Equillium Announces Interim Safety Data and Reduction in Proteinuria for Lupus Patients Treated with Itolizumab in the EQUALISE Study Presented at the ACR Annual Meeting

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Subgroup analyses of lupus patients (without lupus nephritis) that had elevated baseline proteinuria and albuminuria shows reduction of 42% and 54%, respectively, by Day 57

Itolizumab was well tolerated at doses ranging from 0.4 to 2.4 mg/kg

LA JOLLA, Calif.--(BUSINESS WIRE)-- 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 that positive interim data from the Type A portion of the EQUALISE study in systemic lupus erythematosus (SLE) patients were presented in a poster session at the American College of Rheumatology (ACR) annual meeting. The data in poster #1750, authored by Kenneth Kalunian, M.D., professor of Medicine, at University of California San Diego School of Medicine, showed that itolizumab administration was well tolerated and resulted in decreases in proteinuria and albuminuria, two key biomarkers of disease risk.

In the interim exploratory analysis of the TYPE A portion of the study where patients were dosed subcutaneously (SC) once every two weeks (Q2W), the data showed that for SLE patients with baseline urine protein-to-creatinine ratios (UPCR) > 100 mg/g (N=16) and > 200 mg/g (N=6), there was a decline of 34% and 42%, respectively, at Day 57. In addition, for patients with a baseline urine albumin-to-creatinine ratio (UACR) > 30 mg/g (N=4) there was a decline of 54% at Day 57. Pharmacokinetic analysis showed dose dependent increases in itolizumab concentrations while pharmacodynamic data showed a reduction in the CD4 cell surface CD6 levels, with maximal reductions achieved at itolizumab doses ≥ 1.6 mg/kg. Treatment with two doses of itolizumab up to 2.4 mg/kg was found to be well tolerated, with mild injection site reaction and headache reported as the most common adverse events.

“These early results in patients with SLE treated with itolizumab are quite promising,” said Dr. Kalunian. “In particular, the substantial decreases in protein-creatine and albumin-creatine ratios, two key biomarkers of inflammation and disease

severity in this patient population, following just two doses of itolizumab are impressive. I look forward to additional data from EQUALISE, including observations from the Type B portion of the study in patients with lupus nephritis."

The Type A study portion of the Phase 1b EQUALISE study is a multiple ascending-dose trial involving 35 SLE patients to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of SC doses of itolizumab every two weeks. The Type B portion of the EQUALISE study will evaluate up to 20 newly diagnosed or refractory lupus nephritis (LN) patients who will be treated with itolizumab dosed at 1.6 mg/kg SC Q2W for up to 24 weeks.

In separate posters at ACR, Equillium presented new observations on CD6 as a key pharmacodynamic biomarker of drug activity and the importance of urinary ALCAM as a measure of disease activity in LN. In poster #1766, pharmacodynamic data were presented from the Type A portion of the EQUALISE study in which SC delivery of itolizumab induced dose-dependent loss of cell surface CD6 on T cells (with maximal loss observed at Day 15 between 1.6 and 3.2 mg/kg), leading to inhibition of T effector cell activity. Poster #0353 highlighted data demonstrating significantly elevated urinary ALCAM levels in patients with LN compared to control patients without kidney disease ($p<0.001$). The urinary ALCAM levels varied based on the pathologic classification of LN. Over the course of the study urinary ALCAM levels declined as proteinuria improved, suggesting its potential role as a biomarker to monitor disease activity over time.

"As we generate more data in multiple settings, our conviction in the versatility, potency and potential clinical impact of itolizumab grows," said Dolca Thomas, M.D., executive vice president of research and development and chief medical officer of Equillium. "We continue to advance itolizumab in the EQUALISE trial to treat lupus nephritis, as well as in our programs for acute graft-versus-host disease and uncontrolled asthma and look forward to providing updates on these programs in the near future."

To view the poster presentations, visit the Publications & Presentations page of Equillium's website: https://www.equilliumbio.com/technology/publications-presentations/default.aspx.

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 signaling pathway to selectively downregulate pathogenic T effector cells while preserving T regulatory cells critical for maintaining a balanced immune response. 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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