



Enterome initiates first clinical trial with EO2401 – an innovative microbiome-antigen ('OncoMimic') based cancer immunotherapy candidate targeting aggressive brain cancer

EO2401 combines three 'OncoMimics' designed to trigger the immune system into recognizing tumor cells as bacterial (i.e. non-self) and eliciting a targeted cell-killing response

First patient dosed in Phase 1/2 ('ROSALIE') trial investigating EO2401

Paris, France and Cambridge, MA, USA – July 30, 2020

ENTEROME SA, a clinical-stage biopharmaceutical company leveraging its unique knowledge of the microbiome-immunoinflammation axis to develop next-generation therapeutics, announced it has initiated its first clinical trial with EO2401, an innovative microbiome-antigen ('OncoMimic') based cancer immunotherapy candidate. The Phase 1/2 ('ROSALIE') clinical trial is investigating EO2401 in combination with an immune checkpoint inhibitor as a potential new treatment for progressive or first recurrent glioblastoma multiforme (GBM), an aggressive form of brain cancer for which no cure exists. Initial clinical data from the ROSALIE study are expected in 2022.

EO2401 is an innovative, off-the-shelf immune-oncology candidate derived from Enterome's revolutionary 'OncoMimic' platform. OncoMimics are microbiome-derived peptide antigens that closely mimic antigens expressed by tumor cells; they are selected based on their ability to trigger the rapid activation of memory T-cells that respond to gut bacteria and to direct a targeted cell-killing immune response against the tumor. EO2401 combines three OncoMimics present in aggressive cancers such as glioblastoma.

The first clinical trial with EO2401 (ROSALIE, NCT04116658) is a multicenter, open-label, Phase 1/2 study assessing its safety, tolerability, immunogenicity and preliminary efficacy in combination with a checkpoint inhibitor in patients with GBM. A total of 32 patients are expected to be enrolled at 10 clinical sites in Europe and the US.

Prof. Wolfgang Wick, MD, Chairman, Department of Neurology, Heidelberg University Hospital (Heidelberg, Germany), is ROSALIE's Principal Investigator. Professor Wick is a globally renowned neuro-oncologist with extensive clinical research experience in the field of primary and recurrent brain tumors.



Prof. Wolfgang Wick, MD, said: *“There is an urgent need to find a truly effective treatment for glioblastoma to help prevent recurrent or further progression of this deadly form of brain tumor. We have seen increasing evidence of the influence of the gut microbiome over immune responses to cancer and cancer immunotherapies. EO2401 is based on a novel concept that builds on this understanding and I am excited to participate in this first clinical trial with EO2401.”*

Jan Fagerberg, CMO of Enterome, said: *“This first-in-human trial evaluating EO2401 in patients with glioblastoma is a significant milestone for Enterome. EO2401 is the first targeted immunotherapy generated from our unique OncoMimics immunotherapy platform. This novel approach capitalizes on the finding that certain bacterial antigens derived from the gut microbiota bear striking molecular similarities to antigens found in human tumors. We are confident that these similarities will enable our so-called ‘OncoMimics’ to trigger powerful and targeted immune responses against specific cancers, including glioblastoma. We believe that this concept can be applied against multiple cancers. We are proud and pleased to be able to begin clinical studies with EO2401 and to position Enterome as a leader of next-generation cancer immunotherapies.”*

Enterome will start a second clinical study in patients with adrenal malignancies in the coming weeks and plans to initiate another clinical study in patients with B-cell malignancies in 2021.

Contacts

Enterome

Pierre Belichard, CEO

media@enterome.com

Media Relations

Mark Swallow / Sylvie Berrebi / David Dible

Citigate Dewe Rogerson

Tel. +44 207 638 9571 / enterome@citigatedewerogerson.com

Investor Relations

Melody Carey

Rx Communications Group

Tel. +1 917 322 2571 / mcarey@rxir.com



About Enterome

Enterome is a world leader in the discovery and development of novel pharmaceuticals based on its unrivalled understanding of the interaction between the gut microbiome and the immune system (the 'microbiome-immunoinflammation axis'). Enterome is leveraging this expertise to develop a pipeline of clinical and pre-clinical candidates (small molecules, proteins and peptides) with a focus on cancer, autoimmune, inflammatory and metabolic diseases.

Enterome has two unique platforms that are generating highly promising drug candidates:

- **OncoMimics:** highly effective, off-the-shelf immunotherapies against cancers (EO2401, EO2463). EO2401 is in Phase 1/2 clinical trials in patients with glioblastoma and expected to enter first clinical studies in patients with adrenal malignancies during mid-2020. EO2463, is being prepared as a clinical candidate for B-cell malignancies (lymphomas and leukaemias).
- **EndoMimics:** a new generation of biologics for inflammatory diseases (EM101), Type 2 diabetes and inflammatory bowel disease.

These highly productive platforms have been created using Enterome's world-leading Metasecretome technology, which gives it an unrivalled ability to generate precision drugs by using the natural reservoir of thousands of safe and tolerized effector proteins that are produced by the gut bacteria.

Enterome's most advanced drug candidate is EB8018 (also referred to as sibofimloc/TAK-018), which selectively blocks the virulence factor FimH, is advancing through clinical trials in Crohn's disease. EB8018 has been partnered with Takeda globally, with Enterome retaining a significant profit share in the US.

Enterome is headquartered in Paris (France) with operations in Boston (US) and is backed by leading venture capital investors.

For more information please visit the company's website at: www.enterome.com.