Adicet Bio Announces First Patient Dosed in the Phase 1 Clinical Trial of ADI-270 in Metastatic/Advanced Clear Cell Renal Cell Carcinoma

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Enrollment underway for patients with metastatic/advanced clear cell renal cell carcinoma (ccRCC)

Company expects to share preliminary Phase 1 clinical data in the first half of 2025

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Dec. 19, 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 first patient has been dosed in the Phase 1 clinical trial evaluating ADI-270 in patients with metastatic/advanced ccRCC.

“Dosing the first patient in our Phase 1 trial of ADI-270 in metastatic/advanced ccRCC is a significant milestone for Adicet as we advance our first gamma delta 1 CAR T cell product candidate for the treatment of solid tumors, one of the highest unmet needs in oncology,” said Chen Schor, President and Chief Executive Officer at Adicet Bio. “Patients with ccRCC, the most common type of kidney cancer, have a pressing need for safe and effective treatments, as current therapies offer limited benefits for patients with advanced disease. Based on ADI-270’s encouraging preclinical data generated to date, in which ADI-270 demonstrated significant tumor infiltration, resistance to the immunosuppressive tumor microenvironment and potent activity via CAR and innate-mediated targeting, we believe ADI-270 has the potential to offer a promising advancement for solid tumors. We anticipate reporting preliminary clinical data from the trial in the first half of 2025.”

About the Phase 1 Trial

The Phase 1 multicenter, open-label clinical trial is designed to investigate ADI-270 as monotherapy in adults with relapsed or refractory metastatic/advanced ccRCC. 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 trial 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.

For more information about becoming a study site, please email clinicaltrials@adicetbio.com.

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 designed 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) 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 RCC (ccRCC) is 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 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-270; the potential safety, durability, tolerability and activity of ADI-270; the expected progress, timing and success of the Phase 1 clinical trial of ADI-270 in metastatic/advanced ccRCC, including plans to report preliminary clinical data in the first half of 2025, and the potential of ADI-270 to become a treatment for solid tumors and ccRCC.

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 and economic conditions on Adicet’s business and financial results, including with respect to disruptions to Adicet’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; 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 entitled "Risk Factors" in Adicet's most recent annual report on Form 10-K and periodic and current reports on Form 10-Q and Form 8-K filed with the U.S. Securities and Exchange Commission (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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