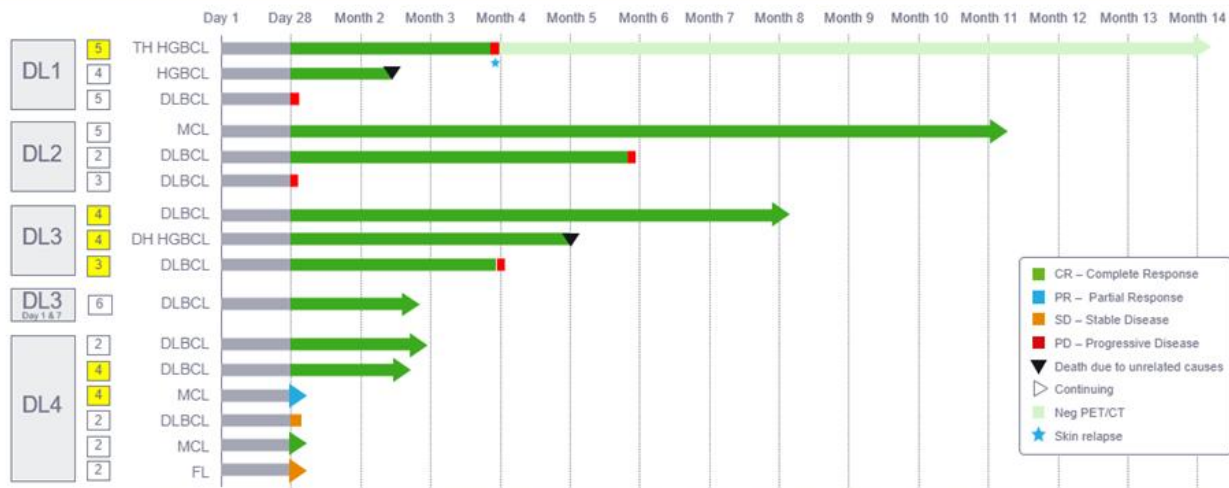
Item 8.01 Other Events.

On December 10, 2022, the Company issued a press release and presented on interim 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). Data highlights as of the December 5, 2022 data-cut date are as follows:

- Of the 16 evaluable patients, three received ADI-001 at dose level 1 (DL1) (30 million CAR+ cells), three received ADI-001 at dose level 2 (DL2) (100 million CAR+ cells), three received ADI-001 at dose level 3 (DL3) (300 million CAR+ cells), one received two infusions of ADI-001 at DL3 (2X 300 million CAR+ cells on day one and seven following a single lymphodepletion), and six received ADI-001 at dose level 4 (DL4) (1 billion CAR+ cells).
- On an exploratory basis, primarily to understand safety and pharmacokinetics of a second ADI-001 dose, the first and second patient in DL3 while testing negative for minimal residual disease (MRD) and in complete response (CR), received a second DL3 dose, three and two months after the first infusion, respectively.
- Patients were heavily pretreated with a median number of prior therapies of four (range two-six) and had a poor prognostic outlook based on their median International Prognostic Index (IPI) score.
- ADI-001 treatment demonstrated a 75% overall response rate (ORR) and 69% CR rate in the study across all dose levels.
- In five large B-cell lymphoma (LBCL) patients that previously relapsed after prior autologous anti-CD19 CAR T therapy, treatment with ADI-001 demonstrated 100% ORR and CR rate (5/5). These patients included a triple-hit high-grade B-cell lymphoma patient, three diffuse large B-cell lymphoma (DLBCL) patients, and a double-hit high-grade B-cell lymphoma patient. ADI-001 resulted in CR in patients who previously showed a partial response (PR) to autologous CAR T (2/2).
- An 86% CR rate (6/7) was observed in LBCL patients across DL3 and above. 75% CR rate (9/12) in LBCL across all dose levels.
- Both DL2 and DL3 demonstrated a six-month CR rate of 33%. Patient follow up continues in DL4 to assess six-month durability.
- Circulating ADI-001 cells were visible through day 28 in peripheral blood at DL4.
- ADI-001 was generally 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.

