Exeliom Biosciences collaborates with REMIND in MAINTAIN POP study

- **Phase II trial will assess efficacy of EXL01 as treatment to prevent post-operative recurrence in patients with Crohn's disease**
- **Trial builds on MAINTAIN Part A study that supports good safety profile of EXL01 as maintenance treatment following steroid-induced remission in patients with mild-to-moderate Crohn's disease**
- **Part A of MAINTAIN study closed due to slow recruitment**
- **MAINTAIN POP trial to start early 2025 with topline results expected in Q1, 2027**

Paris, France, June 25, 2024 – Exeliom Biosciences, a clinical-stage biotechnology company developing new therapies in immuno-inflammation and immuno-oncology, today announces its collaboration with REMIND, a nationwide consortium of 14 French gastroenterology departments, in the MAINTAIN POP study, a phase II post-operative interventional trial in Crohn's disease. It will be a continuation of Exeliom's efforts in Crohn's disease after the company decided to close the MAINTAIN clinical study at the end of Part A due to a slow recruitment.

MAINTAIN POP is a phase II randomized placebo-controlled trial that will involve 13 sites in the REMIND group. It aims to enroll 80 patients with Crohn's disease who have successfully been brought to remission by surgery, to evaluate EXL01 as a stand-alone maintenance treatment or in combination with anti-TNFs. The study will assess both the safety and efficacy of EXL01 against endoscopic endpoints (e.g. endoscopic recurrence at six months post-surgery). This is a post-operative interventional study - coordinated by the REMIND group.

MAINTAIN POP is a continuation of the work undertaken in MAINTAIN (NCT05542355), a first-in-human phase I trial evaluating EXL01 for the maintenance of steroid-induced remission in patients with mild to moderate Crohn's disease. The preliminary results support a good safety profile for EXL01 in combination with corticosteroids and as a monotherapy in patients with Crohn's disease, as recently confirmed by the IDMC.

Despite encouraging safety data from Part A of the study, Exeliom reached the conclusion that continuing the study was no longer operationally feasible. While no participant discontinued EXL01 treatment due to adverse events, recruitment into Part A of the study proved challenging, with a net recruitment rate approximately one-tenth of that projected at the study's outset. The final results are expected to be delivered in the first half of 2025, including preliminary translation data regarding target engagement.

"The decision to halt recruitment in MAINTAIN at the end of Part A does not diminish our commitment to advancing the clinical development of EXL01 in Inflammatory Bowel Disease (IBD), particularly Crohn's disease," said Benjamin Hadida, CEO of Exeliom. "We are happy to announce the launch of this new study, MAINTAIN POP, in collaboration with REMIND, a renowned translational research organization specializing in IBD, to further these efforts."

"There is a clear unmet need for an effective and well-tolerated medicine to help patients with Crohn's disease maintain their periods of remission. Exeliom can build on preliminary results which support the expectation of the good safety profile of EXL01 as a monotherapy for Crohn's patients," said Pr. Harry Sokol, professor of gastroenterology at Saint-Antoine hospital in Paris and co-founder of Exeliom.

"Surgery is a frequent event in the life of Crohn's disease patients, unfortunately followed by a high risk of recurrence. We will assess the impact of EXL01 on preventing this recurrence," said Pr. Matthieu Allez, professor at Saint-Louis hospital in Paris, and co-founder and president of the REMIND group.

The clinical trial authorization for MAINTAIN POP will be submitted in September 2024, with the aim of starting enrollment in early 2025 and publishing topline results in Q1, 2027.

About Crohn's disease
Crohn's disease is a growing public health concern, with a prevalence of more than 1.6 million people in Europe. Up to 70–80% of patients with Crohn's disease require surgery. Surgery is associated with a state of remission but is not curative, as most patients will experience disease recurrence during the following five years, which has a significant impact on quality of life (QoL) and an important socio-economic burden. For several reasons, including cost, safety issues and patient's expectations, approximately half the patients do not receive a treatment immediately after surgery. However, many of these patients experience a significant early endoscopic recurrence, despite no risk factors.

About EXL01
EXL01 is a live biotherapeutic product (LBP) containing an unmodified single-strain of *F. prausnitzii*, a key player in the human gut microbiome, which is being developed as a new immune modulating medicine. EXL01 acts on key innate immune system targets to trigger non-suppressive inflammation resolving mechanisms. Currently, there is no cure for IBD and only two other LBPs have been evaluated in clinic with encouraging results, both for UC. With promising published results of Fecal Microbiota Transplantation (FMT) in Crohn's disease, there is a great potential for LBP treatments for managing Crohn's disease.

About REMIND
The REMIND group was established in 2006 and gives access to a network of gastroenterologists specialized in IBD and working in numerous gastroenterology referral centers in France and Belgium, as well as basic and translational researchers. Most are affiliated to both gastroenterology departments and academic laboratories (Inserm).
The global strategy is to foster interactions between researchers in the IBD field and to provide new insights into the understanding of the physiopathology of IBD; to improve the management and treatment of these complex chronic inflammatory disorders by linking high quality and exhaustive clinical data with dedicated analysis of the patients' samples, using various approaches integrating genetics, immunity and microbiota.
Having already established a first cohort of more than 700 patients with perfectly curated clinical information, the REMIND group has the statistical and bioinformatics knowledge and know-how to integrate larger data sets.
www.grouperemind.org

About Exeliom Biosciences
Exeliom Biosciences is developing new therapies in immuno-oncology and immuno-inflammation. Its candidates improve patients' ability to respond to treatments in settings where dysregulated immunity can impede efficacy, such as inflammatory bowel diseases, solid tumor cancers and chronic infectious diseases. Exeliom Biosciences' lead candidate, EXL01, is a single-strain live biotherapeutic product that exploits the unique ability of a commensal bacterium (*Faecalibacterium prausnitzii*) to simultaneously activate several pivotal regulators of inflammation. As such, it offers a novel strategy to modulate inflammation. EXL01's unique immunomodulatory profile may be exploited to attenuate resistance to existing treatments when administered in combination with them. EXL01 is being

evaluated in several clinical trials, including a phase I trial in Crohn's, three phase II trials in immuno-oncology in combination with immune checkpoint inhibitors and a phase I/II trial in the prevention of recurrent *C. difficile* infection. In parallel, Exeliom Biosciences has developed a multimodal pipeline.

Exeliom is based on strong scientific foundations and has a world-renowned team, led by Pr. Harry Sokol, gastroenterologist and hepatologist at Saint-Antoine Hospital, AP-HP and Sorbonne University, Dr. Philippe Langella, research director at INRAE, and Pr. Patrick Gervais, process engineering specialist at AgroSup.

Founded in 2016 and headquartered in Paris, Exeliom has raised a total of €27 million ($29M) since its inception. The company has been awarded the 'Plan de relance 2030', 'Deeptech' and 'I-Lab' awards by Bpifrance, and the 'EIC Accelerator' by the European Innovation Council Fund. It has also received financial support from the Crohn's & Colitis Foundation of America.

www.exeliombio.com

Media and analysts contact
Andrew Lloyd & Associates
Matthew Gower – Juliette Schmitt
matthew@ala.associates / juliette@ala.associates
UK: +44 1273 952 481