Equillium Announces Publication of Data in the Journal of Clinical Investigation Highlighting the Importance of the CD6-ALCAM Pathway in the Pathogenesis of Lupus Nephritis

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First data to demonstrate the contribution of CD6-ALCAM and T-cells to the pathogenesis of lupus nephritis

Largest, most comprehensive cohort of lupus nephritis patients analyzed to date supports soluble ALCAM as a biomarker for disease activity

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 publication of a manuscript featured on the front cover of the Journal of Clinical Investigation (www.jci.org), confirming the role of T cells activated by the CD6-ALCAM pathway in the development of lupus nephritis (LN). The newly published data supports Equillium's research of itolizumab, a first-in-class anti-CD6 monoclonal antibody that targets the CD6-ALCAM signaling pathway to selectively inhibit pathogenic T effector cells. Equillium is currently evaluating itolizumab in LN patients in the EQUALISE study (NCTT04128579).

The Journal of Clinical Investigation is the premier venue for discoveries in basic and clinical biomedical science that will advance the practice of medicine. The publication, titled "The CD6-ALCAM pathway promotes lupus nephritis via T cell mediated responses," was the result of a collaborative study between investigators from The Accelerated Medicines Partnership (AMP), Chaim Putterman, M.D., (Albert Einstein College of Medicine), Chandra Mohan, M.D., Ph.D., (University of Houston) and Equillium. The work demonstrates the association of soluble urinary ALCAM (uALCAM) with human disease and how modulating the CD6-ALCAM pathway in animal models significantly reduces disease pathology.

"More targeted therapies are urgently needed to effectively treat LN, as well as other T cell mediated diseases," said Dr. Putterman. "This study, using urine biomarkers, tissue biopsy data and animal models, conclusively demonstrates that the CD6-ALCAM pathway is important in the pathogenesis of this disease, and supports the targeting of this pathway using itolizumab in the EQUALISE study."

Building on work first reported by Professor Chandra Mohan, this study examined uALCAM in an extended cross-sectional cohort of 1038 patients of different ethnicities with LN and systemic lupus erythematosus (SLE). These results validate uALCAM as a biomarker that can discern active renal involvement in SLE vs. inactive, or no renal involvement. Notably, in all ethnicities, the uALCAM level correlated with renal SLE disease activity index (SLEDAI), a clinical measure of LN disease severity, linking this protein more closely with renal disease progression. AMP helped this collaboration leverage single cell RNA sequencing data from kidney tissues of LN patients versus normal subjects that indicated an increase in CD6+ T cells and ALCAM on infiltrating leukocytes and resident kidney cells. To establish the role of the CD6-ALCAM pathway in disease pathogenesis, the effect of CD6 blockade in animal models of SLE/LN was investigated. Blockade of CD6 demonstrated the pathway's ability to prolong survival, decrease infiltrating immune cells, lower cytokine levels, and reduce renal pathology in a manner comparable to mycophenolate mofetil and cyclophosphamide, both potent immunosuppressors used in the treatment of LN. Targeting of CD6 on T cells resulted in decreasing activity of T cells as well as other immune cells, including inflammatory macrophages and neutrophils. Combined, these data further support uALCAM as a biomarker that distinguishes active lupus nephritis and validates targeting the CD6-ALCAM pathway to treat SLE and LN.

"Pathogenic T cells are thought to be instrumental in the development and progression of both SLE and LN and this data strengthens our belief that blocking the CD6-ALCAM pathway could prove to be an ideal approach for new therapeutic intervention in these diseases," said Stephen Connelly, Ph.D., chief scientific officer of Equillium. "In the Type A portion of the EQUALISE clinical study, itolizumab, our anti-CD6 monoclonal antibody, has demonstrated encouraging results in SLE patients without LN that had elevated urine protein/creatinine and albumin/creatinine ratios, where we saw a decrease in proteinuria."

Beatrice Goilav, M.D., associate professor of pediatrics, Albert Einstein College of Medicine added, "Itolizumab utilizes a unique mechanism of action that allows it to target an established pathway in the human kidney. This specific approach is informed by actual lupus nephritis patients and preserves T regulatory cells that protect against autoimmune disease. I believe this is a tremendous step forward in precision medicine because this approach was developed not only based on pre-clinical models, but also strong support from mechanisms already demonstrated to be operative in human disease."

About Lupus and Lupus Nephritis

Lupus or systemic lupus erythematosus (SLE) is a chronic, complex autoimmune disease that affects hundreds of thousands of people worldwide. In lupus, the immune system, which is designed to protect against infection, creates antibodies that can attack any part of the body including the kidneys, brain, heart, lungs, blood, skin, and joints. Kidney damage due to attacks by immune cells (lupus nephritis) is one of the most common complications of lupus, affecting as many as half of adults with lupus. When the kidneys become inflamed, they can't effectively get rid of waste products and other toxins from the body. This may lead to blood in the urine, protein in the urine, high blood pressure, impaired kidney function or even kidney failure.

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, many of which are outside of the Company’s control, 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. Investors should take such risks into account and should not rely on forward-looking statements when making investment decisions. 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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