



Adicet Bio Announces FDA Clearance of IND Application for ADI-212

August 27, 2026

Phase 1 study in patients with mCRPC expected to begin enrollment in the fourth quarter of 2026

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 27, 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 that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for ADI-212 for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). The Company plans to initiate Phase 1 enrollment in patients with mCRPC in the fourth quarter of 2026.

"ADI-212 marks an important milestone in Adicet's strategy to address the complexity of solid tumors and represents an important addition to our portfolio of allogeneic gamma delta 1 cell therapies and *in vivo* CAR T programs," said Blake Aftab, Ph.D., Chief Scientific Officer of Adicet Bio. "Designed as a single off-the-shelf product, ADI-212 incorporates multiple platform enhancements by combining gene-editing and the expression of novel immune-stimulating molecules intended to strengthen anti-tumor potency, including improved antigen engagement, capacity for durable tumor-killing and active modulation of tumor microenvironment. The successful IND clearance reinforces our commitment to advancing innovative therapies for patients with cancer."

About ADI-212

ADI-212 is a next-generation gene-edited, armored cell therapy candidate targeting prostate-specific membrane antigen (PSMA), engineered to express a novel CAR binder designed to enhance tolerability and tumor specific recognition. The program combines membrane-tethered IL-12 armoring and CRISPR/Cas9-mediated disruption of subunit 12 of the mediator complex (MED12) designed to improve potency in solid tumors and enable multiple anti-tumor mechanisms within the tumor microenvironment.

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 ADI-212 in mCRPC and the potential safety, tolerability and efficacy for the treatment of cancer; the timing of initiation of enrollment of a Phase 1 trial for ADI-212 in mCRPC; and expectations regarding the potential potency of ADI-212. 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.

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