Equillium Announces Favorable Data From Phase 1b EQUALISE Study in Systemic Lupus Erythematosus Patients

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Itolizumab administered subcutaneously was safe and well tolerated in patients with systemic lupus erythematosus

Dose-dependent changes in pharmacodynamic markers observed with subcutaneous dosing were consistent with intravenous dosing of itolizumab

LA JOLLA, Calif., March 30, 2021 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced favorable topline data from the Type A group of the EQUALISE study in patients with systemic lupus erythematosus (SLE). In this study, itolizumab, a monoclonal antibody selectively targeting the CD6-ALCAM pathway, was safe and well tolerated. In addition, itolizumab demonstrated a dose-dependent reduction of cell surface CD6 expression on effector T cells, a leading indicator of drug activity, consistent with its mechanism of action.

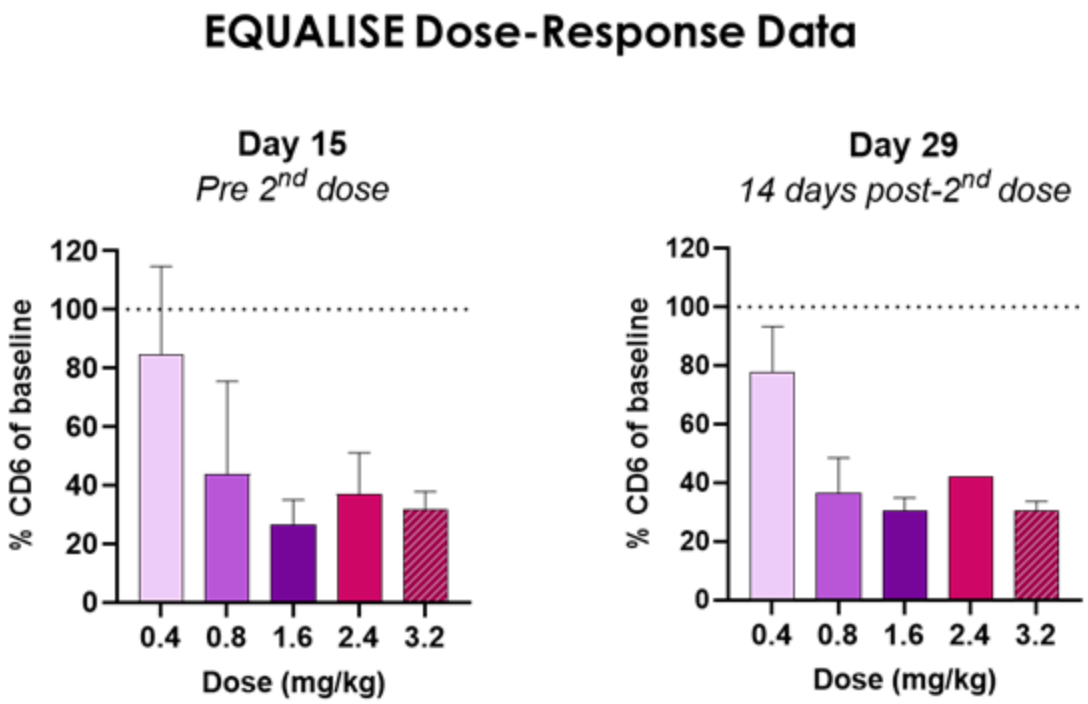
“These initial data from the EQUALISE study demonstrate a favorable safety and tolerability profile for subcutaneous delivery of itolizumab in SLE patients, with the most frequent adverse events being mild to moderate injection site reactions,” said Dolca Thomas, M.D., chief medical officer at Equillium. “These data – the first itolizumab data reporting on subcutaneous delivery – support that subcutaneous administration of itolizumab can deliver systemic pharmacokinetic levels that are needed to evaluate itolizumab’s efficacy and safety in chronic autoimmune disorders that require long term outpatient therapy. We look forward to assessing outcomes with six months of subcutaneous itolizumab administration in the Type B EQUALISE study in lupus nephritis patients.”

The EQUALISE study is a Phase 1b open-label multiple ascending-dose study of itolizumab in subjects with SLE, with or without active proliferative lupus nephritis (LN). The study is evaluating the safety and tolerability of subcutaneous delivery of itolizumab in two separate groups. The Type A group of SLE patients included five cohorts receiving 0.4, 0.8, 1.6, 2.4 or 3.2 mg/kg of itolizumab, with doses administered on days 1 and 15. The Type B group of LN patients will receive either 0.8, 1.6 or 3.2 mg/kg of itolizumab for a total of 13 doses delivered every two weeks.

