



## **Exeliom Biosciences announces three phase II clinical trials in immuno-oncology with lead candidate combined with immune checkpoint inhibitors**

**Phase II clinical trials will investigate efficacy of lead candidate EXL01 - in gastric cancer with GERCOR, in NSCLC with CHU Lille and in hepatocellular carcinoma with Centre Eugène Marquis of Rennes**

**EXL01 first ever single-strain live biotherapeutic product using *F. praunsitzii* to be evaluated in immuno-oncology**

**Paris, France, April 11, 2024** – Exeliom Biosciences, a clinical-stage biotechnology company developing new therapies in immuno-oncology and immuno-inflammation, today announces the launch of three phase II clinical studies of its lead candidate EXL01 combined with immune checkpoint inhibitors to target multiple cancers.

EXL01 will act as an adjuvant by modulating the immune system, with synergistic effects when combined with immune checkpoint inhibitors. This is the first single-strain Live Biotherapeutic Product (LBP) using *Faecalibacterium praunsitzii* [*F. praunsitzii*] to be evaluated in a clinical setting for application in immuno-oncology.

"I am thrilled to enter the immuno-oncology arena with the launch of these clinical trials, spearheaded by talented teams across France. This is a huge milestone for us, establishing the company as a leader in the development of live biotherapeutic products in this field," said Benjamin Hadida, CEO of Exeliom.

EXL01 is a novel drug candidate containing an unmodified single-strain of *F. praunsitzii*, being developed as a new immune modulating medicine. Research shows that this species plays a critical role in the body's ability to respond to immune-checkpoint inhibitors in the treatment of cancer and that increasing levels of *F. praunsitzii* in patients could potentially lead to longer progression-free survival periods.

"The results of these studies have the potential to revolutionize medical practice and provide better treatment outcomes for patients with a relatively poor prognosis," said Pr. Harry Sokol, professor of gastroenterology at Saint-Antoine hospital in Paris and chief medical officer at Exeliom.

The three phase II clinical trials, approved by the French regulatory agency ANSM (Agence Nationale de Sécurité du Médicament), will investigate the use of EXL01 in:

- Gastric cancer – led by GERCOR, a non-profit organization with a network of over 300 centers, whose mission is to improve treatments for solid tumor cancer patients
- Non-Small Cell Lung Cancer (NSCLC) - led by the Lille University Hospital (CHU de Lille), one of the top five university hospitals in France for the quality of its research
- Hepatocellular carcinoma – led by the Centre Eugène Marquis of Rennes, a university hospital associated with the university of Rennes and a member of OncoBretagne, the regional oncology network



In these three indications, respectively only 35%, 20% and 30% of the patients respond to the standard of care even in first line treatment. Increasing the efficacy of these treatments would cater to a large group of patients with severe unmet medical needs.

“Positive results could dramatically change the paradigm of how patients are treated with the existing immunotherapies,” said Dr. Romain Cohen, medical oncologist at Saint-Antoine hospital, Paris, assistant professor of oncology at Sorbonne University and core member at GERCOR.

The EXL01-drug substance is formulated in gastro-resistant capsules for oral administration, designed to enable targeted delivery in the intestines. Exeliom worked extensively on the scale-up manufacturing, facilitating the supply of these phase II trials. The company expects to share results of the trials at the end of 2026, if positive there will be the potential to launch phase III studies.

#### **About GERCOR**

Created in 1997, GERCOR is a non-profit organization whose mission is to improve treatments for cancer patients (solid tumors) through innovative and multidisciplinary clinical research. GERCOR is a promoter of clinical trials (Phases I to III) and strives to conduct them with complete independence. It relies on a national network of 300 centers (university hospitals, cancer centers, general hospitals and private centers), as well as collaborations with other academic groups in France, and is internationally coordinated by an operational team certified by the National Cancer Institute (INCA) and the National League Against Cancer.

[www.gercor.com](http://www.gercor.com)

#### **About Center Eugene Marquis**

The Center Eugène Marquis is a non-profit Private Health Institution that participates in the public hospital service through its three missions: care, research and teaching. It is the Regional Center for Cancer Care in Brittany and a member of the French Federation of Cancer Control Centers (UNICANCER) which has 18 establishments in France 100% dedicated to the fight against cancer.

[www.centre-eugene-marquis.fr](http://www.centre-eugene-marquis.fr)

#### **About CHU de Lille**

With more than 16,000 professionals and ten hospitals grouped together on the same campus, the Centre Hospitalier Universitaire de Lille is one of the four largest university hospital centres in France, and one of the largest in Northern Europe. As a referral, teaching, innovation and research hospital, it serves the six million inhabitants of the Hauts-de-France region. Lille University Hospital is strongly committed to the development of therapeutic innovation and clinical research. Its research strategy focuses on the early diagnosis and treatment of diseases, including cancer, neuroscience, cardiovascular, metabolic, inflammatory and infectious diseases.

[www.chu-lille.fr](http://www.chu-lille.fr)

#### **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.



**exeliom**  
biosciences

Founded in 2016 and headquartered in Paris, Exeliom has raised a total of €24 million (\$26M) 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](http://www.exeliombio.com)

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