Equillium Provides Itolizumab COVID-19 Program Update

November 25, 2020

Analyst Day scheduled for December 4, 2020

LA JOLLA, Calif., Nov. 25, 2020 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced that due to the rapidly evolving COVID-19 treatment landscape, the company will not initiate the EQUINOX Phase 3 clinical trial to evaluate itolizumab in hospitalized COVID-19 patients at this time.

“Based on a thorough review of recent updates regarding the efficacy of new potential vaccines and other treatment options, we have made the strategic decision not to initiate our EQUINOX Phase 3 trial as previously planned. We are continuing to assess the rapidly evolving clinical and commercial landscape related to this pandemic and may consider other options to evaluate itolizumab in COVID-19 patients, including government research initiatives,” said Bruce Steel, chief executive officer of Equillium. “While this is a difficult decision given the current high rates of infection and significant unmet medical need, we believe it is prudent given the recent positive advancements by our biopharma colleagues to combat this serious pandemic. We greatly appreciate the support and effort of our trial investigators, clinical trial sites, and our Equillium team who played a vital role in preparing for the EQUINOX study, especially during this challenging time.”

Mr. Steel added, “Based on recent positive itolizumab interim clinical data in acute graft-versus-host disease (aGVHD) we plan to prioritize our resources on expanding and accelerating this program, as well as advancing our lupus / lupus nephritis and uncontrolled asthma studies. We look forward to providing additional pipeline updates at our Analyst Day on Friday, December 4.”

About Itolizumab

Itolizumab 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. Itolizumab is currently being evaluated in multiple clinical trials in patients with severe diseases, including aGVHD, lupus / lupus nephritis and uncontrolled asthma. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Itolizumab is marketed in India under the trade name “ALZUMAb-L” for the treatment of chronic plaque psoriasis and has received emergency use approval in India to treat cytokine release syndrome in COVID-19 patients with moderate to severe acute respiratory distress syndrome.

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 is developing itolizumab for multiple severe immuno-inflammatory diseases, including, aGVHD, lupus nephritis and uncontrolled asthma.

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, statements regarding the potential benefit of treating patients with aGVHD, uncontrolled asthma, lupus / lupus nephritis, or COVID-19 with itolizumab, Equillium’s business strategy, Equillium’s plans and expected timing for developing itolizumab, including the expected timing of initiating, completing and announcing further results from the EQUATE, EQUIP and EQUALISE studies, the potential benefits of itolizumab, the potential for the any of Equillium’s ongoing or planned clinical trials to show safety or efficacy, the impact of the COVID-19 pandemic. Risks that contribute to the uncertain nature of the forward-looking statements include: the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; potential delays in the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; the risk that studies will not be completed as planned; uncertainties related to Equillium’s capital requirements; Equillium’s plans and product development, including the initiation, restarting and completion of clinical trials; 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; changes in the competitive landscape, and uncertainties 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.

Investor Contact
Michael Moore,
Vice President, Investor Relations & Corporate Communications
+1-619-302-4431
ir@equilliumbio.com

Media Contact
Katherine Carlyle Smith
Senior Account Associate
Canale Communications
+1-805-907-2497
katherine.smith@canalecomm.com