Figure 1: ADI-001: Preliminary Efficacy Data:

ADI-001: Preliminary Efficacy Data



Dec 5, 2022 Data-cut date, n=16 evaluable patients. Data are subject to further review and verification. The third patient in DL4 (PR) result was based on central radiological assessment. Patient tested MRD negative and investigator reported MRD-negative CR, currently under review. On an exploratory basis, primarily to understand safety/PK of a second ADI-001 dose, the first and second patient in DL3 while testing negative for MRD and while in CR, received a second DL3 dose, three and two months after the first infusion, respectively.

DLH= Double hit, DLBCL= Diffuse large B-cell lymphoma, FL= follicular lymphoma, HGBCL= High grade B-cell lymphoma, MCL= Mantle cell lymphoma, TH= Triple hit



Table 2: Summary of Phase 1 ADI-001 Preliminary Safety Data in Efficacy-Evaluable Patients as of the December 5, 2022 data-cut date:+

Adverse Event Types	DL1 (3E7) N=3		DL2 (1E8) N=3		DL3 (3E8) N=3		DL3 (2X 3E8) Day 1&7 N=1		DL4 (1E9) N=6		Total N=16	
	All Grade N (%)	Gr ≥3 N (%)	All Grade N (%)	Gr ≥3 N (%)	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%)	1 (100%)	0	3 (50%)	0 (0%)	6 (38%)	0 (0)
ICANS	0 (0%)	0 (0%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)	0	0	1 (17%)	0 (0%)	2 (13%)	0 (0)
GvHD	0 (0%)	0 (0%)	0 (0%)	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%)	0 (0%)	0 (0)	0 (0)
Infection	1 (33%)	0 (0%)	0 (0%)	0 (0%)	1 (33%)	1 (33%)	0	0	0 (0%)	0 (0%)	2 (13%)	1 (6%)
SAE - TEAE	1 (33%)	1 (33%)	2 (67%)	2 (67%)	2 (67%)	2 (67%)	0	0	1 (17%)	0 (0%)	6 (38%)	5 (31%)

+Safety assessment was performed using the Common Terminology Criteria for Adverse Events (v5) and the American Society for Transplantation and Cellular Therapy criteria.

Enrollment in the Phase 1 clinical study of ADI-001 is currently ongoing to provide additional durability data and further support the recommended Phase 2 dose.

The Company expects to discuss with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) a potential path to support a Biologics License Application (BLA) and Marketing Authorization Application (MAA) for ADI-001, including a potentially pivotal study in post-CAR T LBCL patients in the second quarter of 2023. The Company is also evaluating potential second pivotal study in earlier-line LBCL patients.

The disclosure under this Item 8.01 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. 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, durability, tolerability and efficacy of ADI-001; the expected progress, timing and success of the Phase 1 study of ADI-001 in relapsed/refractory NHL patients, including ongoing patient enrollment and the identification of a

recommended Phase 2 dose; initiation of a potentially pivotal study in the second quarter of 2023 and the potential for a second pivotal study in earlier line LBCL patients; and the Company's plans to discuss with the EMA and FDA regarding the path to support a BLA and MAA for ADI-001.

Any forward-looking statements in this Item 8.01 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 events or 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 preclinical or clinical studies, 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 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. 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 for the year ended December 31, 2021 and subsequent filings with the Securities and Exchange Commission. All disclosure under this Item 8.01 is as of the date of this Form 8-K, and Adicet undertakes no duty to update this information unless required by law.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Adicet Bio, Inc. on December 10, 2022, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ADICET BIO, INC.

Date: December 12, 2022

By: /s/ Nick Harvey

Name: *Nick Harvey*

Title: *Chief Financial Officer*



Adicet Bio Reports Positive Data from Ongoing ADI-001 Phase 1 Trial in Patients with Relapsed or Refractory Aggressive B-Cell Non-Hodgkin's Lymphoma (NHL)

ADI-001 demonstrated 75% overall response rate (ORR) and 69% complete response (CR) across all dose levels with favorable safety and tolerability profile in patients with relapsed/refractory high-grade aggressive NHL, as of December 5, 2022 data-cut date

100% ORR and CR rate in 5/5 anti-CD19 autologous chimeric antigen receptor T cells (CAR-T) relapsed large B-cell lymphoma (LBCL) patients

