



**PRESS RELEASE**

**Biocon Limited initiates clinical study of Itolizumab for Ulcerative Colitis in India**

**Bengaluru, India. December 14, 2022**

**Biocon Limited** (BSE code: 532523, NSE: BIOCON), an innovation-led global biopharmaceutical company, today announced the initiation of the clinical study of Itolizumab in patients with Ulcerative Colitis (UC) in India, in collaboration with Equillium Inc. This is a phase two randomized, double-blind, parallel-group, placebo and active-controlled (adalimumab), two treatment period study to evaluate the safety and efficacy of Itolizumab for the induction of remission in biologics naïve patients with moderate to severely active UC.

Having obtained approval from the Drugs Controller General of India (DCGI), the study will cover several tertiary hospitals specialized in handling UC cases. The first patient who intended to participate in the study was screened on December 1, 2022.

Siddharth Mittal, Managing Director and CEO, Biocon Limited, said, *“We are encouraged by the progress being made on our high-value, multi-indication molecule, Itolizumab, in collaboration with Equillium. The commencement of the Phase two clinical study, that will determine its efficacy for the treatment of Ulcerative Colitis, is an important step forward in our efforts to bring its benefit to patients in India suffering from this disease. The development also underpins Biocon’s commitment to bring innovative, affordable medicines, that address unmet patient needs, to market expeditiously.”*

Dr Sandeep Athalye, Chief Medical Officer, Biocon Biologics, added, *“Among the developing regions of the world, India has the highest reported incidence of 9.31 cases per 100,000 persons for Inflammatory Bowel Disease and 5.41 cases per 100,000 persons for Ulcerative Colitis. Many of these cases do not respond to standard available therapy, such as corticosteroids, 5 Amino Salicylates (5-ASA) and immunosuppressive drugs, including TNF alfa inhibitors. We believe that Itolizumab can address this need for the treatment of UC, with better remission rates, more durable responses, and a better safety profile.”*

Commenting on the development, Dr Maple Fung, Senior Vice President of Clinical Development, Equillium Inc., said: *“T cells play a pivotal role in the immune response that leads to Inflammatory Bowel Disease and preclinical models show a role for CD6 in disease pathogenesis. As Itolizumab has a novel dual mechanism of action that modulates both the activity and trafficking of CD6-expressing T effector cells, it is an ideal candidate for treatment of Ulcerative Colitis, where the severe inflammation can be debilitating. Additional supportive rationale can be found in our ongoing program investigating Itolizumab in severe acute graft-versus-host disease, where our Phase 1b EQUATE study demonstrated meaningful responses, particularly in those with lower gastroenterological symptoms.”*

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### **About Itolizumab**

Itolizumab is a clinical-stage, first-in-class anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM pathway, which can drive several immuno-inflammatory diseases. This unique molecule holds the potential for multiple high-value indications.

Biocon out-licensed Itolizumab to Equillium Inc. in 2017 to develop this molecule for the treatment of severe autoimmune and inflammatory disorders. The company is currently developing Itolizumab for acute graft-versus-host-disease (aGVHD) and Lupus Nephritis. In the studies conducted so far, Itolizumab, in both presentations, i.e., intravenous, and subcutaneous, was found to be safe and well tolerated. Additionally, 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.

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 the Itolizumab clinical study for Ulcerative Colitis**

Ulcerative Colitis is a chronic relapsing disorder, characterized by destructive inflammation and epithelial injury in the gastrointestinal tract, with symptoms like diarrhoea and rectal bleeding. Biocon and Equillium's ongoing clinical study is evaluating the safety and efficacy of Itolizumab for patients with moderate to severely active UC, where patients are administered a fixed dosage of 140 mg every two weeks for six months.

The trial design and initiation has been a collaborative effort, with help from the gastroenterologist community and leading global, clinical and scientific experts in the field of Inflammatory Bowel Disease and UC. The study will also evaluate exploratory biomarkers, including soluble CD6 receptor occupancy, erythrocyte sedimentation rate (ESR) and C-reactive protein, which can help address the heterogeneity of the disease, a key issue for drugs in this field.

For more information on UC and the Biocon-Equillium clinical study of Itolizumab, as well as queries to enrol in the study, write to [ucp2\\_itoli\\_study.team@biocon.com](mailto:ucp2_itoli_study.team@biocon.com)

**About Biocon Limited:** Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led, global biopharmaceutical company committed to enhancing affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune diseases. 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. [www.biocon.com](http://www.biocon.com)

**About Equillium:** Equillium is a clinical-stage biotechnology company leveraging a deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory disorders with high unmet medical need. The company's pipeline consists of the following novel immunomodulatory assets targeting immuno-inflammatory pathways. Itolizumab, a first-in-class monoclonal antibody that targets the CD6-ALCAM signaling pathway which plays a central role in the modulation of effector T cells, is currently in a Phase 3 study for patients with acute graft-versus-host disease (aGVHD) and is in a Phase 1b study for patients with lupus/lupus nephritis. EQ101 is a first-in-class tri-specific cytokine inhibitor that selectively targets IL-2, IL-9, and IL-15. Equillium is currently enrolling patients in a Phase 2 proof-of-concept study of EQ101 for patients with alopecia areata. EQ102 is a bi-specific cytokine inhibitor that selectively targets IL-15 and IL-21.

Equillium is currently enrolling patients in a Phase 1 study of EQ102, including healthy volunteers and celiac disease patients. [www.equilliumbio.com](http://www.equilliumbio.com)

**Forward-Looking Statements: Biocon**

*This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.*

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