



Enterome completes patient enrollment of Phase 2 ROSALIE study evaluating its lead immunotherapy, EO2401, in recurrent glioblastoma

EO2401 is a first-in-class OncoMimics™ peptide-based immunotherapy able to rapidly activate and significantly expand existing effector memory CD8+ T cells against tumor-associated driver antigens due to their strong cross-reactivity with OncoMimics™ peptides

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Enterome, a clinical stage company developing first-in-class immunomodulatory drugs based on its gut bacterial Mimicry drug discovery platform, today announces completion of patient enrollment in its Phase 2 clinical trial (ROSALIE) evaluating its lead OncoMimics™ candidate, EO2401, in combination with an immune checkpoint inhibitor (nivolumab) +/- an anti-VEGF therapy (bevacizumab) in patients with first progression/recurrence of glioblastoma, an aggressive form of brain cancer.

The Phase 2 trial (NCT04116658) is an open-label, multicenter study assessing the safety, tolerability, immunogenicity and preliminary efficacy of EO2401. A total of 100 patients have started treatment in the different study cohorts at 10 clinical sites in Europe and the US. Initial and highly promising immunological and clinical results were obtained in 2022 and presented at leading clinical oncology meetings during 2022.

Prof. David Reardon, MD, Clinical Director for Dana-Farber Cancer Institute, discussed the key takeaways from the ROSALIE study on *The ASCO Post*. The video can be viewed [here](#).

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) expressed on tumoral cells, resulting in a rapid targeted cytotoxic response against cancer.

EO2401 combines three OncoMimics™ peptides mimicking IL13Ra2, BIRC5 and FOXM1, TAAs present in aggressive cancers such as glioblastoma, combined with the helper peptide UCP2 (Universal Cancer Peptide 2).

*"The completion of enrollment in ROSALIE moves us one step closer to establishing OncoMimics™ immunotherapies as potential breakthrough drugs for treating aggressive forms of cancer, resisting today's most effective treatments, in broad patient populations," said **Pierre Bélichard, co-founder and Chief Executive Officer of Enterome**. "Thanks to the eagerness and dedication among global investigators, and an impressive effort from our team, we were able to enroll 100 patients within the projected timeframe. I consider it a remarkable achievement for the first immune-oncology study ever sponsored and conducted by Enterome. We extend our sincere thanks to the patients, caregivers, clinical investigators and staff who are participating in the ROSALIE trial, and we look forward to presenting further results in 2023."*

Key highlights from the Phase 2 ROSALIE trial presented during 2022 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 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 8.7%, 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 5.5 months), objective response rate (to 55%), and median PFS (to 5.5 months).
- With a median follow-up of 15.4 months median survival for EO2401 in combination with nivolumab and bevacizumab has reached 14.5 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 cell responses were observed as early as two weeks after the first administration and maintenance of a strong and stable immune response could be detected for more than 10 months.

Clinical and immunological data from ROSALIE have been presented at five different scientific meetings in 2022: ASCO, ESMO, EANO, SITC and SNO. Further updates on the trial were presented last week at the ESMO IO Annual Congress which took place in Geneva (Switzerland).

Materials from scientific presentations can be found under 'Posters' on Enterome's [website](#).

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About EO2401

EO2401 is Enterome's first-in-class off-the-shelf OncoMimics™ peptide-based immunotherapy. It combines three microbial-derived OncoMimics™ peptides that closely mimic specific cytotoxic T cell (CD8+ T cell) epitopes on the Tumor-Associated Antigens IL13Ra2, BIRC5 and FOXM1, combined with the helper peptide (CD4+ T cell epitope) Universal Cancer Peptide 2 (UCP2). EO2401 is designed to trigger the immune system into recognizing these epitopes on glioblastoma cells as foreign (non-self) and eliciting a targeted memory T-cell driven cell-killing response against the tumor cells.

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About Enterome

Enterome is a clinical-stage 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, allowing it to analyze and uncover new biological insights from the millions of gut bacterial proteins in constant cross-talk with the human body. Its 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 1/2 clinical trial for indolent non-Hodgkin lymphomas, with clinical proof-of-concept data expected in H1 2023. EO2040, a new immune therapy, is expected to start a Phase 2 trial by year end 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, are being developed in collaboration with Nestlé Health Science, for the treatment of immune diseases. Lead candidate, EB1010, expected to enter the clinic in 2023, is a potent local inducer of IL-10, designed to improve therapeutic outcomes for patients with inflammatory bowel disease (IBD).

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