Equillium Announces Plan to Develop EQ001 for the Treatment of Lupus Nephritis

February 26, 2019

Clinical trial evaluating EQ001 for the treatment of refractory lupus nephritis to commence in 2H 2019

Ongoing EQ001 development programs in acute graft-versus-host disease and severe asthma remain on-track

Company to host conference call today, Tuesday, February 26, at 4:30 p.m. ET

LA JOLLA, Calif., Feb. 26, 2019 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced that it plans to develop EQ001 for the treatment of lupus nephritis (LN). Equillium remains on track to initiate the EQUATE Phase 1b/2 trial in acute graft-versus-host disease (aGVHD) in the first quarter of 2019 and initiate a proof-of-concept trial in severe asthma in the second quarter of 2019. Equillium will host a conference call today to provide further details.

“Our decision to explore EQ001 for the treatment of lupus nephritis is consistent with our goal of developing promising new therapies that help patients with severe and underserved autoimmune diseases,” said Daniel Bradbury, chairman and chief executive officer of Equillium. “With over 100,000 LN patients in the United States alone and no currently FDA-approved therapies, there is a strong clinical rationale for pursuing this indication. Additionally, we believe EQ001’s unique mechanism of modulating both the activity and trafficking of pathogenic T cells provides a strong scientific rationale and highly differentiated approach to treat this difficult disease.”

LN is a life-threatening complication of systemic lupus erythematosus (SLE) and occurs when the body’s immune system attacks the kidneys. Current standard of care therapies, including prednisone, mycophenolate, and cyclophosphamide, rarely lead to long-term disease remission and can have significant toxicities. As many as 50 to 75 percent of LN patients are refractory to standard of care treatment, and, for those who respond, the majority will relapse within five years. Additionally, 10 to 30 percent of LN patients and up to 40 percent of patients with severe proliferative disease progress to end stage renal disease, necessitating chronic dialysis or transplant.

EQ001 blocks the CD6-Activated Leukocyte Cell Adhesion Molecule (ALCAM) pathway thereby inhibiting T cell activation and trafficking into tissues. Equillium believes EQ001 represents a promising therapeutic approach in LN that is highly differentiated relative to B cell, single cytokine and other co-stimulatory therapies that have largely failed in attempts to develop treatments for lupus and LN.

A targeted approach to blocking the CD6-ALCAM pathway is further supported by translational research conducted by Chandra Mohan, M.D., a rheumatologist and Hugh Roy and Lillie Cranz Cullen Endowed Professor of Biomedical Engineering at the University of Houston, who has identified urinary ALCAM in LN patients as a predictive biomarker in detecting patients with active LN. Equillium believes this research, which is supported by a *Target Identification in Lupus* grant from the Lupus Research Alliance, has important implications in the development of EQ001 in LN, and forms the initial basis for a companion diagnostic strategy that could potentially help identify the patients who are most likely to respond to therapy, monitor disease, and guide treatment.

“Targeting LN is an important expansion of our pipeline that we are accelerating; given the central role that T cells play in LN immunopathogenesis, the CD6-ALCAM pathway represents an attractive and promising target in this indication for EQ001,” said Krishna Polu, M.D., a nephrologist and chief medical officer of Equillium. “By further leveraging and building upon the research conducted by Dr. Mohan, we believe that urinary biomarkers can be used as an efficient and pragmatic tool to study disease pathways and identify LN patients in which the CD6-ALCAM pathway may be a strong driver of the disease. Leveraging urinary biomarkers to guide the development of targeted therapeutics is groundbreaking in this field, and we believe increases the likelihood of getting the right therapies to the right LN patients. We look forward to initiating the LN clinical development program later this year.”

Lupus Research Alliance president and chief executive officer Kenneth M. Farber added, “Lupus nephritis is one of the most common and dangerous complications of lupus. Enabling the generation of therapies for this condition is critical to the Lupus Research Alliance. Using urinary biomarkers to guide therapeutic development aligns with our strategy of supporting work that will help accelerate delivery of new treatments.”

