Adicet Bio Receives FDA Fast Track Designation for Lead Candidate ADI-001

April 19, 2022

MENLO PARK, Calif. & BOSTON--(BUSINESS WIRE)--Apr. 19, 2022-- Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing first-in-class allogeneic gamma delta chimeric antigen receptor (CAR) T cell therapies for cancer, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to its lead program ADI-001, an investigational therapy targeting CD20 for the potential treatment of relapsed or refractory B-cell Non-Hodgkin's lymphoma (NHL).

ADI-001 is currently being evaluated in an ongoing dose escalation Phase 1 study evaluating the safety and tolerability of ADI-001 for the potential treatment of NHL. The Fast Track Designation was granted based on ADI-001's potential to address an unmet need within the adult NHL patient population.

"Fast Track Designation represents an important milestone in the clinical development of ADI-001," said Chen Schor, President and Chief Executive Officer of Adicet Bio. "We believe ADI-001 is unique in that it is designed to target malignant B cells by leveraging the innate and adaptive receptors found naturally on gamma delta T cells with the added benefit of an engineered anti CD20 CAR. We remain optimistic about the potential of our program and look forward to reporting additional data from the Phase 1 trial of ADI-001 in the first half of 2022."

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

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer. Adicet is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with CAR and T cell receptor-like targeting moieties to enhance selective tumor targeting, facilitate innate and adaptive anti-tumor immune response, and improve persistence for durable activity in patients. For more information, please visit our website at http://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. These forward-looking statements include, but are not limited to, express or implied statements regarding Adicet's beliefs and expectations regarding: the expected potential therapeutic effects, safety and tolerability profile, design, implementation, timing, and success of ADI-001; and the significance and expected benefits of FDA's Fast Track Designation for ADI-001.

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 COVID-19 on Adicet's business and financial results, including with respect to disruptions to Adicet's clinical trials, business operations, and ability to raise additional capital; Adicet's ability to execute on its strategy; that positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; future 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; regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; regulatory developments in the United States and foreign countries; and the company's estimates regarding expenses, future revenue, and capital requirements. 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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