Enterome to present positive interim Phase 2 data for lead OncoMimics™ immunotherapy EO2463 in follicular lymphoma at American Society for Hematology (ASH) meeting

- New data from cohort 3 show EO2463 can be safely added to rituximab in first-line low-tumor-burden follicular lymphoma in need of treatment
- All six patients responded positively to the combination
- Overall response data in cohort 2 confirm EO2463 monotherapy produces marked efficacy in patients in watch-and-wait setting
- Registrational Phase 3 trial could start in 2026 in the watch-and-wait setting

Paris, France – 13 NOVEMBER 2025 (08:30 CET)

Enterome, a clinical-stage company pioneering OncoMimics™, 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 announced positive new interim data from two cohorts of patients with low tumor-burden follicular lymphoma in the ongoing Phase 2 study of its lead OncoMimics™ immunotherapy EO2463. In cohort 3, data from the SIDNEY study showed a benign safety profile for EO2463 in combination with rituximab as first-line treatment for previously untreated patients with low tumor-burden follicular lymphoma in need of treatment, adding only injection site reactions to the well-known safety profile of rituximab. In addition, all six patients in this feasibility assessment responded to the combination treatment.

Data from cohort 2 continue to show that EO2463 monotherapy produces excellent response rates when offered to patients with newly diagnosed follicular lymphoma or marginal zone lymphoma as an alternative to standard watchful waiting, an unmet clinical need setting. Per the abstract, data from 19 evaluable patients as of July showed an overall response rate (ORR) of 47%, including 3 complete responses (CRs) and 6 partial responses (PRs). No treatment is given to patients who currently follow the standard watch and wait setting practice as long as they do not show troublesome symptoms, despite the fact that they can remain anxious about their disease, and have a decreased quality of life.

The company will present the next update on both sets of data at the 67th American Society of Hematology (ASH) meeting in Orlando, Florida, in December.

“These encouraging data further strengthen our conviction in the broad potential of EO2463 as a novel active immunotherapy. The data from the “watch-and-wait” setting confirm our earlier positive findings, while those from cohort 3 – which we had not reported on before – point in the same direction,” **said Jan Fagerberg, Chief Medical Officer at Enterome**.

“This is another exciting set of new data, ahead of our lead asset EO2463 entering Phase 3 testing in the “watch-and-wait” setting in 2026. The data come shortly after we received Fast Track designation for EO2463 from the U.S. FDA for the watch-and-wait setting, raising our confidence that Enterome’s OncoMimics™ platform has the potential to be applied across a broad range of cancers,” said **Pierre Belichard, Chief Executive Officer of Enterome.**

Details of the poster presentations:

Abstract #5377

- **Title**: EO2463 (EO) peptide immunotherapy in patients (pts) with newly diagnosed asymptomatic follicular lymphoma (FL) and marginal zone lymphoma (MZL): Study EONHL1-20/SIDNEY (NCT04669171) primary endpoint Lugano objective response analysis
- **Presenting Author:** Jose Caetano (JC) Villasboas, MD Mayo Clinic
- **Session: 623**. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III
- **Session date**: 7 December 2025
- **Presentation time**: 06:00-08:00 PM
- **Location**: Room OCCC, West Halls B3-B4

Abstract #3594

- **Title**: EO2463 (EO) peptide immunotherapy combined with rituximab (R) for first-line treatment of low-tumor burden follicular lymphoma (FL): A feasibility evaluation in Study EONHL1-20/SIDNEY (NCT04669171)
- **Presenting Author:** Stephen Smith, M.D., UW Medicine, Fred Hutchinson Cancer Research Center
- **Session: 623.** Mantle Cell, Follicular, Waldenstrom’s, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological
- **Session date:** 8 December 2025
- **Presentation time:** 06:00-8:00 PM
- **Location:** Room OCCC, West Halls B3-B4

Follicular Lymphoma, one of several types of indolent Non-Hodgkin Lymphoma, is a difficult to treat chronic condition with relapses, characterized by slow progression and few symptoms, and reduced life expectancy. It is usually diagnosed by the appearance of swollen lymph nodes, and the early stages of the disease can be characterized by a lack of troublesome symptoms such as night sweats, fever or weight loss. There is a widespread consensus among leading investigators on the need for a well-tolerated and effective monotherapy to stop or slow progression for patients in the watch-and-wait setting.

EO2463 is an innovative, off-the-shelf OncoMimics™ active immunotherapy that combines four synthetic peptides. These non-self, microbial-derived peptides correspond to CD8 HLA-A2 epitopes that exhibit molecular mimicry with the B lymphocyte-specific lineage markers CD20, CD22, CD37, and CD268 (BAFF receptor). It also includes the helper peptide (CD4+ epitope) universal cancer peptide 2 (UCP2). The unique ability of EO2463 to selectively target multiple B cell markers enables the destruction of malignant B lymphocytes. By ensuring broad target coverage across malignant B cells, this novel approach aims to simultaneously improve safety and maximize efficacy, reducing the tumor cells’ capacity to develop immune-resistance mechanisms such as antigen escape.

OncoMimics™ 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™ avoid the self-tolerance that limits many cancer immunotherapies to enable rapid, potent, and durable responses to tumors. 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™ are easy to manufacture, store, distribute and administer as an "off-the-shelf" subcutaneous injection. OncoMimics™ 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™, a breakthrough in *in vivo* immune therapies for cancer. The three most advanced product candidates have shown positive early data in Phase 2 clinical development in more than **230 patients across solid tumors and haematological 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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