Equillium Granted U.S. FDA Fast Track Designation for Itolizumab for the Treatment of Lupus Nephritis

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LA JOLLA, Calif., Dec. 09, 2019 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for itolizumab for the treatment of lupus nephritis. Equillium initiated the EQUALISE Phase 1b study of itolizumab in patients with lupus and lupus nephritis in September 2019.

The FDA's Fast Track program is designed to facilitate the development of new treatments for serious or life-threatening conditions for which there is a significant unmet medical need. Companies with investigational drugs that receive Fast Track designation benefit from more frequent meetings or communications with the FDA to discuss the drug's development plan and may be eligible for accelerated approval and priority review.

"Receiving Fast Track designation recognizes the promising therapeutic potential of itolizumab for the treatment for lupus nephritis, particularly given its ability to modulate both the activity and trafficking of effector T cells," said Krishna Polu, M.D., chief medical officer. "Additionally, by monitoring levels of the CD6-ALCAM pathway in the urine in the EQUALISE trial we will be assessing the opportunity to take a personalized medicine approach to identify patients where the CD6-ALCAM pathway may be a dominant driver of the disease."

Kenneth Kalunian, M.D., professor of clinical medicine at the University of California San Diego School of Medicine and the lead principal investigator on the EQUALISE trial added, "Lupus nephritis, a complication of systemic lupus, is a devastating disease that affects roughly 100,000 patients in the United States. While existing immunosuppressive therapies have improved five-year survival for lupus nephritis patients, more than half don't have an adequate response to treatment, and many progress to end-stage renal disease requiring dialysis or transplant. There are no FDA approved therapies for lupus nephritis; however, the evaluation of itolizumab provides optimism that we may alleviate this significant unmet medical need for lupus nephritis patients."

The EQUALISE study is a Phase 1b randomized, double-blind, placebo-controlled study to evaluate the safety and tolerability of itolizumab in patients with lupus and lupus nephritis (NCT 04128579). The study will have two cohorts: Type A is an open-label cohort and will treat patients with systemic lupus erythematosus for 4 weeks; Type B is a double-blind, placebo-controlled cohort and will treat patients with active proliferative lupus nephritis for 12 weeks. The trial design was informed by members of the lupus community, including leading clinical and scientific experts in the lupus field, the Lupus Research Alliance, and patients living with lupus and/or lupus nephritis.

About Equillium
Equillium is a clinical-stage 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 activity 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 the following severe immuno-inflammatory disorders: uncontrolled asthma, acute graft-versus-host disease, and lupus nephritis. 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 for developing itolizumab, the potential benefits of itolizumab for lupus nephritis and expected benefits to be received from Fast Track designation. Risks that contribute to the uncertain nature of the forward-looking statements include uncertainties related to the completion of clinical trials, action on the part of the FDA and whether the results from the EQUALISE Phase 1b clinical trial 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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