Adicet Bio Announces Positive Safety and Efficacy Data from Prula-cel (formerly ADI-001) Study in Patients with Systemic Lupus Erythematosus with or without Lupus Nephritis

September 28, 2026

- Prula-cel shown to be generally well tolerated with no CRS greater than Grade 2 and no IEC-HS or ICANS -

-At 12-months, 54% of evaluable patients achieved DORIS remission and 50% of patients achieved CRR-

-All patients discontinued immunosuppressants –

- All but one patient tapered background steroids to ≤5 mg prednisone equivalent per day-

-Rapid reductions in SLEDAI-2K and PGA scores, consistent with autologous alpha beta CAR-T cell therapies-

-Plan to initiate pivotal lupus nephritis trial start-up activities in 4Q/2026; high DORIS remission rate may support expansion of pivotal study to include lupus without nephritis based on regulatory precedent-

-Company to host investor webcast at 8:00am ET today-

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sep. 28, 2026-- Adicet Bio, Inc. (Nasdaq: ACET), a clinical-stage biotechnology company discovering and developing allogeneic gamma delta CAR-T cell and *in vivo* CAR-T therapies for autoimmune diseases, hematologic malignancies and solid tumors, today announced safety and efficacy data from the Phase 1 study evaluating prulacabtagene leucel (prula-cel) as a potential treatment for patients with systemic lupus erythematosus (SLE) with or without lupus nephritis (LN). The data cut as of August 28, 2026 includes 22 efficacy evaluable patients (16 LN patients and 6 extra-renal SLE patients). All patients have follow-up of at least 6 months, and 13 patients have at least 12 months of follow-up. Based on these findings, the Company plans to initiate start-up activities for a pivotal study in LN in the fourth quarter of 2026. Given the high Definition of Remission in Systemic lupus (DORIS) remission rate observed in the study, the pivotal study may expand to include lupus patients without nephritis.

“We are excited to report clinical data for prula-cel reinforcing its potential to deliver meaningful, lasting remission after a single treatment for patients with SLE, including those with lupus nephritis,” said Lloyd Klickstein, M.D., Ph.D., Interim Chief Medical Officer and a Member of the Board of Directors. “We observed complete renal responses and DORIS remissions after a single dose of prula-cel in patients who had failed multiple prior therapies. Notably, these remissions were achieved off immunosuppression and were accompanied by biological evidence of an immune reset. In a disease where chronic therapy with limited efficacy and significant tolerability and safety considerations remains the standard of care, the prospect of durable, treatment-free remission after a single treatment could be transformative for individuals living with lupus.”

“Today’s results mark an exciting step forward for Adicet and for lupus patients with or without nephritis. The data suggests prula-cel has the potential to offer lupus patients a highly differentiated treatment option: a single dose, off-the-shelf therapy, with a favorable safety profile, that may lead to immunosuppressant free remission,” said Chen Schor, President and Chief Executive Officer of Adicet Bio “Importantly, the compelling efficacy data observed to date has been accompanied by a generally favorable safety profile with no cases of IEC-HS, no ICANS and no CRS beyond Grade 2 reported in the study. Combined with the FDA’s support of outpatient administration of prula-cel, and the scalability of our off-the-shelf manufacturing, these findings support the potential of prula-cel to redefine the treatment expectations for patients living with systemic lupus erythematosus with or without lupus nephritis. We look forward to progressing towards a potentially pivotal study by the end of 2026.”

Data highlights as of August 28, 2026, cut-off date were as follows:

- 22 patients (16 LN and 6 extra renal SLE) were evaluated with follow-up ranging from 6-21 months.
- **Efficacy endpoints.** Prula-cel treatment yielded high rates of immunosuppressant-free responses in a heavily pretreated population. Patients had a mean baseline of Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) of 13 and those with LN had mean urine protein-to-creatinine ratio (UPCR) of 2.8, and all had received at least three prior therapies (71% received four or more). At the 12-month mark, 50% of evaluable lupus nephritis patients achieved a complete renal response (CRR) and 54% of evaluable patients achieved DORIS remission. All 12-month responses were ongoing at 12 to 21 months of follow-up, except 1 patient with UPCR 0.65 g/g who remains off immunosuppressants. Reductions in mean SLEDAI-2K and Physician’s Global Assessment (PGA) were rapid and sustained, consistent with autologous alpha beta CD19 CAR-T therapies, and 85% of patients with 12-month follow-up achieved a PGA score below 0.5.
- **Safety Profile.** As of August 28, 2026, prula-cel was generally well tolerated and showed a favorable safety profile appropriate for outpatient dosing. Across the 24 safety-evaluable patients dosed with prula-cel, there was no cytokine release syndrome (CRS) greater than Grade 2. Grade 1 or 2 CRS occurred in 25% of patients. There were no dose-limiting toxicities (DLTs), no immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS), and no Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). Infections were reported in 54% of patients, with Grade 3 or higher in 8.3%. There were no cases of graft vs host disease (GvHD) observed. Per alignment with the U.S. Food and Drug Administration (FDA), this profile supports outpatient administration.
- **Immunosuppression and steroids.** All patients discontinued immunosuppressants, and all but one tapered background

