Adicet Bio Receives FDA Fast Track Designation for ADI-001 in Lupus Nephritis

June 5, 2024

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Jun. 5, 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-001 for the potential treatment of relapsed/refractory class III or class IV lupus nephritis.

“The FDA’s decision to grant ADI-001 Fast Track Designation for lupus nephritis underscores the urgent need for new therapies for this chronic disease,” said Chen Schor, President and Chief Executive Officer of Adicet Bio. “We plan to initiate our Phase 1 clinical study in lupus nephritis later this month. With clinical data for ADI-001 in non-Hodgkin’s lymphoma demonstrating CD19+ B-cell depletion that mirrors data by autologous alpha-beta CAR T in academic clinical studies in several autoimmune diseases, we believe we are well positioned to expand our autoimmune program to address additional indications beyond lupus nephritis. We look forward to providing a comprehensive update on our autoimmune program to investors in the near term.”

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 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-001; the expected progress, timing and success of the Phase 1 clinical study of ADI-001 in lupus nephritis; and the Company’s expectations regarding ADI-001’s potential to be effective in other indications

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 entitled “Risk Factors” in Adicet’s most recent annual report on Form 10-K and our periodic 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20240605481965/en/

Adicet Bio, Inc.
Investor and Media Contacts

Anne Bowdidge
abowdidge@adicetbio.com

Janhavi Mohite
Precision AQ
212-362-1200

Source: Adicet Bio, Inc.