



## **Enterome announces first patient dosed in Phase 2 trial with OncoMimics™ immunotherapy EO2040 in Colorectal Cancer with ctDNA-defined Minimal Residual Disease**

***First clinical trial of an OncoMimics™ immunotherapy to use liquid biopsy monitoring to measure ctDNA clearance as an indicator of treatment efficacy***

***EO2040 is Enterome's fourth OncoMimics™ peptide-based immunotherapy to enter clinical development***

**Paris, France – July 11, 2023**

**Enterome, a clinical-stage company developing first-in-class immunomodulatory drugs for cancer and immune diseases based on its unique Mimicry platform,** today announces that the first patient has been dosed at The University of Texas MD Anderson Cancer Center (Houston, TX) in the Phase 2 'CLAUDE' trial evaluating EO2040, the Company's fourth OncoMimics™ immunotherapy candidate to enter clinical development. The CLAUDE trial will assess the immunogenicity and the preliminary efficacy of EO2040 in combination with nivolumab and as a monotherapy in patients with circulating tumor DNA (ctDNA) defined minimal residual disease (MRD) stage II-IV colorectal cancer (CRC) after completion of surgical resection and all other standard of care treatments.

EO2040 is an innovative, off-the-shelf immunotherapy that combines two synthetic OncoMimics™ peptides. These non-self, microbial-derived peptides correspond to CD8 HLA-A2 epitopes that exhibit molecular mimicry with the tumor-associated antigens (TAAs) FOXM1 & BIRC5. EO2040 also includes universal cancer peptide 2 (UCP2), a helper peptide representing the CD4+ epitope.

The CLAUDE study (EOCRC1-22; NCT05350501) is the first trial to use liquid biopsy monitoring to measure ctDNA clearance as an indicator of OncoMimics™ immunotherapy efficacy. A total of 34 patients are expected to be enrolled in this multi-center, open-label Phase 2 study in the US and Europe.

Circulating tumor DNA (ctDNA) assays can reveal minimal residual disease after surgical resection of a tumor in patients who appear radiographically free of disease, by detecting and analyzing traces of tumor DNA in a blood sample. Detection of ctDNA after completion of curative-intent therapy predicts with nearly 100% specificity the risk of cancer recurrence. The lead time between ctDNA detection and radiographic evidence of cancer recurrence is up to nine months, providing a window for the evaluation of novel therapeutic strategies.

The primary objective of the CLAUDE trial is to assess the six-month ctDNA clearance rate – with ctDNA clearance being used as a surrogate endpoint for prolongation of disease-free survival (DFS). ctDNA clearance is characterized by the disappearance of all somatic mutations identified in the blood, as well as no appearance of any additional new somatic mutations, and radiographic investigations showing no evidence of CRC.

**Dr Pierre Belichard, CEO of Enterome, said:** *“We are delighted to begin a new clinical study to evaluate the potential of our new OncoMimics™ immunotherapy EO2040 to treat a second colorectal cancer indication. This latest trial is particularly interesting due to its use of liquid biopsy monitoring to measure ctDNA clearance as an indicator of treatment efficacy. If CLAUDE is successful, then it could open multiple opportunities in other major cancer indications where the use of ctDNA monitoring to detect residual disease after surgery and other standard of care treatment is used. This would support Enterome’s ambition to build a significant and valuable OncoMimics™ franchise and provide the Company with a uniquely differentiated position and ability to deliver a broad pipeline of next-generation OncoMimics™ immunotherapies.”*

## Contacts

ENTEROME	MEDIA RELATIONS
<b>Guillaume Bayre</b> <b>Head of External Communications</b> <b>Tel; +33 (0)1 76 21 58 15</b> <a href="mailto:communication@enterome.com">communication@enterome.com</a>	<b>Sylvie Berrebi / Mark Swallow / David Dible</b> <b>MEDISTRAVA Consulting</b> <b>Tel. +44 (0) 203 928 6900</b> <a href="mailto:enterome@medistrava.com">enterome@medistrava.com</a>

## About OncoMimics™

OncoMimics™ immunotherapies are designed to activate pre-existing effector memory T cells that target bacterial (non-self) peptides, which are strongly cross-reactive against selected Tumor-Associated Antigens (TAAs), or B cell markers expressed on tumoral cells, resulting in a rapid, targeted cytotoxic response against cancer.