steroids to 5 mg or less of prednisone equivalent.
- **Immune reset.** Multiple independent biomarkers provided evidence of an immune reset. All efficacy evaluable patients (22 of 22) achieved undetectable CD19+ B cells, followed by naïve-dominant B-cell reconstitution. Reductions in anti-dsDNA antibodies were observed in 91% (10 of 11) of baseline-positive patients, and 90% (9 of 10) of patients with low baseline complement demonstrated complement recovery.

The Company approached the FDA regarding a pivotal study in lupus nephritis and aligned on a single-arm study in lupus nephritis patients with inadequate response to at least two immunosuppressants. The study is expected to enroll a double digit number of patients and the primary efficacy endpoint will be complete renal response at 12 months. The Company plans to initiate start-up activities for a pivotal study in LN in the fourth quarter of 2026.

The high DORIS remission rate observed to date may support the potential inclusion of lupus patients without nephritis in the single arm pivotal study, subject to regulatory alignment. The company plans to discuss with the FDA such potential expansion of the pivotal study to include lupus without nephritis in the fourth quarter of 2026.

There are approximately 35,000 LN patients and 35,000 patients with non-renal SLE who have organ/life threatening disease in the U.S. alone. Based on prula-cel enrollment track record to date and the level of interest expressed by patients and investigators in prula-cel, Adicet expects rapid enrollment to the pivotal study.

Anticipated milestones for prula-cel include:

- **Fourth quarter of 2026:** Initiate pivotal start up activities and align with FDA on the pivotal study population, including potential inclusion of SLE
- **First Half 2027:** Anticipated clinical data update in systemic sclerosis (SSc)
- **Mid 2027:** Anticipated clinical data update in LN/SLE

For more information about the Phase 1 study, please visit: Study Details | NCT06375993 | A Phase 1 Study of Prulacabtagene Leucel (Prula-cel, Formerly ADI-001) in Autoimmune Disease | ClinicalTrials.gov

Webcast/Conference Call Information Adicet will host a webcast presentation on Monday, September 28, 2026 at 8:00am ET. The live webcast of the presentation can be accessed by registering via this link or under “Presentations & Events” in the investors section of the Company’s website at https://www.adicetbio.com. 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 Prulacabtagene leucel (prula-cel)

Prula-cel is an investigational allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapy targeting B-cells via an anti-CD20 CAR. ADI-001 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed/refractory class III or class IV lupus nephritis (LN), refractory systemic lupus erythematosus (SLE) with extrarenal involvement and systemic sclerosis (SSc).

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical-stage biotechnology company discovering and developing a broad pipeline of allogeneic gamma delta T cell therapies, engineered with chimeric antigen receptors (CARs), alongside differentiated *in vivo* CAR-T therapies with the potential to redefine treatment across autoimmune diseases, hematologic malignancies and solid tumors. 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: clinical development of Adicet’s product candidates, including future plans or expectations for prula-cel in autoimmune diseases and the potential safety, tolerability and efficacy for the treatment of autoimmune diseases and cancer as well as expectations to achieve a complete immune reset; expectations regarding future alignment with the FDA on regulatory path to approval and discussions to date; timing and success of the Phase 1 clinical trial of prula-cel in multiple autoimmune indications, including timing and expectations for enrollment and future data releases; expectations regarding the timing and initiation of a pivotal study for prula-cel in SLE patients with or without LN and potential expansion to include non-renal lupus; expectations regarding prula-cel’s potential to transform treatment for patients with lupus; expectations regarding the suitability of prula-cel for outpatient administration; expectations regarding the scalability of the Company’s off-the-shelf manufacturing platform; expectations regarding the pace of enrollment in the pivotal study for prula-cel in SLE patients with or without LN; and estimates for the addressable patient population and commercial opportunity for prula-cel in LN and SLE.

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 titled “Risk Factors” in Adicet’s most recent

annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Adicet's other filings with the U.S. Securities and Exchange Commission, including its quarterly report on Form 10-Q. 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260928907981/en/

Adicet Bio, Inc.
Investor and Media Contacts

Anne Bowdidge
abowdidge@adicetbio.com

Penelope Belnap
Precision AQ
penelope.belnap@precisionaq.com

Source: Adicet Bio, Inc.