Equillium Announces Initiation of the EQUIP Phase 1b Clinical Trial of Itolizumab for Patients with Uncontrolled Asthma

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LA JOLLA, Calif., July 10, 2019 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced it has initiated the EQUIP Phase 1b clinical trial of its CD6 targeted therapy, itolizumab (EQ001), in patients with uncontrolled moderate to severe asthma.

“There continues to be a need for new therapies to treat patients with uncontrolled asthma, many of whom continue to experience symptoms despite the use of current standard of care treatments including bronchodilators and inhaled corticosteroids and in some cases, existing targeted biologics. Given the heterogeneous and complex biology of this disease, there is a need for novel targeted therapies with unique mechanisms of action that could be effective across the spectrum of asthma phenotypes, regardless of eosinophil levels,” said Prof. Jo Douglass, M.D., head of Immunology and Allergy at Royal Melbourne Hospital and principal investigator of the EQUIP Phase 1b study. “Itolizumab offers the potential to inhibit the activation and trafficking of different effector T cell subtypes, including Th2 and Th17, important in the pathogenesis of asthma and may modulate the immune system in a way that leads to a durable effect without broadly suppressing the immune system. Our team is eager to evaluate itolizumab in the clinic and expand the treatment options for patients with uncontrolled moderate to severe asthma who might benefit from immunotherapy.”

“The initiation of the EQUIP Phase 1b trial represents an important milestone for Equillium and patients with uncontrolled asthma who fail to achieve symptom control with current standard of care,” said Krishna Polu, M.D., chief medical officer at Equillium. “We look forward to working with distinguished asthma centers and specialists to develop a promising treatment for patients with uncontrolled moderate to severe asthma and to gather insights into the safety and activity of itolizumab in a broad group of asthma patients.”

EQUIP is a Phase 1b randomized, double-blind, placebo-controlled study to evaluate the safety and tolerability of itolizumab in patients with uncontrolled moderate to severe asthma (NCT 04007198). The trial was initiated in June 2019 and is being conducted at world-class asthma centers in Australia and New Zealand under the leadership of Prof. Jo Douglass and will enroll up to 40 patients between the ages of 18 and 75. In this 12-week multiple ascending dose study, patients will receive either itolizumab or placebo administered subcutaneously every two weeks (over 8 weeks) for a total of 5 doses with 4 weeks of follow-up. The primary endpoints of the study are to evaluate safety and tolerability of itolizumab in patients with uncontrolled moderate to severe asthma. The secondary endpoints include characterizing pharmacokinetics (PK), pharmacodynamics (PD), PK/PD relationship and clinical activity of itolizumab. Top-line data from the EQUIP Phase 1b trial is expected in the second half of 2020.

About Uncontrolled Asthma
Asthma is a complex and highly prevalent inflammatory lung disease, characterized by reversible airway obstruction and chronic inflammation that, in severe cases, can significantly impact patient quality of life. Asthma is estimated to affect 26 million people in the United States – with a subset of that population exhibiting eosinophilic and non-eosinophilic asthma (Th2 or non-Th2, respectively), which impacts distinct phenotypes and disease severity. Preclinical data has demonstrated that modulating the CD6-ALCAM pathway has the potential to inhibit the activation and trafficking of both Th2 and Th17 effector T cells. Therefore, Equillium is initiating a broad development strategy that will evaluate itolizumab in uncontrolled moderate to severe asthma, regardless of eosinophilia level, to assess the breadth of its clinical utility.

About Equillium
Equillium is a biotechnology company leveraging deep understanding of immunobiology to develop 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 novel immune checkpoint receptor CD6. CD6 plays a central role in modulating the activation and trafficking of T cells that drive a number of immuno-inflammatory diseases. Itolizumab is a clinically-validated therapeutic that has demonstrated a favorable safety and tolerability profile. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic and is advancing itolizumab into clinical development in multiple immuno-inflammatory indications with high unmet medical need. 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 Equillium’s plans and expected timing for developing itolizumab, including the expected timing of clinical trial results, and the potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include uncertainties related to the completion of clinical trials and whether the results from clinical trials will validate and support the safety and efficacy of itolizumab. 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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