Adicet Bio Receives FDA Fast Track Designation for ADI-270 in Metastatic/Advanced Clear Cell Renal Cell Carcinoma

July 8, 2024

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Jul. 8, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to ADI-270 for the potential treatment of patients with metastatic/advanced clear cell renal cell carcinoma (ccRCC) who have been treated with an immune checkpoint inhibitor and a vascular endothelial growth factor inhibitor.

“We are pleased that ADI-270, our first ever gamma delta 1 CAR T cell therapy candidate to enter clinical trials for solid tumors, has been granted Fast Track Designation by the FDA,” said Chen Schor, President and Chief Executive Officer of Adicet Bio. “ccRCC is the most common type of kidney cancer, and this significant milestone underscores our commitment to advancing innovative treatments to these patients as quickly as possible.”

Fast Track Designation is a process designed to facilitate development and expedite the review of drugs intended to treat serious conditions and fill an unmet medical need.

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 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; and the potential of ADI-270 to become a treatment for patients with metastatic/advanced 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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