

Enterome Receives FDA IND Clearance for EO2463, an 'OncoMimic' based Immunotherapy Targeting Liquid Tumors

Phase 1/2 clinical trials in patients with follicular lymphoma and marginal zone lymphoma expected to begin in Q2 2021

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ENTEROME SA, a clinical stage biopharmaceutical company developing novel drugs based on its unique ability to de-code molecular interactions in the gut microbiome impacting human health, today announces that it has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) to proceed with a Phase 1/2 clinical trial of EO2463, a potential treatment for indolent non-Hodgkin B-cell lymphomas (iNHL). EO2463 will be Enterome's second OncoMimics candidate to enter the clinic.

EO2463 is an innovative, off-the-shelf immuno-oncology candidate that combines four OncoMimics of B lymphocytes-specific lineage markers. The clinical rationale behind targeting these specific lineage cell markers is to induce the full depletion of malignant B lymphocytes enriched in iNHL.

OncoMimics are peptides, derived from bacteria present in the gut microbiome, that closely mimic either overexpressed tumor-associated antigen (TAA) or lineage-specific markers in solid and liquid tumors, respectively. OncoMimics are selected based on their ability to trigger the rapid activation of memory T-cells that were previously exposed to gut bacteria antigens similar to TAAs, and to direct a targeted cell-killing immune response against the tumor.

The primary objective of the study is to demonstrate safety, tolerability and efficacy of EO2463 as a monotherapy and in combination with standard of care (rituximab and rituximab in combination with lenalidomide) in 60 patients with follicular lymphoma (FL) and marginal zone lymphoma (MZL).

"With EO2463, we are expanding the potential utility of our OncoMimics pipeline into the field of liquid tumors. This milestone highlights the rapid progress that we are making with this potentially transformative cancer immunotherapy approach and builds on the ongoing trials of EO2401 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 look forward to updating you on the progress of this clinical trial, which is expected to start in the second quarter of 2021," said Jan Fagerberg, Chief Medical Officer of Enterome.



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About Enterome

Enterome is a clinical stage biopharmaceutical company developing novel drugs based on its unique ability to de-code molecular interactions in the gut microbiome impacting human health. Enterome's success is based on its unique ability to identify small proteins and peptides ("effectors") from gut bacteria that can deliver a therapeutic benefit in humans.

Enterome is leveraging this unique ability to develop two highly promising pipelines of clinical and preclinical candidates with a focus on cancer, inflammatory and metabolic diseases:

- 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 about to enter clinical development for indolent non-Hodgkin B-cell lymphomas.
- **EndoMimics**: a new generation of biologics targeting inflammatory diseases (EM101) and metabolic diseases such as Type 2 diabetes.

These pipelines have been created using Enterome's highly efficient proprietary drug discovery platform that uses machine learning and lab assays to interrogate and decode the world's largest database of gut bacterial proteins, a unique source of novel precision drugs.

In addition, Enterome's clinical candidate Sibofimloc (also referred to as TAK-018) is advancing through Phase 2 clinical trials in Crohn's disease. Sibofimloc has been partnered with Takeda globally, with Enterome retaining a significant profit share in the US.

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

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