Enterome OncoMimics™ immunotherapy EO2401 shows survival benefit in Phase 2 glioblastoma trial

- EO2401 *in vivo* immune therapy + nivolumab +/- bevacizumab shows survival benefit in first recurrent glioblastoma
- Data presented at 2025 SNO conference by lead investigator

Paris, France – 2 DECEMBER 2025 (08:30 CET)

Enterome, a clinical-stage company pioneering OncoMimics™ peptides, a new class of off-the-shelf, multi-targeted *in vivo* immune therapies that induce a fast and potent expansion of memory T cells to fight cancer, today announces new survival analyses from Cohort 3 of the Phase 1/2 ROSALIE clinical trial. The data were reported at the 2025 Society for Neuro-Oncology (SNO) Annual Meeting. The ROSALIE trial is evaluating Enterome's OncoMimics™ immune therapy EO2401 in combination with immune checkpoint inhibitor nivolumab, with or without anti-VEGF therapy bevacizumab, in patients with glioblastoma at first progression/recurrence. Top-line data from the trial **had previously been released** in November 2023.

The analyses demonstrated a statistically significant survival benefit for patients who underwent a second surgery after their first glioblastoma recurrence when treated with EO2401 in combination with nivolumab and bevacizumab, compared with patients who did not undergo surgery ($p = 0.027$). Importantly, no survival benefit was observed for the supportive therapies, nivolumab or bevacizumab on a stand-alone basis after surgery, compared with no surgery. The investigators concluded in their poster that: "The data indicate that a randomized study evaluating EO2401 is warranted."

The poster was presented at SNO by the lead investigator of the trial, David Reardon M.D., and Professor of Medicine at Harvard Medical School and Clinical Director of the Center for Neuro-Oncology at Dana-Farber Cancer Institute, under the title: "EO2401 peptide immunotherapy + nivolumab +/- bevacizumab in first recurrent glioblastoma: treatment strategy optimization in the phase 1/2 study EOGBM1-18 / ROSALIE (NCT04116658)". The poster will be made available on the Enterome website.

ROSALIE is a multicenter, open-label, first-in-human study of EO2401 in 100 patients with glioblastoma. EO2401 / nivolumab +/- bevacizumab was well tolerated with a safety profile consistent with the safety profile of nivolumab, and when applicable bevacizumab, except the addition of local administration site reactions. EO2401 plus nivolumab generated fast, strong, and durable specific CD8 T cell immune responses against the EO2401-mimic peptides and target epitopes on tumor associated antigens. Furthermore, the investigators wrote in their poster that the addition of bevacizumab (to EO2401/nivolumab), which exerts strong antiedema properties, and putatively counteracts immunosuppression by VEGF, increased treatment duration and efficacy.

"This finding from the ROSALIE trial in this incredibly challenging patient population is another strong indication of the potential benefit that OncoMimics™ peptides can offer

patients across a broad range of cancers," **said Pierre Belichard, Chief Executive Officer of Enterome.** "This, and the earlier clinical results make clear that larger, randomized studies of EO2401 are warranted."

EO2401 is an innovative, off-the-shelf OncoMimics™ multi-targeted *in vivo* immune therapy composed of three synthetically produced, short non-self HLA-A2 peptides with sequences derived from gut-bacteria (EO2316, EO2317, and EO2318). It is designed to rapidly expand – through peptide molecular mimicry – pre-existing CD8 T cells that cross-react with key glioblastoma tumor associated antigens (TAAs; IL13Ra2, BIRC5/survivin, and FOXM1). EO2401 also includes a universal CD4 helper epitope, UCP2 derived from hTERT, to support and enhance the immune response.

OncoMimics™ peptides consist of bacteria-derived peptide antigens that closely mimic tumor-associated antigens (TAAs). These antigens induce a fast and potent *in vivo* expansion of cytotoxic memory CD8+ T cells that were primed by gut bacteria, and are cross-reactive with TAAs. Because the peptides are "non-self", OncoMimics™ peptides avoid the self-tolerance that limits many cancer immunotherapies, enabling rapid, potent, and durable responses. The synthetically produced peptides are designed *in silico,* mining Enterome's proprietary database of 23 million commensal bacteria genes. Each product combines multiple high-affinity peptides to broaden target coverage and mitigate tumor heterogeneity.

OncoMimics™ peptides are easy to manufacture, store, distribute and administer as an "off-the-shelf" subcutaneous injection. OncoMimics™ peptides have achieved rapid and potent responses in clinical testing in over 230 patients to date, with a benign safety profile.

Enterome SA (**www.enterome.com**) is a privately held clinical-stage biopharmaceutical company developing OncoMimics™ peptides, a breakthrough in *in vivo* immune therapy for cancer. The three most advanced candidates have shown positive early data in Phase 2 clinical development in more than 230 patients across solid tumors and hematological malignancies, showing correlation between clinical efficacy and induced immunogenicity and a benign safety profile, activating large quantities of endogenous memory T-cells.

For more information, please contact:

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