# Equillium Announces Successful Completion of FDA Pre-IND Meeting Enabling Advancement of Itolizumab into a Potential Registration Study as a Treatment for Hospitalized COVID-19 Patients

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***Equillium anticipates filing a U.S. IND for Itolizumab for COVID-19 and initiating a global Phase 3 clinical study in Q4 2020***

LA JOLLA, Calif., Sept. 15, 2020 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced it has completed a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) under the Coronavirus Treatment Acceleration Program (CTAP). The FDA provided positive feedback supporting Equillium's clinical development plans for evaluating itolizumab (EQ001) as a potential treatment for hospitalized patients with COVID-19. With this feedback, Equillium plans on finalizing the protocol and anticipates submitting its U.S. IND application to the FDA in October 2020 in preparation for initiating a global Phase 3, randomized, double-blind, placebo-controlled clinical trial during the fourth quarter of this year. At the same time, Equillium anticipates beginning formal applications to governmental agencies for funding support of the clinical study. Importantly, the FDA indicated that the proposed study, if it meets its primary and key secondary endpoints, may be sufficient for a Biologic License Application (BLA) submission.

"This feedback from the FDA is a significant milestone for Equillium in executing our clinical development program for itolizumab in treating hospitalized patients suffering from life-threatening consequences as a result of COVID-19," said Bruce Steel, chief executive officer, Equillium. "We believe itolizumab's novel immune-modulating mechanism, which down regulates the cytokine cascade, and data from prior human clinical trials – including recent positive interim data from our Phase 1b clinical study in acute graft-versus-host disease and Phase 2 study data in COVID-19 patients reported by our partner Biocon Limited – support our hypothesis that itolizumab may have promise in addressing immuno-inflammatory complications experienced by COVID-19 patients. This guidance from the FDA provides us a well-defined regulatory pathway and we will continue working expeditiously to file our IND with the goal of initiating the study in Q4 2020."

A pre-IND meeting provides an opportunity for an open communication between the sponsor and the FDA to discuss the IND development plan and to obtain the FDA's guidance for clinical trials for the sponsor's drug candidate. The FDA has created CTAP as a special emergency program for possible coronavirus therapies, which is designed to use every available method to move new treatments to patients as quickly as possible, while evaluating safety and effectiveness.

**About Equillium**

Equillium is a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop novel products to treat severe autoimmune and inflammatory disorders with high unmet medical need.

Equillium's initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the CD6-ALCAM pathway. This pathway plays a central role in modulating the activity and trafficking of T cells that drive a number of immuno-inflammatory diseases. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Itolizumab is currently marketed by Biocon in India under the trade name "ALZUMab" for the treatment of chronic plaque psoriasis, and in July 2020 received emergency use approval in India to treat cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS).

Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic in several indications and is developing itolizumab (EQ001) in multiple severe immuno-inflammatory disorders – acute graft-versus-host disease, uncontrolled asthma, and lupus nephritis – and is planning to submit an investigational new drug application for the treatment of COVID-19 patients. For more information, visit www.equilliumbio.com.

**Forward Looking Statements**

*Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, the potential benefit of treating COVID-19 patients with itolizumab, Equillium's business strategy, Equillium's plans and expected timing for developing itolizumab, including the ability to submit an IND to the FDA and initiate a clinical trial in patients with COVID-19, the potential benefits of itolizumab, Equillium's ability to submit applications for, or receive, funding support for the clinical trial in patients with COVID-19, whether the clinical trial will be sufficient to support a BLA application, Equillium's cash runway and the impact of the COVID-19 pandemic. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to Equillium's capital requirements; Equillium's plans and product development, including the initiation, restarting and completion of clinical trials, including a clinical trial of patients with COVID-19; uncertainties related to the actual impacts and length of such impacts caused by the COVID-19 pandemic; uncertainties caused by the recent restarting of the EQUIP and EQUALISE clinical trials after a pause; whether the results from clinical trials will validate and support the safety and efficacy of itolizumab; having to use cash in ways or on timing other than expected and the impact of market volatility on cash reserves. These and other risks and uncertainties are described more fully under the caption "Risk Factors" and elsewhere in Equillium's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Equillium undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.*

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