PRESS RELEASE

Enterome receives U.S. FDA Orphan Drug Designation for EO2463 OncoMimics™ to treat "watch-and-wait" indolent non-Hodgkin lymphoma

- Orphan Drug Designation confers regulatory, financial and strategic advantages
- EO2463 has shown potentially disease modifying activity in clinical testing in watch-and-wait iNHL patients
- EO2463 has shown complementary efficacy to rituximab and other cancer drugs in more advanced iNHL patients
- Active discussions with potential partners and investors to advance EO2463 development

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Enterome SA, a clinical-stage company pioneering OncoMimics™, a new class of off-the-shelf, multi-targeted in vivo immune therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to EO2463 for the treatment of patients with indolent non-Hodgkin lymphoma (iNHL) in the low-tumor-burden, "watch-and-wait" setting. The U.S. FDA Fast Track designation was also **granted** in October 2025 to EO2463 for follicular lymphoma in the watch-and-wait setting, further underscoring its potential and the unmet medical need.

The US FDA orphan drug designation (ODD) confers several substantial financial, regulatory, and strategic advantages to sponsors developing therapies for rare diseases affecting fewer than 200,000 people in the United States. For example, upon marketing approval, orphan-designated products receive 7 years of market exclusivity in the US.

"Receiving FDA Orphan Drug Designation is an important regulatory milestone for EO2463 and re-affirms our strong commercial potential. Today, the only option for non-symptomatic low tumor burden "watch-and-wait" iNHL patients is to go without treatment and be observed until the cancer progresses. We believe this places undue stress on patients and their families and is unacceptable; it is gratifying to see the U.S. regulatory agency recognizes that 'watch-and-wait' patients deserve a real treatment option like EO2463," **said Pierre Belichard, Chief Executive Officer of Enterome.** "Together with the Fast Track designation granted late last year, FDA's ODD further facilitates and validates our efforts to advance EO2463 toward registrational development in the watch-and-wait population. We are actively engaging with potential partners and investors to find the best path forward to rapidly advance EO2463 development in this indication."

Data from SIDNEY, which have been reported at multiple peer-reviewed medical conferences, demonstrate that EO2463 is particularly well suited for watch-and-wait iNHL patients because it has been well tolerated in clinical testing and has shown potentially disease modifying monotherapy activity in patients who generally are not eligible to receive anti-lymphoma treatment under current practice until their disease progresses. Data also suggest that EO2463 may be highly complementary when used in combination with marketed cancer therapeutics, offering potential additional disease modifying effects.

In the low-tumor-burden watch-and-wait population of SIDNEY Cohort 2, Enterome **reported** that EO2463 monotherapy produced a 52.6% objective response rate in 19 evaluable patients with follicular lymphoma and a 47.6% objective response rate in the overall group of 21 evaluable patients with follicular lymphoma or marginal zone lymphoma, including 14.3% complete responses and 33.3% partial responses.

Separately, Enterome **reported** that EO2463 rapidly induced extensive in vivo expansion of B-cell-target-specific CD8 T cells and established a correlation between EO2463-induced and B-cell-target-specific CD8 T-cell expansion and Lugano objective response, suggesting this immune readout may serve as a predictive biomarker in indolent NHL, something that would further serve to alleviate anxiety in watch-and-wait patients and help physicians decide which patients to monitor more closely.

And in addition to the impact in watch-and-wait patients, Enterome **reported** that EO2463 combined with lenalidomide and rituximab achieved a 60% complete response rate in 20 patients with relapsed/refractory follicular and marginal zone lymphoma, was well tolerated, and showed CD8 T-cell expansion correlating with the probability of complete remission, findings the company described as complementary to the monotherapy signal seen in watch-and-wait patients and show that EO2463 may also be complementary when used in combination with rituximab and other cancer therapeutics.

SIDNEY is an ongoing open-label Phase 1/2 study evaluating the safety, tolerability, immunogenicity and preliminary efficacy of EO2463 as monotherapy and in combination regimens in up to 55 patients with follicular lymphoma and marginal zone lymphoma. The trial includes a dedicated watch-and-wait monotherapy cohort, a first-line low-tumor-burden combination cohort with rituximab, and relapsed/refractory cohorts treated with EO2463 plus lenalidomide and rituximab.

EO2463 is an off-the-shelf OncoMimics™ active immunotherapy composed of four synthetic microbial-derived peptides designed to mimic the B-cell lineage markers CD20, CD22, CD37 and CD268 (BAFF receptor), plus the helper peptide UCP2. According to Enterome, this multi-target approach is intended to expand pre-existing memory CD8 T cells, selectively target malignant B cells, broaden target coverage and reduce the risk of antigen escape.

OncoMimics™ consist of bacteria-derived peptide antigens that closely mimic tumor-associated antigens (TAAs) of solid tumors, or cell linage markers (e.g. as observed in B cell lymphomas). These antigens induce a fast and potent *in vivo* expansion of cytotoxic memory CD8 T-cells, primed by gut bacteria, and cross-reactive with TAAs/B cell markers. 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.

Enterome SA (www.enterome.com) is a privately held clinical-stage biopharmaceutical company developing breakthrough OncoMimics™ immunotherapeutics for cancer. The three most advanced product candidates have shown positive early data in Phase 2 clinical development, supporting the novel OncoMimics™ modality. The company's pioneering approach to drug discovery is based on the unique and powerful bacterial Mimicry drug discovery platform, which allows it to discover OncoMimics™ with high similarity to tumor associated antigens (TAA) based on the big-data insights from millions of gut bacterial proteins that live in humans.

For more information, please contact:

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