Adicet Bio Announces Initiation of its First-in-Human Phase 1 Trial of ADI-001 for the Treatment of B Cell Non-Hodgkin's Lymphoma

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Company's lead candidate, ADI-001, is believed to be the first IND-cleared allogeneic CAR gamma-delta T cell therapy to reach human trials

MENLO PARK, Calif. and BOSTON, Mass., March 10, 2021 /PRNewswire/ -- Adicet Bio, Inc. (Nasdaq: ACET), a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases, today announced that it has initiated its First-in-Human Phase I clinical trial evaluating ADI-001 for the treatment of B cell non-Hodgkin's lymphoma (NHL). ADI-001 is an investigational first-in-class allogeneic gamma delta T cell therapy expressing a chimeric antigen receptor (CAR) targeting CD20, engineered to potentially enhance selective tumor targeting, facilitate innate and adaptive anti-tumor immune response, and improve persistence for durable activity in patients.

"Initiating the Phase 1 trial represents an important milestone in the development of our lead product candidate, ADI-001, for patients with NHL, and for Adicet's emerging pipeline of "off-the-shelf" gamma delta T cell product candidates. Based on ADI-001's encouraging preclinical data, we believe our novel CAR gamma delta T cell therapy has the potential to provide an attractive treatment option for NHL patients," said Francesco Galimi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Adicet. "We are excited to bring ADI-001 into clinical development and look forward to advancing our product pipeline to address additional solid and hematologic tumors."

Adicet's Phase I trial is an open-label, multi-center study of ADI-001 enrolling adults diagnosed with B cell malignancies who have either relapsed, or are refractory to at least two prior regimens. The primary objectives of the trial are to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of ADI-001, and to determine optimal dosing as a monotherapy. A combination of ADI-001 and interleukin 2 may also be evaluated in this trial. The trial is expected to enroll approximately 75 patients, with preliminary safety and tolerability data expected by the end of 2021, subject to the impact of COVID-19. For more information about the clinical trial design, please visit: www.clinicaltrials.gov (NCT04735471).

About non-Hodgkin's lymphoma

NHL is the most common cancer of the lymphatic system, and develops in white blood cells called lymphocytes. Approximately 90% of NHL patients in western countries are diagnosed with B cell lymphomas of various types. Diffuse Large B cell lymphoma, or DLBCL, is the most common type of NHL, accounting for 30% of NHL diagnoses. Most types of NHL are incurable with available therapies, and more than 70,000 new cases of NHL are diagnosed each year in the United States.

About ADI-001

ADI-001 is an investigational allogeneic gamma delta T cell therapy being developed as a treatment for B-cell non-Hodgkin's lymphoma (NHL). ADI-001 targets malignant B-cells via an anti-CD20 CAR and via the gamma delta T cell endogenous cytotoxicity receptors. Gamma delta T cells engineered with an anti-CD20 CAR have demonstrated potent antitumor activity in preclinical models, leading to long-term control of tumor growth

About Adicet Bio, Inc.

Adicet Bio, Inc. is a biotechnology company discovering and developing allogeneic gamma delta T cell therapies for cancer and other diseases. Adicet is advancing a pipeline of "off-the-shelf" gamma delta T cells, engineered with chimeric antigen receptors and T cell receptor-like antibodies 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 including, but not limited to the initiation of Adicet's Phase 1 trial of ADI-001 for the treatment of B cell non-Hodgkin's lymphoma, including future plans or expectations as well as the expected potential therapeutic effects, the timing and outcome of discussions with FDA and other regulatory agencies, expectations regarding the design, implementation, timing, and success of future clinical studies of ADI-001, including whether they are pivotal or would support registration, and expectations regarding its other CAR gamma delta T cell therapy development activities.

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 our business and financial results, including with respect to disruptions to our 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 our 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 our 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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