Adicet Bio Announces Completion of Last Patient Visit for Planned Analysis of prula-cel (formerly ADI-001) Study in Patients with Systemic Lupus Erythematosus With or Without Lupus Nephritis and Provides Corporate Update

September 1, 2026

Prula-cel topline results from planned analysis expected September 2026

FDA clearance of IND for ADI-212 in mCRPC; Phase 1 clinical study expected to initiate in 4Q 2026

Unveiling next-generation in vivo CAR-T platform and pipeline targeting hematological malignancies and solid tumors; first candidate expected to enter clinical development in 2H 2027

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Sep. 1, 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 completion of the last patient visit for the planned Phase 1 safety and efficacy analysis of prulacabtagene leucel (prula-cel) in patients with systemic lupus erythematosus (SLE) with or without lupus nephritis (LN). The Company expects to report topline data in September 2026.

The Company plans to host an investor webcast upon release of the topline data to discuss the results and next steps for the program.

“We are pleased with the level of interest from investigators and patients in our study evaluating prula-cel in patients with SLE with or without LN and look forward to the planned readout later this month,” said Chen Schor, President and Chief Executive Officer of Adicet Bio. “As we advance this program, we are also executing across our broader pipeline, including initiating startup activities for our Phase 1 study of ADI-212 in mCRPC, following the recent IND clearance by the FDA, while continuing to progress our differentiated *in vivo* CAR-T platform, with our first candidate expected to enter clinical development in the second half of 2027.”

Prula-cel Autoimmune Program on Track for 3Q 2026 Data Readout

- **Prula-cel topline data from SLE patients with or without LN expected in September 2026.** The planned analysis includes data from 22 SLE patients with or without LN with a minimum of 6 months of follow-up, including 13 patients with at least 12 months of follow-up.
- **Potential registrational trial design in development following FDA interaction.** Additional information regarding potential pivotal trial design is expected as part of the upcoming prula-cel clinical update later this month.
- **Expanded prula-cel administration into outpatient setting following FDA alignment**, enabling LN and other SLE patients in current and future studies to receive treatment in the outpatient setting.
- **Clinical update in patients with systemic sclerosis** expected in the fourth quarter of 2026.

ADI-212 IND Cleared by FDA; Program Advancing into Clinic

- **FDA clearance of IND application for ADI-212, a next-generation, gene-edited, armored cell therapy candidate designed to address the complexity of solid tumors.** In August 2026, the FDA cleared the Company’s Investigational New Drug Application (IND) for ADI-212 for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). The Company plans to initiate enrollment in the fourth quarter of 2026 in patients with mCRPC. Designed as an off-the-shelf product, ADI-212 incorporates multiple platform enhancements by incorporating gene-editing and expression of a novel immune-stimulating molecule intended to strengthen anti-tumor potency, including improved antigen engagement, capacity for durable tumor-killing and active modulation of the tumor microenvironment.

Advancing the Company’s Diversified In Vivo CAR-T Portfolio Towards Clinical Development

- **Progressing a diversified portfolio of *in vivo* CAR-T programs designed to address significant unmet needs in both hematologic malignancies and solid tumors.** The Company is advancing a differentiated *in vivo* CAR-T platform and pipeline to potentially optimize *in vivo* T cell transduction to yield highly cytolytic CAR-T therapy. Ongoing preclinical activities include programs targeting multiple myeloma, non-Hodgkin’s lymphoma, and solid tumor indications. Based on progress to date, the Company expects to advance the first candidate from its *in vivo* CAR-T portfolio into clinical development in the second half of 2027.

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; expectations regarding future alignment with the FDA on regulatory path to approval; 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 patients with SLE with or without LN; the timing of a clinical update in the Company’s ongoing Phase 1 trial of prula-cel in systemic sclerosis; the preclinical and clinical development of ADI-212, including the timing of regulatory filings, clinical startup activities, clinical updates and future data releases; the timing of initiation of enrollment of a Phase 1 trial for ADI-212 in mCRPC; expectations regarding the potential potency of ADI-212; expectations regarding the potential to optimize *in vivo* T cell transduction to yield highly cytolytic CAR-T therapy; timing of updates to the Company’s *in vivo* CAR-T platform pipeline; and ongoing preclinical programs and activities relating to autoimmune diseases, hematological malignancies and solid tumors.

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 the production and product release processes necessary to commercialize Adicet's product candidates are similarly 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, 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.

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