86% CR rate in LBCL patients across dose level three (DL3) and above (75% CR rate in LBCL patients across all dose levels)

Both dose level 2 (DL2) and DL3 demonstrated a six-month CR rate of 33%; Patient follow up continues in dose level 4 (DL4) to assess six-month durability

Circulating ADI-001 cells visible through day 28 in peripheral blood at DL4

Company expects to initiate a potentially pivotal study in post-CAR T LBCL patients in the second quarter of 2023; Evaluating potential second pivotal study in earlier-line LBCL patients

Company to host investor webcast Sunday, December 11 at 9:00 am ET

Redwood City, CA and Boston – December 10, 2022 – Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer, today announced positive safety and efficacy data from the Company's ongoing Phase 1 study of ADI-001 for the potential treatment of relapsed or refractory B-cell NHL. The Company believes these data continue to support the potential of Adicet's investigational gamma delta CAR T cell therapy to provide significant benefit both in terms of anti-tumor activity and safety. Based on the study findings as of a December 5, 2022 data cut-date, Adicet plans to transition ADI-001 into a potentially pivotal program in the second quarter of 2023.

"It is very encouraging to see durability of response at six months and beyond along with a continued favorable safety profile in patients with aggressive lymphomas," said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet Bio. "Notably, a 100% complete response rate with ADI-001 in post-autologous CAR T-relapsed LBCL patients may offer a potential treatment option to those patients, who do not currently have effective therapies."

“These data are exciting and support our belief that ADI-001 has the potential to generate meaningful clinical responses for patients,” said Chen Schor, President and Chief Executive Officer of Adicet Bio. “Based on the positive data reported today, we plan to transition ADI-001 into a potential pivotal program with a potentially best-in-class ORR, CR and durability profile in the second quarter of 2023.”

“As these data mature, it is impressive to see continued complete responses across all dose levels including six-month durable responses and a 100% ORR and CR rate in LBCL patients previously treated with autologous CAR T therapy,” said Sattva Neelapu, M.D., Professor in the Department of Lymphoma/Myeloma at The University of Texas MD Anderson Cancer Center. “Achieving these results in such high-risk patients with aggressive disease suggests that an allogeneic gamma delta CAR T cell therapy like ADI-001 could provide a significant advance for NHL patients.”

Data highlights as of the December 5, 2022 data-cut date were as follows:

- Of the 16 evaluable patients, three received ADI-001 at dose level 1 (DL1) (30 million CAR+ cells), three received ADI-001 at DL2 (100 million CAR+ cells), three received ADI-001 at DL3 (300 million CAR+ cells), one received two infusions of ADI-001 at DL3 (2X 300 million CAR+ cells on day one and seven following a single lymphodepletion), and six received ADI-001 at DL4 (1 billion CAR+ cells).
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- An 86% CR rate (6/7) was observed in LBCL patients across DL3 and above. 75% CR rate (9/12) in LBCL across all dose levels.
- Both DL2 and DL3 demonstrated a six-month CR rate of 33%; Patient follow up continues in DL4 to assess six-month durability.

- Circulating ADI-001 cells were visible through day 28 in peripheral blood at DL4.
- ADI-001 was generally 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.