Equillium plans to initiate a Phase 1b proof-of-concept trial of EQ001 in LN in the second half of 2019 to evaluate safety, pharmacokinetics, and clinically-relevant endpoints in patients with refractory LN. As part of its early development program in LN, Equillium plans to also include the co-development and validation of the CD6-ALCAM pathway and other urinary biomarkers as part of the trial and is exploring partnership opportunities in concert with Dr. Mohan and the Lupus Research Alliance to accelerate this research and validation.

Equillium today also provided an update on its existing clinical programs in graft-versus-host-disease (GVHD) and severe asthma.

Acute Graft Versus Host Disease
aGVHD occurs when donor immune cells attack host tissues and organs following an allogeneic hematopoietic stem cell transplant (HSCT). Approximately 50 percent of HSCT recipients develop aGVHD, which is the leading cause of non-relapse mortality following HSCT. Equillium is partnering with leading HSCT centers and plans to initiate the Phase 1b/2 EQUATE trial of EQ001 for the frontline treatment of aGVHD by the end of the first quarter of 2019.

Following discussions with the its advisors, Equillium has decided to take a sequential approach to developing EQ001 in GVHD as it contemplates expanding the program. Learnings from the Phase 1b portion of the aGVHD trial will inform our clinical development strategy that includes a broader life-cycle approach, including chronic GVHD, as well as the prevention of GVHD. Equillium believes that this sequential approach enables a more efficient and optimized development program in GVHD.

EQ001 has been granted Fast Track designation for the treatment of aGVHD and Orphan Drug designations for both the prevention and treatment of aGVHD from the U.S. Food and Drug Administration.

Severe Asthma
Asthma is a complex and highly prevalent inflammatory lung disease, characterized by reversible airway obstruction and chronic inflammation that, in severe cases, can significantly impact patient quality of life. Asthma is estimated to affect 26 million people in the United States, but differing cellular and molecular mechanisms vary between patients, resulting in distinct phenotypes and disease severity, for example T_h2 or non-T_h2 patients, typically referred to as eosinophilic and non-eosinophilic asthma, respectively. Translational data has indicated increased activity of the CD6-ALCAM pathway in severe asthma patients and preclinical data demonstrates that modulating the CD6-ALCAM pathway can inhibit the activity and trafficking of both T_h2 and T_h17 effector T cells. Therefore, Equillium will initiate a broad development strategy that will evaluate EQ001 in severe asthma, regardless of eosinophilia level, to assess the breadth of its clinical utility.

Equillium plans to initiate a Phase 1b proof-of-concept trial, called the EQUIP trial, in Australia during the second quarter of this year. The trial will focus on patients with uncontrolled asthma despite the use of standard of care treatments. Trial objectives include the assessment of pharmacokinetics, pharmacodynamics, dose finding, safety, and clinically-relevant endpoints. Equillium anticipates reporting topline data from the EQUIP trial in the second half of 2020.

Conference Call and Webcast Information

Equillium management is hosting a conference call to review these and other upcoming milestones in more detail. Details of the call are as follows:

Date: February 26, 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: 7497024. Please dial in 5 to 10 minutes prior to scheduled start time.

Live Webcast: www.equilliumbio.com, accessed through the “Investors” section of the 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, EQ001 (itolizumab), 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 EQ001 through an exclusive partnership with Biocon Limited. Equillium believes that EQ001 has the potential to be a best-in-class disease modifying therapeutic and is advancing EQ001 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 the Company’s business strategy, the Company’s plans and expected timing for developing EQ001, including with respect to LN, the impact of certain translational research and the potential benefits of EQ001. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the Company’s plans and product development, including the initiation and completion of clinical trials and whether the results from clinical trials will validate and support the safety and efficacy of EQ001. 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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