Equillium Announces Update to EQUALISE Study of Itolizumab in Patients with Systemic Lupus Erythematosus and Lupus Nephritis

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Analysis of our Type A systemic lupus erythematosus patients without lupus nephritis that had elevated baseline urine protein/creatinine and albumin/creatinine ratios demonstrated a mean decrease of 42% and 53% respectively by Day 57 following two doses of Itolizumab

The Type B lupus nephritis cohort has been expanded to include newly diagnosed patients, in addition to refractory patients, and will evaluate a single subcutaneous dose level based on Type A PK/PD results

LA JOLLA, Calif.--(BUSINESS WIRE)--Aug. 11, 2021-- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced additional data from the EQUALISE Type A portion of the study in systemic lupus erythematosus (SLE) patients. The exploratory data set shows that patients without a diagnosis of lupus nephritis (LN) but with elevated urine protein/creatine ratio (UPCR) >200 mg/g (N=6, baseline geometric mean 378 mg/g)[1] experienced a mean decrease from baseline in UPCR of 33% and 42% at Days 29 and 57 respectively, following subcutaneous doses of itolizumab on Days 1 and 15. Notably, one subject who had baseline UPCR of 1,505 mg/g declined to 974 mg/g at Day 29 and 857 mg/g by Day 57. Additionally, patients with elevated albumin/creatinine ratio (ACR) >30 mg/g (N=4, baseline geometric mean 97 mg/g)[1] experienced a mean decrease from baseline in ACR of 22% and 53% at Days 29 and 57 respectively.

“We are intrigued by this observation from our Type A portion of the study in SLE patients who did not have a diagnosis of lupus nephritis and entered the study with elevated proteinuria, and experienced reductions in UPCR and ACR following two doses of itolizumab,” said Dolca Thomas, executive vice president of research and development and chief medical officer of Equillium. “There is ongoing research in the field of rheumatology and nephrology that suggests patients who have elevated proteinuria with UPCR greater than 200 mg/g or ACR greater that 30 mg/g, which is below the typical diagnostic threshold for LN and other kidney diseases, may have subclinical disease - sometimes referred to as silent LN - where early intervention with a safe and active therapy may prevent more severe outcomes. We are continuing to analyze this exploratory data and look forward to initial results from active LN patients in the Type B portion of the EQUALISE study that is now enrolling.”

Equillium is implementing an amendment to the Type B portion of the EQUALISE study in LN patients to include newly diagnosed patients in addition to refractory patients. The study will evaluate up to 20 patients dosed at 1.6 mg/kg subcutaneously bi-weekly for up to 24 weeks. The selection of the 1.6 mg/kg dose was based on the totality of the safety, tolerability, and PK/PD data in the Type A portion of the study that demonstrated a plateau in the reduction of CD6 cell surface expression above the 0.8 mg/kg dose; as previously reported itolizumab was safe and well tolerated through the 2.4 mg/kg dose level. Equillium expects to announce interim data from the Type B portion of the study by the end of the year. Equillium has received fast track designation from the FDA for itolizumab for the treatment of patients with lupus nephritis.

[1] *Missing data: UPCR on one patient at Day 57, ACR on two patients at Day 29*

About Systemic Lupus Erythematosus (SLE) / Lupus Nephritis (LN)

Systemic lupus erythematosus is an autoimmune disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels. Lupus nephritis is a serious complication of SLE, occurring in approximately 30% – 60% of individuals with SLE. In LN, the body’s own immune system attacks the kidneys, causing inflammation and significantly reducing kidney function over time.

About the EQUALISE Study

The EQUALISE study is a Phase 1b open-label proof-of-concept multiple ascending-dose clinical study of itolizumab in patients with systemic lupus erythematosus and lupus nephritis. The study is evaluating the safety and tolerability of subcutaneous delivery of itolizumab in patients with systemic lupus erythematosus and lupus nephritis. The treatment period for patients with systemic lupus erythematosus is two weeks in duration, while treatment for patients with active proliferative lupus nephritis is 24 weeks in duration.

About Itolizumab

Itolizumab is a clinical-stage, first-in-class anti-CD6 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.

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 acute graft-versus-host-disease (aGVHD), lupus/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. Forward-looking statements may be identified by the use of words such as "anticipate", "believe", "could", "continue", "expect", "estimate", "may", "plan", "outlook", "future" and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. 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, or lupus/lupus nephritis with itolizumab, 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 for any of Equillium's ongoing or planned clinical studies to show safety or efficacy, statements regarding the impact of new leadership team members, Equillium's anticipated timing of regulatory review and feedback, Equillium's cash runway, and Equillium's plans and expected timing for developing itolizumab and potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the abilities of the leadership team to perform as expected; Equillium's ability to execute its plans and strategies; risks related to performing clinical studies; the risk that interim results of a clinical study 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 studies and the reporting of data therefrom; the risk that studies will not be completed as planned; Equillium's plans and product development, including the initiation and completion of clinical studies and the reporting of data therefrom; whether the results from clinical studies will validate and support the safety and efficacy of itolizumab; changes in the competitive landscape; uncertainties related to Equillium's capital requirements; and 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 SEC. 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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