PRESS RELEASE

Clinical Study for Itolizumab in Lupus Nephritis Initiated in India, Post DCGI Approval

Bengaluru, India, December 23, 2021 –

Biocon Biologics Ltd., a subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced that U.S.-based Equillium Inc., Biocon's partner, has expanded its EQUALISE study in Systemic Lupus Erythematosus (SLE) and Lupus Nephritis for Itolizumab (ALZUMAb-L*) to clinical centers in India. EQUALISE is a Phase 1b open-label, proof-of-concept clinical study currently studying Lupus Nephritis patients in the Part B portion of the clinical trial.

Equillium has initiated this study across several tertiary hospitals specialised to deal with Lupus Nephritis patients in India after obtaining approval from the Drugs Controller General of India (DCGI).

Systemic Lupus Erythematosus, or Lupus, is an autoimmune chronic inflammatory disease. The prevalence of SLE in the U.S. has been reported to be between 20 to 150 cases per 100,000. In India, the reported prevalence of SLE is 3.2 per 100,000.

Dr. Sandeep Athalye, Chief Medical Officer, Biocon Biologics, said: *"We are happy to announce the commencement of our partner Equillium's Phase 1b clinical study in India to evaluate the safety and early efficacy of Biocon Biologics' novel antibody, Itolizumab, in treating Lupus Nephritis. In India, approximately 45,000 patients are diagnosed with Systemic Lupus Erythematosus (SLE), of which over 20,000 patients have kidney involvement (nephritis), many of which do not respond to standard available therapy with steroids and immunosuppressive drugs.*

"We believe that ALZUMAb-L (Itolizumab) can address this unmet need for Lupus with better remission rates, more durable responses, and a better safety profile. Our partner Equillium has observed positive trends in the Part A portion of the Phase 1b study in SLE patients and hence is expanding the Part B portion of the study in Lupus Nephritis patients in the U.S. and India."

"Even with recent U.S. FDA approvals, treatments for patients with lupus nephritis have significant side effect profiles and do not result in complete responses for most patients, which are critical for long-term kidney survival," said **Dolca Thomas, M.D.,**

Equillium's Executive Vice President of Research & Development and **Chief Medical Officer**. *"We're very excited to see our study expand to India in hopes of filling a significant unmet medical need for lupus nephritis patients."*

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 several immuno-inflammatory diseases. This unique molecule holds the potential for multiple high-value indications. As an innovation-led organization committed to bringing novel therapeutics to the market to address unmet patient needs across the world, Biocon out-licensed Itolizumab to U.S.-based biotechnology company Equillium in 2017 for them to develop this molecule for the treatment of severe autoimmune and inflammatory disorders. Equillium is currently developing Itolizumab for multiple indications, including acute graft-versus-host-disease (aGVHD), Lupus and Lupus Nephritis and uncontrolled Asthma.

Equillium had in March this year unveiled favorable topline data from the Type A group of the EQUALISE study in patients with SLE. In this study, Itolizumab, 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. The initial data from the EQUALISE study demonstrated a favorable safety and tolerability profile for subcutaneous delivery of Itolizumab in SLE patients.

The **EQUALISE** study is evaluating the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD), and clinical activity of Itolizumab in patients with SLE and Lupus Nephritis. The trial design and initiation has been a joint effort with the Lupus community including working closely with leading global clinical and scientific experts in the Lupus field, the Lupus Research Alliance, and patients living with Lupus and/or Lupus Nephritis. Importantly, the study is also evaluating urinary biomarkers including soluble ALCAM and CD6, which 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.

***ALZUMAb-L** is Biocon Biologics' brand of Itolizumab, developed by Biocon and commercialized in India since 2013 as a novel anti-CD6 antibody for chronic plaque psoriasis. It has also received restricted emergency use authorization from the DCGI for the treatment of moderate to severe acute respiratory distress syndrome (ARDS) in COVID-19 patients and since then has saved thousands of lives.

About Systemic Lupus Erythematosus (SLE) / Lupus Nephritis (LN)

Systemic Lupus Erythematosus (SLE), or Lupus, 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 for patients with systemic lupus erythematosus is two weeks in duration in ascending dose cohorts, while treatment for patients with active proliferative lupus nephritis is 24 weeks in duration at dose level 1.6 mg/kg.

For more information on SLE, LN and the EQUALISE study, please visit Equillium's website. https://equilliumbio.com/patients/therapeutic-areas/lupus-nephritis/.

For additional information on the study, including potential to enroll in the study, please email Equillium's clinical team at clinicaltrials@equilliumbio.com.

About Biocon Biologics Ltd.

Biocon Biologics Limited, a subsidiary of Biocon Limited, is a fully integrated global biosimilars organization. It is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a strong research pipeline of biosimilar molecules across diabetes, oncology, immunology, and other non- communicable diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, in developed markets like United States, EU, Australia, Canada, Japan and key emerging markets. It has many firsts to its credit including the most recent USFDA approval of world's first interchangeable biosimilar, received for its Insulin Glargine. With a team of ~ 4,800 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients' worldwide. Website: www.biocon.com/businesses/biosimilars/

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About Biocon Limited

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer

and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. Website: www.biocon.com; Follow-us on Twitter: @bioconlimited

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