Enterome Announces Successful Completion of Phase 2 ROSALIE Study of EO2401 in Recurrent Glioblastoma

EO2401, a pioneering OncoMimics™ peptide-based immunotherapy, has demonstrated rapid activation and significant expansion of existing effector memory T cells against tumor-associated driver antigens due to their strong cross-reactivity with OncoMimics™ peptides

Clinical benefits were observed in approximately one-third of patients (vs. one-tenth with Standard of Care)

The full results are expected to be presented in a peer-reviewed journal by the end of 2024

Paris, France – April 17th, 2024

Enterome, a clinical-stage company developing first-in-class immunomodulatory drugs for solid and liquid malignancies and inflammatory diseases based on its unique Mimicry platform, today announced database lock of its Phase 2 study of EO2401, in combination with an immune checkpoint inhibitor (nivolumab) +/- an anti-VEGF therapy (bevacizumab), for the treatment of patients with recurrent glioblastoma (EOGBM1-18/ROSALIE trial).

A total of 100 patients have been enrolled in ROSALIE, an international, open-label Phase 1/2 trial of EO2401 an innovative, off-the-shelf immunotherapy derived from Enterome's oncomimicry platform. Interim results have been presented at multiple congresses, most recently at the Society for Neuro-Oncology (SNO) 2023 annual meeting demonstrating a 43.1% survival rate at 18 months in a 26-patient cohort dosed with EO2401 in combination with nivolumab+bevacizumab.

Jan Fagerberg, Chief Medical Officer of Enterome, said: "The achievement of the first trial evaluating EO2401 represents a major milestone for Enterome. With a total of 100 patients enrolled, of which 41 received the combination of EO2401 with nivolumab and bevacizumab, alongside extensive follow-up, we are confident that the ROSALIE study provides a compelling foundation for evaluating this novel immunotherapy as a potential treatment for patients with recurrent glioblastoma. With an encouraging clinical efficacy, we are now looking forward to sharing the final data with the scientific community in the coming months."

OncoMimics™ immunotherapies utilize bacteria-derived peptide antigens that closely mimic those expressed by tumor cells. In contrast to Tumor-Associated Antigens (TAAs), OncoMimics™ peptides are recognized as non-self by the immune system, inducing a strong and durable cytotoxic $CD8^+$ immune response stemming from circulating, effector memory T cells cross-reacting against the tumor, therefore offering enormous potential to create a new class of immunotherapies.

To date, Enterome has generated a repertoire of OncoMimics™ peptides targeting TAAs across a wide range of solid and liquid tumors. In addition to EO2401, the other candidates include

EO2463, in Phase 2 clinical trial for indolent Non-Hodgkin Lymphomas, and EO4010, in Phase 2 clinical trial for metastatic colorectal cancer.

Pierre Bélichard, Chief Executive Officer of Enterome, said: “T cells are Nature's most effective weapons against cancer cells, yet their potential is restrained by immunological self-tolerance. The ROSALIE study represents the first demonstration of OncoMimics™ immunotherapies’ ability to overcome immune tolerance, promising new avenues for targeting cancer cells. The trial provides a strong basis for pursuing a registrational path for EO2401 and expanding our pipeline to other indications. I am proud of the immense work accomplished by the Enterome team since the recruitment of the first patient in 2020. I also would like to thank patients, their families, and investigators whose dedication made this groundbreaking study possible."

About ROSALIE

ROSALIE (EOGBM1-18, ClinicalTrials.gov Identifier: NCT04116658) is a multicenter, open-label, first-in-human, Phase 1/2 study of EO2401 in combination with an immune checkpoint inhibitor (nivolumab, Opdivo®) +/- bevacizumab for the treatment of patients with first progression/recurrence of glioblastoma. The study aims to assess the safety, tolerability, immunogenicity, and preliminary efficacy of the combination in 100 patients enrolled at 10 clinical sites in Europe and the US. Clinical publications on ROSALIE include:

- Reardon et al., EO2401 Peptide Immunotherapy + Nivolumab +/- Bevacizumad in First Recurrent Glioblastoma: The Phase 1/2 EOGBM1-18/ROSALIE Study, *Neuro-Oncology*, Volume 25, Issue Supplement_5, November 2023 **DOI: 10.1093/neuonc/noad179.0265**
- Wick et al., EO2401 peptide immunotherapy + nivolumab +/- bevacizumab in recurrent glioblastoma: EOGBM1-18/ROSALIE. *Journal of Clinical Oncology* 41 2023 **DOI:10.1200/JCO.2023.41.16_suppl.2020**
- Reardon et al., EO2401 Therapeutic Vaccine for Patients with Recurrent Glioblastoma: Phase 1/2 ROSALIE Study, *Neuro-Oncology*, Volume 24, Issue Supplement_7, November 2022 **DOI:10.1093/neuonc/noac209.249**
- Maia et al., Strong immune response to therapeutic vaccination with EO2401 microbiome derived therapeutic vaccine + nivolumab: interim report of the EOGBM1–18/ROSALIE study, *Journal for ImmunoTherapy of Cancer* 2022 **DOI:10.1136/jitc-2022-SITC2022.0641**
- Reardon et al., EO2401 therapeutic vaccine for patients with recurrent glioblastoma: Phase I/II ROSALIE study, *Annals of Oncology*, Volume 33, Supplement 7, September 2022 **DOI:10.1016/j.annonc.2022.07.437**
- Reardon et al., 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, *Journal for ImmunoTherapy of Cancer* 2022 **DOI:10.1136/jitc-2022-SITC2022.0642**
- Wick et al., EO2401, a novel microbiome-derived therapeutic vaccine for patients with recurrent glioblastoma: ROSALIE study, *Journal of Clinical Oncology* Volume 40, Number 16_suppl **DOI:10.1200/JCO.2022.40.16_suppl.2034**
- Idbaih et al., EO2401, a novel microbiome-derived therapeutic vaccine for patients with recurrent glioblastoma: ROSALIE study, *Neuro-Oncology*, Volume 24, Issue Supplement_2, September 2022 **DOI:10.1093/neuonc/noac174.004**

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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, 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 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. The lead candidate, EO2401 is in Phase 2 clinical trials in patients with glioblastoma and adrenal tumors and has demonstrated clinical proof of concept. EO2463 and EO4010 are in Phase 2 clinical trials for indolent non-Hodgkin lymphomas and third-line colorectal cancer, respectively.
- **EndoMimics™** peptides, a pipeline of next generation bioactives acting like human hormones or cytokines, are being developed in collaboration with Nestlé Health Science, for food allergies and inflammatory bowel disease (IBD). The lead candidate, EB1010, is expected to enter clinical development in 2024.

Enterome employs 70 people and 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 from pharmaceutical partnerships.

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