Enterome Presents Encouraging Initial Clinical Data on EO4010 in Colorectal Cancer at ESMO IO 2024

- ***Data from the ongoing Phase 2 of EO4010 demonstrate tumor target specific immune responses and objective tumor responses, including in liver mets, in patients with previously treated microsatellite stable metastatic colorectal cancer (mCRC)***

Paris, France – December 11th, 2024

Enterome, a clinical-stage company developing first-in-class immunomodulatory drugs for cancer based on its unique Mimicry platform, today announced that initial clinical data from the ongoing Phase 1/2 'AUDREY' trial evaluating its innovative OncoMimics™ immunotherapy EO4010 in microsatellite stable metastatic colorectal cancer (CRC), will be presented at the ESMO Immuno-Oncology (IO) Congress, taking place in Geneva, Switzerland, December 11-13, 2024.

The AUDREY trial (EOCRC2-22) assesses the safety, tolerability, and preliminary efficacy of EO4010, in combination with nivolumab +/- bevacizumab, in patients with microsatellite stable (MSS), unresectable, and previously treated metastatic colorectal cancer (mCRC) — an indication with limited effective treatment options and poor clinical outcomes. EO4010 includes five OncoMimics™ peptides that mimic tumor-associated antigens (TAAs) highly expressed in colorectal cancer, designed to stimulate $CD8^+$ T cells to target and eliminate tumor cells.

Poster presentation details:

Abstract #457

- **Title**: *EO4010 (EO) + nivolumab (N) ± bevacizumab (B) in patients (pts) with microsatellite stable (MSS) metastatic colorectal carcinoma (mCRC)*
- **Presenting Author:** Dr. Romain Cohen, Department of medical oncology, Saint-Antoine hospital, AP-HP, and Assistant Professor of Oncology at Sorbonne University, Paris
- **Poster Session: presentation time December 12, 12:00 PM-13:00 PM CET**

Key findings:

Among the 17 patients evaluated in Cohort 2 of the AUDREY trial, one achieved a partial response, showing a 46% reduction in liver metastases, a 34% reduction in lung metastases, and normalization of carcinoembryonic antigen (CEA) levels. Two additional patients achieved stable disease; one demonstrated a 7% reduction in lung metastases and a marked reduction of tumor biomarkers CEA/CA19-9, while another maintained stable disease beyond 17 weeks. Six patients showed stable disease in target lesions, though with progression in non-target lesions, along with some biomarker reductions.

In Cohort 3, which included bevacizumab in addition to EO4010 and nivolumab, three out of five evaluated patients achieved stable disease, with one continuing treatment > 24 weeks (lung met's +8%, CEA normalized).

Immune response analysis showed EO4010-specific CD8+ T cells in 12 out of 13 tested patients, with cross-reactivity to the targeted tumor antigens. Notably, over 80% of these cells were effector memory T cells after five weeks, demonstrating a sustained, targeted immune response.

Dr. Romain Cohen, Coordinating Investigator for the AUDREY trial, commented, "These early data highlight EO4010's potential to induce targeted immune responses and shrinkage of liver metastases in patients with pretreated microsatellite stable metastatic colorectal cancer. We look forward to continued follow-up and further results from the AUDREY trial."

Pierre Bélichard, Chief Executive Officer of Enterome, added, "The presentation of EO4010 data at ESMO IO reflects our dedication to pioneering next-generation immunotherapies for cancers with high unmet needs. These findings support the potential of our OncoMimics™ platform to deliver new options for patients, leveraging multi-target engagement to address tumor heterogeneity and prevent immune escape."

About OncoMimics™

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

About EO4010

EO4010, Enterome's third clinical-stage OncoMimics™ candidate, combines five microbial-derived peptides that mimic HLA-A2 restricted CD8+ T cell epitopes from five TAAs: BIRC5/survivin, FOXM1, UBE2C (UBCH10), CDC20, and KIF2C (MCAK). It also includes a CD4 helper peptide, Universal Cancer Peptide 2 (UCP2), to bolster immune activation. The BIRC5 and FOXM1 mimic peptides, also used in EO2401, have shown strong immune responses and correlated clinical outcomes in combination with nivolumab +/- bevacizumab for glioblastoma.

About AUDREY

AUDREY (EOCRC2-22/NCT05589597) is a multicenter, open-label Phase 1/2 trial investigating EO4010 in monotherapy and in combination with nivolumab for treatment of patients with unresectable, previously treated, metastatic colorectal cancer. The trial is assessing safety, tolerability, immunogenicity and preliminary efficacy in 42 patients at centers in Europe and the US.

About colorectal cancer

Colorectal cancer (CRC) is the third most common cancer in men and the second in women, contributing to 10% of all cancers worldwide. It is the fourth most common cause of cancer-related death, with more than 600,000 deaths annually. Despite all efforts regarding surgery and adjuvant therapy, 25% of patients with localized CRC later develop metastases, and around 20% of cases are metastatic at diagnosis. 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.

Contacts

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About Enterome

Enterome is a clinical-stage biopharmaceutical company developing breakthrough immunomodulatory drugs for the treatment of cancer. Enterome's pioneering approach to drug discovery is based on its unique and powerful bacterial Mimicry drug discovery platform, which allows it to analyze and uncover new biological insights from the millions of gut bacterial proteins in constant cross-talk with the human body.

Enterome's first-in-class drug candidates are based on synthetically produced, commensal-derived peptides that modulate the immune system by closely mimicking the structure of specific antigens.

The company's oncology pipeline includes the following OncoMimics™ peptide-based immunotherapies:

- EO2463, currently in the Phase 2 'SIDNEY' clinical trial for indolent non-Hodgkin lymphomas, has shown a favorable safety profile with promising early signs of efficacy;
- EO2401, administered in combination with nivolumab and bevacizumab, has demonstrated clinical activity in approximately one-third of patients with recurring glioblastoma in the completed Phase 1/2 'ROSALIE' study;
- EO4010 is being evaluated in metastatic colorectal cancer in the Phase 1/2 'AUDREY' study.

Enterome is headquartered in Paris, France. Since its inception, the company has raised a total of €118 million from Europe- and US-based life science investors, and more than €100 million through pharmaceutical partnerships.

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