



Enterome – First Patient Dosed in a Phase 1/2 Trial with EO2401, an Innovative ‘OncoMimic’ based Immunotherapy Candidate Targeting Adrenal Tumors

- **EO2401 is an innovative, off-the-shelf microbiome-antigen (‘OncoMimic’) based immunotherapy candidate**
- **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**
- **Clinical trial with EO2401 now underway in two cancer indications: brain cancer (glioblastoma) and adrenal tumors**

Paris, France and Cambridge, MA, USA – September 9, 2020

ENTEROME SA, a clinical-stage biopharmaceutical company leveraging its unique knowledge of the microbiome-immunoinflammation axis to develop next-generation therapeutics, today announced that it has initiated a new clinical trial with EO2401, an innovative microbiome-antigen (‘OncoMimic’) based cancer immunotherapy candidate, in a second cancer indication. The new Phase 1/2 clinical trial, named ‘SPENCER’, is investigating EO2401 in combination with an immune checkpoint inhibitor (CPI) as a potential new treatment for adrenal malignancies.

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 cancers such as glioblastoma and adrenal tumors.

Christophe Bonny, Chief Scientific Officer of Enterome, explained: *“We have now launched two clinical trials that demonstrate our strategy to potentially address different tumor-types with one combination of OncoMimics. This is because the targeted tumor antigens selected for EO2401 are expressed both in glioblastoma and in adrenal tumors. We are extremely excited by our OncoMimics approach as we believe it can be used to target any tumor antigen, and thus has therapeutic potential across all cancers. We expect the robust immune response driven by EO2401 when combined with a checkpoint inhibitor to generate clinically meaningful efficacy for these hard-to-treat patients.”*



The SPENCER trial (NCT04187404) is a multicenter, open-label, Phase 1/2 study assessing the safety, tolerability, immunogenicity and preliminary efficacy of EO2401 in combination with a CPI in patients with adrenal tumors (adrenocortical carcinoma and malignant pheochromocytoma/paraganglioma). A maximum of 72 patients are expected to be enrolled at nine clinical sites in Europe and the US.

Eric Baudin, MD is SPENCER's Global Coordinating Investigator. Dr. Baudin is Associate Professor and Head of the Endocrine Oncology Unit at the *Institut Gustave Roussy* (Villejuif, France) and is a world-renowned expert regarding adrenal tumors.

Dr. Baudin commented: *"Adrenal tumors are rare diseases where patients with both main types, i.e. adrenocortical carcinoma and malignant pheochromocytoma/paraganglioma, are in need of new effective therapies both as initial systemic therapy and as therapy for more advanced disease. We look forward to assessing the potential benefits of the novel immunotherapy approach of EO2401 in combination with a checkpoint inhibitor in this underserved patient population."*

Jan Fagerberg, Chief Medical Officer of Enterome, said: *"This new trial evaluating EO2401 in patients with adrenal malignancies, is another significant milestone for Enterome. EO2401 is the first off-the-shelf, targeted immunotherapy generated from our unique OncoMimics platform. We are delighted to initiate this second trial with EO2401 and believe that the data we expect to generate from both the SPENCER and ROSALIE studies will position Enterome as a clear leader of next-generation cancer immunotherapies."*

Enterome started a first clinical study with EO2401 in patients with glioblastoma in July 2020 and is exploring other immunotherapy opportunities for its OncoMimic platform. The Company plans to initiate the clinical development of its second OncoMimic candidate, EO2463, in patients with B-cell malignancies in 2021.

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About Adrenal Tumors

Two different primary malignancies can arise from the adrenal gland: (1) adrenocortical carcinoma (ACC) from the adrenal cortex, which are in most cases steroid hormone-producing; and (2) malignant pheochromocytoma from the adrenal medulla. Pheochromocytomas are catecholamine-producing (epinephrine and norepinephrine) neuroendocrine tumors arising from chromaffin cells, which can also be located in extra-adrenal paraganglia, and are referred to as paraganglioma. The two subtypes combined are referred to as malignant pheochromocytoma/paraganglioma (MPP).

Surgery is the only curative treatment modality for both ACC and pheochromocytoma at the primary diagnosis, and when possible also at recurrence. Most patients with ACC have resectable disease at presentation, however, more than half of the patients who have undergone complete removal of the tumor will relapse, often with metastases. Similarly, radical resection is not a guarantee of cure for pheochromocytomas.

The median overall survival (OS) of all patients with ACC is 3–4 years. Prognosis for patients with locally advanced inoperable and metastatic ACC is poorer, with five-year overall survival being <15%. The median survival of patients with advanced ACC not amenable to radical surgical resection who were treated with polychemotherapy as first line therapy in the FIRMACT trial (the first randomized trial in ACC) was 14.8 months.

Malignant MPP is characterized by prognostic heterogeneity. A retrospective multicenter study of malignant MPP including 169 patients from 18 European centers diagnosed between 1998 and 2010 indicated a median survival 6.7 years.



Treatment options for patients with unresectable adrenal tumors are few and no new treatment options have been added recently. The current first-line therapies in both subtypes only achieves tumor regression in approximately one in four patients at the cost of a relatively high toxicity burden, especially from the polychemotherapy. New treatment concepts therefore have the potential to challenge first-line treatments to meet these unmet needs.

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 adrenal tumors. EO2463, is being prepared as a clinical candidate for B-cell malignancies (lymphomas and leukemias).
- **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.