Adicet Bio Announces FDA Clearance of IND Application for ADI-270 in Renal Cell Carcinoma

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ADI-270 is the first gamma delta 1 CAR T candidate to enter clinical development for solid tumors

Phase 1 clinical study to evaluate safety and anti-tumor activity of ADI-270 in relapsed/refractory RCC patients

Phase 1 clinical study to be initiated in 2H 2024; preliminary clinical data expected in 1H 2025

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Jun. 24, 2024-- Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application to evaluate ADI-270, an armored allogeneic "off-the-shelf" gamma delta chimeric antigen receptor (CAR) T cell therapy candidate targeting CD70+ cancers, for the treatment of relapsed/refractory renal cell carcinoma (RCC). The Company plans to initiate a Phase 1 clinical trial to assess the safety and anti-tumor activity of ADI-270 in RCC patients in the second half of 2024.

"ADI-270 is the first ever gamma delta 1 CAR T cell therapy candidate to enter clinical trials for the treatment of solid tumors," said Chen Schor, President and Chief Executive Officer of Adicet Bio. "The FDA's clearance of our IND application to evaluate ADI-270 in patients with RCC underscores a significant achievement for Adicet. ADI-270 is a third-generation CAR T designed to target CD70+ tumors with high specificity, increased exposure, persistence and tumor infiltration, while addressing immunosuppressive factors in the tumor microenvironment. RCC is the most common type of kidney cancer and has a high unmet need with limited viable treatment options available. With its highly differentiated profile, we believe that ADI-270 has the potential to become an important therapeutic option for patients with RCC and other CD70+ tumors."

The Phase 1 multicenter, open-label clinical trial is designed to investigate ADI-270 as monotherapy in adults with relapsed or refractory clear cell RCC. Following lymphodepletion, patients will be eligible to receive a single dose of ADI-270 with a starting dose level of 3E8 CAR+ cells. Subject to meeting protocol defined criteria, patients enrolled in the study may be eligible to receive a second dose of ADI-270.

The dose escalation and dose expansion portions of the trial will evaluate safety, tolerability, and pharmacokinetics as well as anti-tumor activity as assessed by overall response rate, duration of response and disease control rate.

About ADI-270

ADI-270 is an armored allogeneic "off-the-shelf" gamma delta CAR T cell therapy candidate targeting CD70-positive cancers. CD70 is a compelling target due to its high expression in both solid and hematological malignancies. ADI-270 is engineered with a third-generation CAR design to target CD70 using its natural receptor, CD27, as the binding moiety and is further armored with a dominant negative form of the Transforming growth factor-β receptor II (dnTGFβRII) designed to provide functional resilience to the immunosuppressive tumor microenvironment. ADI-270 is also designed to increase exposure and persistence by reducing susceptibility to host vs. graft elimination. These properties of ADI-270 combined with the potent tumor infiltration demonstrated with gamma delta 1 T cells aim to improve clinical responses of RCC patients and other patients with CD70+ tumors.

About Renal Cell Carcinoma

Renal cell carcinoma (RCC) is the most common tumor of the kidney, constituting 80% to 85% of primary renal neoplasms. Clear cell RCCs (ccRCC) are the most common subtype, accounting for 80% of all RCCs. ccRCC is an aggressive subtype arising from renal stem cells commonly arising in the proximal nephron and tubular epithelium, and often metastasizes to the lungs, liver, and bones. Approximately 20% of newly diagnosed cases of RCC are locally advanced or metastatic and up to 30% of patients will develop metastatic disease following nephrectomy. While the 5-year survival rate for localized RCC is 93%, the 5-year survival rate for advanced disease is 15%.

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. Adicet is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients. For more information, please visit the Company's 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 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: preclinical and clinical development of Adicet's product candidates, including future plans or expectations for ADI-270, the potential safety, durability, tolerability and activity of ADI-270; the potential of ADI-270 to become an important therapeutic option for RCC patients and other patients with CD70+ tumors; and the expected progress, enrollment, timing and success of the Phase 1 study of ADI-270 in relapsed or refractory RCC patients, including expectations around Phase 1 trial initiation in the second half of 2024 and availability of preliminary clinical data in the first half of 2025.

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 geopolitical conflicts, economic conditions and public health emergencies on

Adicet's business and financial results, including with respect to disruptions to the Company's 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 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 and periodic reports on Form 10-Q and Form 8-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Adicet's other 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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