



Enterome's OncoMimics™ immunotherapy EO2401 significantly improves survival rate in recurrent glioblastoma

Positive data from the ROSALIE Phase 1/2 trial presented at 2023 SNO Annual Meeting

Median survival of 14.5 months and 18-months survival rate of 43.1% in a 26-patient cohort where EO2401 was administered in combination with nivolumab+bevacizumab

Paris, France – November 20th 2023

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 updated efficacy data from 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 featured in an oral presentation at the Society for Neuro-Oncology (SNO) Annual Meeting, in Vancouver, British Columbia, Canada, on November 17th.

The presentation entitled "EO2401 peptide immunotherapy + nivolumab +/- bevacizumab in first recurrent glioblastoma: the phase 1/2 EOGMB1-18/ROSALIE study" was delivered by David Reardon, M.D., Professor of Medicine at Harvard Medical School and Clinical Director of the Center for Neuro-Oncology at Dana-Farber Cancer Institute.

"We are very pleased to present extensive data from the Phase 1/2 ROSALIE study of EO2401, our lead OncoMimics™ peptide-based immunotherapy, in glioblastoma," said Pierre Belichard, Chief Executive Officer of Enterome. "EO2401 continues to generate strong, durable, and target-specific immune responses associated with encouraging efficacy. Based on the promising results presented at SNO 2023, which include an 18-months survival rate of 43%, we now look forward to developing a registrational path for EO2401."

Prof. David Reardon, lead investigator of the study and presenting author, commented: "Recurrent glioblastoma is one of the most challenging cancers to treat. It is encouraging to see that the robust and durable immune response observed in a significant percentage of patients could translate into promising clinical outcome in the ROSALIE study. Our hope is now that the improvement in survival associated with the combination regimen of EO2401 with nivolumab and bevacizumab will convert into meaningful therapeutic benefit for patients with brain tumors in large scale studies."

Key highlights from the presentation delivered at SNO conference:

- EO2401 in combination with nivolumab and bevacizumab, as administered to 26 patients with recurrent glioblastoma comprising Cohort 3 of the ROSALIE study, was well tolerated with a safety profile consistent with the profile of nivolumab and bevacizumab, with the addition of local administration site reaction.
- The combination demonstrated encouraging results including a median survival of 14.5 months, median duration of response of 13.1 months, and median progression-free survival (PFS) of 5.5 months.

- The survival rate of 57.4% and 43.1% was observed at 12 months and 18 months respectively.
- EO2401/nivolumab generated fast, strong, and durable systemic immune responses against the targeted tumor-associated antigens IL13R α 2, BIRC5/survivin, and FOXM1.
- In Cohort 3, 23 patients (92% of tested, 88% of total) had a specific CD8⁺ T cell response against EO2401 and all of those patients (100%) had CD8⁺ T cells cross-reactive with the targeted TAAs, i.e., recognizing IL13R α 2, BIRC5/survivin, and/or FOXM1.

About ROSALIE

ROSALIE (EOGBM1-18) 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. Enrollment was completed in December 2022.

For more information on the Phase 1/2 trial of EO2401 in recurrent glioblastoma, please refer to ClinicalTrials.gov Identifier: NCT04116658

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.

Contacts

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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. 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 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 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