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Cabaletta Bio Receives FDA Fast Track Designation for DSG3-CAART for the Treatment of Mucosal Pemphigus Vulgaris

PHILADELPHIA--(BUSINESS WIRE)-- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for DSG3-CAART (Desmoglein 3 Chimeric AutoAntibody Receptor T cells), the Company's lead product candidate for treatment of mucosal pemphigus vulgaris (mPV), for improving healing of mucosal blisters in patients with mPV.

"We believe that this Fast Track Designation, coming shortly after the Orphan Drug Designation for DSG3-CAART, further demonstrates that mPV is a devastating, rare disease for which patients have limited treatment options resulting in a large unmet need. The Fast Track Designation represents an important next step in our clinical development plans," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. "We appreciate the benefits provided by this designation, including the opportunity for increased access to the FDA and potential acceleration of our clinical development path and regulatory review process."

DSG3-CAART is designed to specifically target the cause of mPV, B cells that express pathogenic autoantibodies directed against the DSG3 protein, while preserving normal B cell immune function. The Company plans to initiate its Phase 1 DesCAARTes™ trial to evaluate the safety and tolerability of DSG3-CAART in relapsed and/or refractory patients in 2020. DSG3-CAART is based on technology licensed from and has been developed in collaboration with the University of Pennsylvania.

About Fast Track Designation

The FDA grants Fast Track Designation to drugs or biologics to facilitate the expedited development and review for therapeutics intended to treat serious or life-threatening conditions and to address unmet medical needs. Companies that receive Fast Track Designation are eligible for several potential benefits including the opportunity for more frequent meetings and interactions with the FDA during clinical development as well as eligibility for accelerated approval and/or priority review, if relevant criteria are met. Companies may also be allowed to submit sections of their Biologics License Application (BLA) on a rolling basis.

About Pemphigus Vulgaris

PV is a rare autoimmune blistering disease that is characterized by the loss of adhesion between cells of the skin or mucous membranes. PV is caused by the production of autoantibodies that disrupt structural proteins within the skin and/or mucosa that connect with other proteins to enable the skin and/or mucosal cells to connect with each other. The

autoantibodies can target desmoglein 3 (DSG3) and/or desmoglein 1 (DSG1), which are primarily expressed in the mucosal membranes and skin, respectively. mPV is characterized by autoantibodies against DSG3 only whereas mucocutaneous PV (mcPV) is characterized by autoantibodies against DSG3 and DSG1.

About CAAR T Cell Investigational Therapy

Chimeric AutoAntibody Receptor (CAAR) T cells are designed to selectively bind and eliminate only disease-causing B cells, while sparing the normal B cells that are essential for human health. CAAR T cells are based on the chimeric antigen receptor (CAR) T cell technology. While CAR T cells typically contain a CD19-targeting molecule, CAAR T cells express an autoantibody-targeted antigen on their surface. The co-stimulatory domain and the signaling domain of both a CAR T cell and a CAAR T cell carry out the same activation and cytotoxic functions. Thus, Cabaletta's CAARs are designed to direct the patient's T cells to kill only the pathogenic cells that express disease-causing autoantibodies on their surface, potentially leading to complete and durable remission of disease while sparing all other B cell populations that provide beneficial immunity from infection.

About Cabaletta Bio

Cabaletta Bio is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies for patients with B cell-mediated autoimmune diseases. The Cabaletta Approach to selective B cell Ablation (CABA) platform, in combination with Cabaletta's proprietary technology, utilizes Chimeric AutoAntibody Receptor (CAAR) T cells that are designed to selectively bind and eliminate only specific autoantibody-producing B cells while sparing normal antibody-producing B cells, which are essential for human health. The Company's lead product candidate, DSG3-CAART, is in development as a potential treatment for a prototypical B cell-mediated autoimmune disease, mucosal pemphigus vulgaris. For more information, visit www.cabalettabio.com.

Forward-Looking Statements

This press release contains "forward-looking statements" of Cabaletta Bio, Inc. ("Cabaletta" or the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cabaletta's beliefs and expectations regarding its: expectations regarding the intended incentives conferred by Fast Track Designation for DSG3-CAART for the treatment of mPV; expectations of the potential impact of COVID-19 on strategy, future operations, and the timing of its clinical trials, including the potential impacts on enrollment and initiation of its Phase 1 DesCAARTes™ trial; plans to initiate patient dosing in an open-label Phase 1 clinical trial to evaluate DSG3-CAART safety and tolerability in relapsed/refractory mPV patients in 2020; and statements regarding regulatory filings regarding its development programs.

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. These risks and uncertainties include, but are not limited to: risks related to the impact of public health epidemics affecting countries or regions in which we have operations or do business, such as COVID-19;

Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation for DSG3-CAART for the treatment of PV; risks related to Cabaletta's ability to protect and maintain its intellectual property position; uncertainties related to the initiation and conduct of studies and other development requirements for its product candidates; and the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

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