# Enterome's OncoMimics™ peptide-based immunotherapy EO2401 generates and maintains elevated anti-tumor T cell responses for more than 10 months in patients with recurrent glioblastoma

***Memory CD8+ T cell response found as early as two weeks after the first administration of EO2401, expanding to up to 5% of circulating specific CD8+ T cells in some patients***

***Immunological responses correlate with clinical efficacy***

***Addition of the anti-edema compound bevacizumab to EO2401 + nivolumab improved efficacy in some patients***

**Paris, France – November 10, 2022**

**Enterome, a clinical stage biopharmaceutical company developing first-in-class immunomodulatory drugs based on its bacterial Mimicry drug discovery platform**, today announces updated safety, immunogenicity and efficacy data of its Phase 1/2 clinical trial of EO2401 in combination with an immune checkpoint inhibitor (nivolumab) +/- an anti-VEGF therapy (bevacizumab), for the treatment of patients with first progression/recurrence of glioblastoma (ROSALIE trial). The data were presented in an oral and a poster presentation at the 37th Society for Immunotherapy of Cancer (SITC) Annual Meeting in Boston, MA, US, today.

**Jan Fagerberg, Chief Medical Officer of Enterome said, "***We are very excited to present these updated data from the ROSALIE trial, evaluating EO2401 in combination with checkpoint blockade, and with checkpoint blockade plus anti-VEGF therapy, at SITC 2022. These new data show that the memory CD8+ T cell response was found as early as two weeks after the first administration and that a strong and stable immune response continued to be detected for more than 10 months. Additionally, the observation that some patients exhibit up to 5% of circulating specific CD8+ T cells following administration is remarkable, and together with the clinical responses seen, reinforces the strong potential of our OncoMimics™ peptide-based immunotherapy in this difficult-to-treat patient population."*

EO2401 is Enterome's first-in-class off-the-shelf OncoMimics™ peptide-based immunotherapy. It is designed to activate the patient's memory T cells that cross-react with tumor associated antigens (TAAs) present on the cancer being treated. EO2401 includes synthetically produced HLA-A2 peptides with molecular mimicry to TAAs upregulated in glioblastoma (IL13Ra2, BIRC5 and FOXM1) and the CD4 helper peptide UCP2.

Enterome selected these OncoMimics™ peptides using its Mimicry platform, which applies best-in-class biocomputational tools and bioassays to identify novel therapeutics from its proprietary database of 20+ million bioactive peptides and proteins isolated from gut bacteria.

**Key highlights from the EO2401 oral and poster presentation covering the Phase 1/2 ROSALIE trial were:**

- Data published to date confirm that EO2401 in combination with nivolumab +/- bevacizumab is well tolerated with a safety profile consistent with the safety profiles of nivolumab and bevacizumab, with the addition of local administration site reactions.

- EO2401 in combination with nivolumab generated strong systemic immune responses through activation of specific effector memory CD8+ T cells, correlating with clinical efficacy.

- As compared to the administration of EO2401 in combination with nivolumab without the addition of the strong anti-edema compound bevacizumab, the symptom-driven addition of low-dose, time-limited, bevacizumab (LDB) resulted in longer treatment durations (median treatment duration 3.2 months with LDB vs 1.4 months without LDB), and some improvement of efficacy (ORR 20% vs 13%, median PFS 3.6 months vs 1.6 months).

- In a subsequent cohort, the addition of continuous standard bevacizumab (as labelled in the USA) to EO2401 in combination with nivolumab further improved median treatment duration (to 5.0 months), objective response rate (to 55%), and median PFS (to 5.5 months).

- Median survivals have not yet been reached for both EO2401 in combination with nivolumab and with LDB (median follow-up 7.8 months) or EO2401 in combination with nivolumab and bevacizumab (median follow-up 14.1 months).

- CD8+ T cells against at least one of the EO2401 peptides was detected in 26 out of 28 patients with some patients exhibiting up to 5% of circulating specific CD8+ T cells. Memory specific CD8+ T cells response were found as early as two weeks after the first vaccination and maintenance of a strong and stable immune response could be detected for more than 10 months.

- Additional patients are to be treated with triple combination of EO2401 in combination with nivolumab and bevacizumab to support final regimen selection.

**Details on Enterome's oral and poster presentations at SITC (ROSALIE study)**

**Oral Presentation Details – Abstract #642**

Title: EO2401 microbiome derived therapeutic vaccine + nivolumab, with/without standard continuous, or low-dose symptom directed, bevacizumab, in recurrent glioblastoma: phase 1-2 EOGBM1-18/ROSALIE study

Link to abstract #642 can be found **here** and the presentation will be available **on Enterome's website**.

**Poster Presentation Details – Abstract #641**

Title: Strong immune response to therapeutic vaccination with EO2401 microbiome derived therapeutic vaccine + nivolumab: interim report of the EOGBM1-18/ROSALIE study

Link to abstract #641 can be found **here** and the presentation will be available **on Enterome's website**.

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**About ROSALIE**

ROSALIE (EOGBM1-18, NCT04116658) is a multicenter, open-label, Phase 1/2 trial investigating EO2401 in combination with nivolumab, and in combination with nivolumab/bevacizumab in patients with glioblastoma at first progression/recurrence after surgery and adjuvant radiotherapy/temozolomide. The

trial is assessing safety, tolerability, immunogenicity and preliminary efficacy in approximately 80 patients at centers in the US and Europe.

## Contacts

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## About Enterome

Enterome is a clinical-stage biopharmaceutical company focused on 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.

Enterome's 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.

Enterome is presently advancing two pipelines of drug candidates, OncoMimics™ and EndoMimics™, which have the potential to address cancer, inflammatory and autoimmune diseases, respectively:

- OncoMimics™ peptides, a pipeline of peptide-based immunotherapies. The lead candidate EO2401 is in Phase 1/2 clinical trials in patients with glioblastoma and adrenal tumors and has demonstrated clinical proof of concept. A second OncoMimics™ candidate, EO2463 is in a Phase 1/2 clinical trial for indolent non-Hodgkin lymphomas. Clinical proof-of-concept data are expected in H1 2023. EO2040 is a new immune therapy expected to start a Phase 2 trial in Q4 2022 in patients suffering from colorectal cancer with ctDNA-defined, minimal residual disease. EO4010 is in development for third-line colorectal cancer and targeted to enter clinical trials in 2023.
- EndoMimics™ peptides, a pipeline of next generation bioactives acting like human hormones or cytokines for the treatment of immune diseases. EB1010, the lead candidate, is a potent local inducer of IL-10 designed to provide improved therapeutic outcomes for patients with IBD. EB1010 is expected to enter the clinic in 2023. EndoMimics™ pipeline and EB1010 are being developed in collaboration with Nestlé Health Science.

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**