Equillium Announces Initiation of the EQUALISE Phase 1b Clinical Trial of Itolizumab for Patients with Lupus Nephritis and Provides Business Update

October 1, 2019

Company secures up to $20 million debt facility with Silicon Valley Bank and Oxford Finance LLC

Company receives exclusive rights to negotiate licensing rights to develop and commercialize itolizumab in select major markets outside of North America

Management to host conference call today, Tuesday, October 1, at 4:30 p.m. ET

LA JOLLA, Calif., Oct. 01, 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 it has initiated the EQUALISE Phase 1b clinical trial of itolizumab (EQ001) in patients with lupus nephritis and provided an update on its ongoing clinical programs. Additionally, Equillium announced an agreement with Silicon Valley Bank and Oxford Finance to secure a term loan for up to $20 million, and that the company has secured exclusive rights to negotiate licensing rights with third parties to develop and commercialize itolizumab in select major markets outside of North America.

“We are pleased with the progress that we’ve made in a short period of time. We have initiated three clinical trials of itolizumab in lupus nephritis, uncontrolled asthma and acute graft-versus-host disease where there is a substantial need to address the severe aspects of these diseases for patients where there are few to no therapies approved,” said Daniel Bradbury, chairman and chief executive officer of Equillium. “We are optimistic about our trajectory to advance itolizumab for patients in these indications and are proud to partner with Silicon Valley Bank and Oxford Finance to further strengthen our cash position.”

EQUALISE is a Phase 1b multiple ascending dose trial that is evaluating the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD), and clinical activity of itolizumab in patients with systemic lupus erythematosus (SLE) and lupus nephritis. Data from the SLE cohort of this trial is expected in the second half of 2020, with data from the lupus nephritis cohort expected in the first half of 2021. The trial design and initiation has been a joint effort with the lupus community including working closely with leading clinical and scientific experts in the lupus field, the Lupus Research Alliance, and patients living with lupus and/or lupus nephritis.

“The current treatment landscape for patients with lupus nephritis presents limited options with a host of side effects, such as hypertension, diabetes complications, weight gain and predispositions to infections,” said Dr. Ken Kalunian, professor of clinical medicine at the University of California San Diego School of Medicine and the lead principal investigator on the EQUALISE trial. “The EQUALISE trial leverages a novel drug that can broadly target multiple parts of the pathways that lead to disease. Up until now, I’ve only seen medicines that focus on single targets that have produced limited results for patients. Our team looks forward to evaluating itolizumab in the clinic with the hope of filling this significant unmet medical need for lupus nephritis patients.”

"The initiation of the EQUALISE trial is a welcome advance toward testing a potential new treatment for this dangerous and common complication of lupus," noted Lupus Research Alliance president and chief executive officer Kenneth M. Farber. "We commend Equillium for enlisting the lupus community in the development of educational materials about the trial as patients' thorough understanding of the clinical research process is vital to participation."

Importantly, the EQUALISE trial is also evaluating urinary biomarkers including soluble ALCAM and CD6 to inform a patient selection approach as part of a companion diagnostic strategy. This approach may help address the heterogeneity of the disease and tackle a key issue that has been a challenging aspect of developing drugs in this field. To advance the diagnostic strategy and assay development, Equillium has partnered with Exagen, a commercial diagnostics company with expertise in diagnosing, prognosing and monitoring lupus patients. Translational data underpinning this strategy as well as preclinical proof of concept data will be presented at the upcoming Annual Meeting of the American College of Rheumatology in November 2019.

Equillium today also provided an update on its existing clinical programs in uncontrolled asthma and acute graft-versus-host disease (aGVHD), as well as a general corporate update.

Uncontrolled Asthma:
EQUIP is a Phase 1b trial of itolizumab in patients with moderate to severe uncontrolled asthma and is enrolling a broad range of asthma phenotypes including T_h2 and non-T_h2 driven asthma. The trial was initiated in June 2019 and is being conducted at leading asthma centers in Australia and New Zealand. A majority of clinical trial sites have been activated and enrollment is progressing as anticipated. The company remains on track to announce topline data in the second half of 2020.

Acute Graft-Versus-Host Disease:
EQUATE is a Phase 1b/2 trial of itolizumab in patients with aGVHD. Enrollment in the first part of the study, the Phase 1b portion, has been progressing slower than expected. The reasons for slow enrollment include longer site activation timelines at academic centers, a smaller number of available severe aGVHD patients as defined by the High-Risk MacMillan Criteria, which constitutes a smaller portion of the overall aGVHD population,

and higher screen failure rates due to comorbid conditions in this severe aGVHD population.

Physician interest and engagement in this program remains very high, and Equillium continues to activate additional centers to further increase the size of the pool of eligible patients. The company expects that opening these centers will help shift the dynamic of enrollment by allowing Equillium more opportunities to find eligible patients. Further, the company is working with U.S. Food and Drug Administration to re-evaluate the entry criteria into the Phase 1b portion of the trial to further expand the pool of patients eligible for the study. Given the current progress, the company is revising guidance to announce topline data from the Phase 1b portion of this study to the second half of 2020.

General Corporate Update:
Equillium has partnered with Silicon Valley Bank and Oxford Finance to secure a term loan for up to $20 million in three tranches. On September 30, 2019, the company closed on the first tranche of $10 million. Additional tranches of $5 million each may close within certain timeframes upon achieving sufficient data from the Phase 1b EQUIP trial in uncontrolled asthma and the Phase 1b portion of the EQUATE trial in aGVHD. This financing, together with the company's existing cash on the balance sheet, is expected to fund currently planned clinical development programs into the second half of 2021 and through the anticipated initial data readouts.

Additionally, in August 2019, the company entered into an agreement with Biocon that grants exclusive rights to Equillium to negotiate licensing rights with third parties to develop and commercialize itolizumab in select major markets outside of North America. This agreement allows Equillium to represent itolizumab more broadly commercially and participate in value that may be created with strategic partners across geographies.

Conference Call and Webcast Information:

Equillium management will be hosting a conference call to provide additional details and discuss upcoming milestones. Call details are as follows:

Date: October 1, 2019
Time: 4:30 p.m. ET | 1:30 p.m. PT
Dial-in: (866) 930-5156 (International callers please use (409) 937-8975) and use reservation code: 7080957. Please dial in 5 to 10 minutes prior to scheduled start time.

Webcast: www.equilliumbio.com, accessed through the "Investors" section of Equillium's website. The webcast will be archived and available for replay on Equillium's website for 30 days following the call. Please log on approximately 5 to 10 minutes prior to scheduled start time to download and install any audio software if needed.

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 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 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, the potential benefits of itolizumab and cash runway. Risks that contribute to the uncertain nature of the forward-looking statements include uncertainties related to the completion of clinical trials, whether the results from clinical trials will validate and support the safety and efficacy of itolizumab and having to use cash in ways or on timing other than expected. 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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