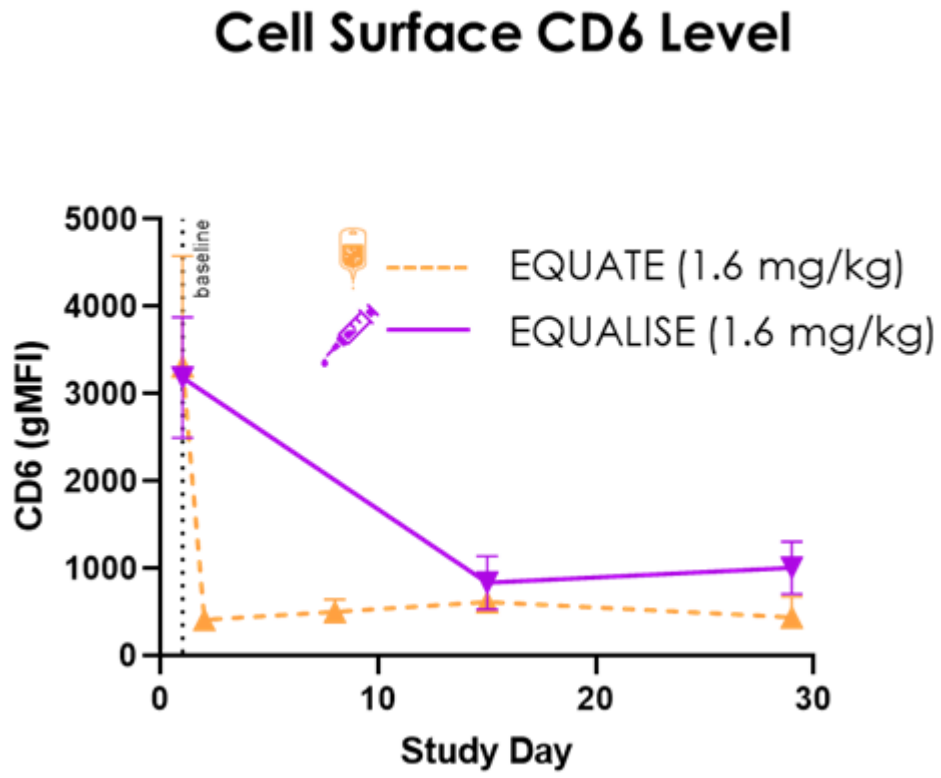
In the Type A SLE group, a total of 34 patients received at least one dose of subcutaneously delivered itolizumab across all dosing cohorts. Subcutaneous administration in dosing cohorts 0.4 mg/kg through 2.4 mg/kg (N=26) was safe and well tolerated, with three patients not receiving both doses, one as a result of a protocol eligibility deviation and two as a result of adverse events. The most frequent adverse events reported in these dosing cohorts were mild to moderate injection site reactions (erythema and pruritis) with no serious adverse events reported. For the highest dosing cohort (3.2 mg/kg) a total of eight subjects received at least one subcutaneous dose of itolizumab in two separate injection sites. In this cohort the most frequently reported adverse events were injection site reactions, the majority of which were moderate grade 2, and there were two non-treatment related serious adverse events reported in one patient (hypotension and syncope) in the follow-up period after dosing was complete. There were four patients that discontinued in the highest dosing cohort after one dose, two were due to non-serious adverse events and two were due to voluntary patient discontinuation. Adverse events that led to discontinuation in these two patients were moderate grade 2 chills and grade 2 headache.

In addition to the favorable safety and tolerability, changes in pharmacodynamic markers that are consistent with the pharmacokinetics and mechanism of action of itolizumab were observed. “Dose-dependent responses were observed in the pharmacodynamic markers of reduced cell surface CD6 on effector T cells concurrent with increased soluble CD6, consistent with the pharmacokinetic profile,” said Steve Connelly, Ph.D., chief scientific officer at Equillium. “Notably, in terms of potency, the pharmacodynamic data from the cohort receiving 1.6 mg/kg subcutaneously in the EQUALISE study is comparable to the 1.6 mg/kg cohort in the intravenously administered EQUATE study in patients with acute graft-versus-host disease.”

The complete data set from the Type A SLE patients is expected to be presented at a future medical conference and interim data from the Type B LN patients is expected to be announced before the end of the year.



Dose-responsive reduction in surface levels of CD6. *Collected whole blood is fixed using a proteomic stabilizer for batched analysis. Fixed whole blood is analyzed for total levels of surface CD6 on T cells by flow cytometry using a non-competing CD6 antibody. Percent (%) CD6 of baseline is calculated by taking the ratio of CD6 geometric mean fluorescent intensity (gMFI) on CD4+ cells at each visit by the CD6 gMFI on CD4+ cells at baseline (pre-1st dose). Some patients are missing data points due to loss of sample.*



Fluorescent detection of cell surface CD6 on CD4+ T cells as measured by flow cytometry. Fluorescence expressed as geometric mean fluorescent intensity (gMFI).

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 multiple ascending-dose study of itolizumab in subjects with systemic lupus erythematosus with or without active proliferative 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, 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. 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 systemic lupus erythematosus and lupus nephritis with itolizumab, the ability of subcutaneous administration of itolizumab to be used in patients that require long term outpatient therapy, expected timing of further results from the EQUALISE study, 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: Equillium's ability to execute its plans and strategies; risks related to performing clinical trials; 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; Equillium's plans and product development, including the initiation and completion of clinical trials and the reporting of data therefrom; whether the results from clinical trials will validate and support the safety and efficacy of itolizumab; and changes in the competitive landscape. 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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