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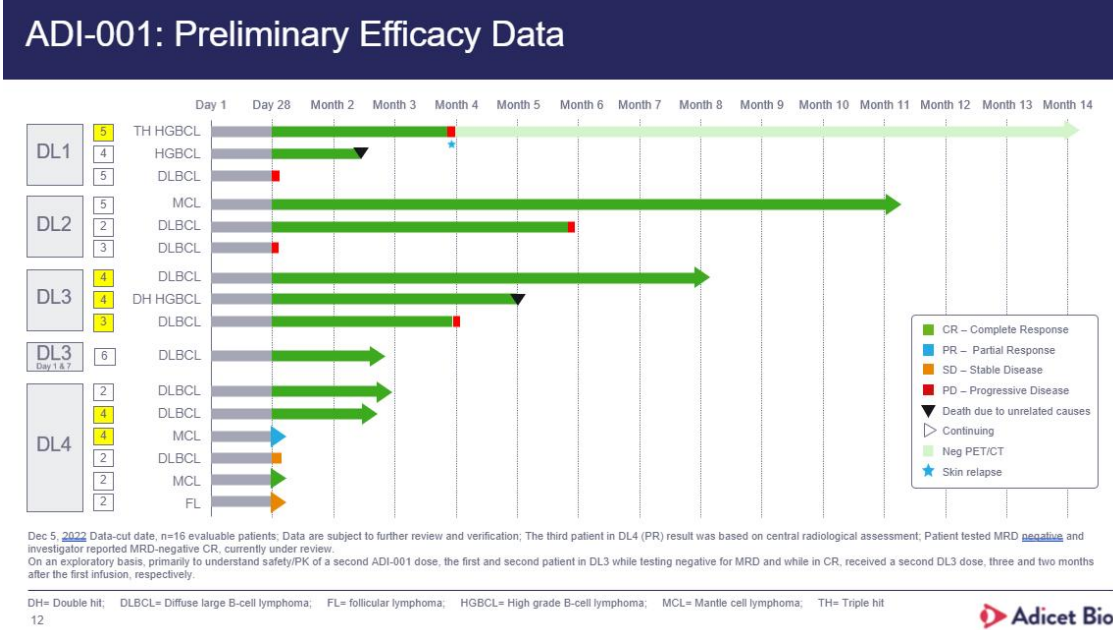


Table 2: Summary of Phase 1 ADI-001 Preliminary Safety Data in Efficacy-Evaluable Patients as of the December 5, 2022 data-cut date:†

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CRS	2 (67%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0	3 (50%)	0 (0%)	6(38%)	0 (0)
ICANS	0 (0%)	0 (0%)	1 (33%)	0 (0%)	0 (0%)	0 (0%)	0	0	1(17%)	0 (0%)	2(13%)	0 (0)
GvHD	0 (0%)	0 (0%)	0 (0%)	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%)	0 (0%)	0 (0)	0 (0)
Infection	1 (33%)	0 (0%)	0 (0%)	0 (0%)	1 (33%)	1 (33%)	0	0	0 (0%)	0 (0%)	2 (13%)	1 (6%)

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Enrollment in the Phase 1 clinical study of ADI-001 is currently ongoing to provide additional durability data and further support the recommended Phase 2 dose.

The Company expects to discuss with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) a potential path to support a Biologics License Application (BLA) and Marketing Authorization Application (MAA) for ADI-001, including potential pivotal studies in post-CAR-T LBCL patients and in earlier line LBCL patients, respectively.

Webcast/ Conference Call information

Adicet will host a webcast presentation on Sunday, December 11, 2022 at 9:00 a.m. EST to discuss the most recent data-cut from its ongoing Phase 1 study evaluating the safety and tolerability of ADI-001 for the potential treatment of relapsed or refractory B-cell NHL. The event will feature Sattva Neelapu, M.D., Professor in the Department of Lymphoma-Myeloma, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center, alongside members of the Adicet management team.

The live webcast of the presentation can be accessed by registering under “Presentations & Events” in the investors section of the Company’s website at <https://www.adicetbio.com>. Upon registration, all participants will receive a confirmation email with a unique passcode to provide access to the webcast event. To participate via telephone, please join by dialing 1-833-548-0276 (domestic) or 1-646-876-9923 (international) and referencing the conference ID 98173615816.

An archived replay will be available for 30 days following the presentation. 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 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 chimeric antigen receptors (CARs) and adaptors (CAbs), to enhance selective tumor targeting and facilitate innate and adaptive anti-tumor immune response for durable activity in patients. For more information, please visit our website at <https://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. 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, durability, tolerability and efficacy of ADI-001; the expected progress, timing and success of the Phase 1 study of ADI-001 in relapsed/refractory NHL patients, including ongoing patient enrollment and the identification of a recommended Phase 2 dose; initiation of a potentially pivotal study in the second quarter of 2023 and the potential for a second pivotal study in earlier line LBCL patients; and the Company’s plans to discuss with the EMA and FDA regarding the path to support a BLA and MAA for ADI-001.

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 preclinical or clinical studies, 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 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. 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.

**Adicet Bio., Inc.
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