
***

# EXELIOM BIOSCIENCES ANNOUNCES FIRST PATIENT ENROLLED IN PHASE 1 STUDY FOR THE MAINTENANCE IN REMISSION IN ADULT PATIENTS WITH MILD TO MODERATE CROHN'S DISEASE

March 21, 2023 (Paris, Dijon, France) – Exeliom Biosciences, a biotechnology company, announced today the enrollment of the first patient in its Phase 1 clinical study of an investigational oral single-strain microbiome therapeutic (EXL-01) developed to prolong the maintenance in remission in adult patients with mild to moderate forms of Crohn's disease.

EXL01 is a, once daily, potentially first-in-class, microbiome-based immunotherapy containing a well characterized, unmodified, single-strain of the major dominant commensal bacterium *Faecalibacterium prausnitzii.*

"There is no cure for Crohn's Disease. The main aim of existing treatments is to relieve inflammatory symptoms by treating flares, put the disease in remission, and maintain remission. There is an urgent need to develop new, well tolerated treatments that maintain patients in remission, without the serious side effects associated with some of the immunosuppressant therapies in current use", said Prof. Harry Sokol, acting Chief Medical Officer and co-founder of Exeliom Biosciences."Our drug candidate, EXL01, offers a new modality to patients that taps into the natural immuno-modulatory properties of *Faecalibacterium prausnitzii,* a key bacterial species of our gut microbiome, already well known by many patients."

"The start of our Phase 1 study, MAINTAIN, is an important milestone for patients, and for Exeliom", said Benjamin Hadida, CEO and co-founder of Exeliom Biosciences. "Our preclinical studies suggest that EXL01 is a potentially transformative therapeutic candidate, validating our conviction that the *Faecalibacterium prausnitzii* plays an active role in the evolution of the disease. We are thrilled to see this study take off and finally give patients access to a *Faecalibacterium prausnitzii-based product*".

Crohn's Disease is one of the most common chronic inflammatory diseases, with 1.4 million patients in the US, Japan and the five biggest countries in Europe. Poor response as well as a loss of response lead to frequent incomplete control of the disease and a need for frequent changes of therapeutics; intestinal damage accumulates, and most patients will ultimately require surgery. 50% of patients with Crohn's disease undergo surgical treatment (removal of damaged segments of the small or large bowel) within 10 years of receiving the diagnosis.

The Phase 1 study is a multicentre, 2-part, randomised, parallel arm, placebo controlled, partially double-blind study that will evaluate the safety and target engagement of our drug candidate EXL-01 in the maintenance of corticosteroids-induced remission in participants with mild-to-moderate Crohn's disease. The primary outcome is the systemic and intestinal safety and tolerability. Secondary endpoints include target engagement through twenty-four weeks following the administration of our drug candidate compared with a placebo. The study is actively enrolling and will be conducted at approximately 10 centres across Europe.

For more information, please visit: https://clinicaltrials.gov/ct2/show/NCT05542355

## About Exeliom Biosciences

Exeliom Biosciences is a biotechnology company specialized in the development of microbiome-based immunotherapies with a mission to bring innovation to the pharmaceutical treatment of inflammatory bowel diseases and cancer.
Its lead asset, EXL01, a rationally selected, oral live biotherapeutic product is in clinical development for the treatment of Crohn's disease.

For more information, please visit: https://www.exeliombio.com/

**Contact:**
Benjamin Hadida
CEO Exeliom Biosciences
+33672437294
bhadida@exeliombio.com
Source: Exeliom Biosciences, S.A.S.