## About EO2040

EO2040 is an innovative, off-the-shelf immunotherapy that combines two synthetic OncoMimics™ peptides. These non-self, microbial-derived peptides correspond to CD8 HLA-A2 epitopes that exhibit molecular mimicry with the tumor-associated antigens (TAAs) FOXM1 & BIRC5. EO2040 also includes universal cancer peptide 2 (UCP2), a helper peptide representing the CD4+ epitope.

## About CLAUDE

CLAUDE (EOCRC1-22; NCT05350501) is a multi-center, open-label Phase 2 trial investigating EO2040 in combination with nivolumab in patients with circulating tumor DNA-defined Minimal Residual Disease (MRD) of colorectal cancer stage II, III, or IV after completion of standard curative therapy. The trial is assessing safety, tolerability, immunogenicity and preliminary efficacy (percentage of patients with ctDNA clearance and no radiographic evidence of recurrence after six months) in 34 patients at centers in the US and Europe. Patient enrollment is ongoing.

## About Colorectal Cancer

Colorectal cancer (CRC) is the third most common tumor in men and the second in women, accounting for 10% of all tumor types worldwide. With more than 600,000 deaths estimated each



year, CRC is the fourth most common cancer-related cause of death globally. Despite all efforts regarding surgery and adjuvant therapy, approximately 25% of patients with localized disease will later develop metastases. In addition, 20% of newly diagnosed patients have metastatic disease already at presentation. Thus, CRC continues to be a major therapeutic challenge with a considerable number of patients experiencing premature death, fewer than 20% of those diagnosed with recurring/metastatic disease surviving beyond 5 years from diagnosis.

### About Enterome

Enterome is a clinical-stage biopharmaceutical company developing breakthrough immunomodulatory drugs for the treatment of cancer and immune diseases. Enterome's pioneering approach to drug discovery is based on its unique and powerful bacterial Mimicry drug discovery platform, allowing it to analyze and uncover new biological insights from the millions of gut bacterial proteins in constant cross-talk with the human body. Its first-in-class, small protein and peptide drug candidates modulate the immune system by closely mimicking the structure, effect or actions of specific antigens, hormones, or cytokines.

The company's two pipelines of drug candidates include:

- **OncoMimics™** peptides, a pipeline of peptide-based immunotherapies. Lead candidate, EO2401, is in Phase 2 clinical trials in patients with glioblastoma and adrenal tumors and has demonstrated clinical proof of concept. EO2463 is in a Phase 1/2 clinical trial for indolent non-Hodgkin lymphomas, and has demonstrated a good safety profile with first signs of efficacy. EO4010 is in clinical development for third-line colorectal cancer and EO2040 is in a Phase 2 trial in patients suffering from colorectal cancer with ctDNA-defined, minimal residual disease.
- **EndoMimics™** peptides, a pipeline of next generation bioactive molecules acting like human hormones or cytokines, are being developed in collaboration with Nestlé Health Science, for food allergies and inflammatory bowel disease (IBD). Lead candidate, EB1010, expected to enter clinical development in 2024, is a potent local inducer of IL-10, designed to improve therapeutic outcomes for patients with IBD.

Enterome employs 70 people and is headquartered in Paris, France. Since its inception, the Company has raised a total of €116 million from Europe- and US-based life science investors and more than €100 million from pharmaceutical partnerships.

For more information, please visit the company's website at: [www.enterome.com](http://www.enterome.com)