Enterome receives FDA Fast Track designation in follicular lymphoma for lead OncoMimics™ immunotherapy EO2463

- Covers low tumor burden "watch-and-wait" setting, an unmet medical need
- Registrational Phase 3 watch-and-wait to start in 2026
- EO2463 has broad potential to treat hemato-oncology indications

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Enterome, a clinical-stage company developing first-in-class OncoMimics™ immunotherapies to treat cancer, announces today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for follicular lymphoma in the low tumor burden "watch-and-wait" setting for its lead OncoMimics™ immunotherapy, EO2463. The decision highlights EO2463's efficacy, excellent safety and tolerability as a first-in-class monotherapy in clinical testing to date in patients who currently do not normally receive any treatment as long as they do not show clinical symptoms, despite having been diagnosed with a cancer that progresses in the vast majority of cases.

"The FDA's decision is an important validation of the unique potential of Enterome's OncoMimics™ program," said **Pierre Belichard, CEO of Enterome.** "It will expedite the clinical development and the regulatory pathways for EO2463, which is ready to enter registrational testing as early as next year after this Fast Track designation and a recent positive type-C meeting with the FDA."

The Fast Track designation provides increased opportunities for interaction with the FDA, rolling review and potential eligibility for priority review. EO2463 is ready for Phase 3 testing in watch-and-wait patients after showing **marked efficacy as a monotherapy** in interim data from the watch-and-wait population in the ongoing Phase 2 SIDNEY trial. The treatment was well tolerated, suggesting Enterome's EO2463 immunotherapy may offer a safe and effective treatment option for patients in this setting, who have been diagnosed with a type of cancer they know is likely to progress, but show no troublesome symptoms and do not usually receive treatment.

Follicular Lymphoma (FL), one of several types of indolent Non-Hodgkin Lymphoma, is an incurable chronic condition with frequent relapses, characterized by slow progression and few symptoms, yet 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 of the need for a well-tolerated and effective monotherapy to stop or slow progression for watch-and-wait patients.

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™ are bacteria-derived peptide antigens that closely mimic tumor-associated antigens or lineage markers. These synthetically produced peptides are designed *in silico* using AI and machine learning to mine Enterome's extensive proprietary database of 23 million commensal bacteria genes. Because these peptides are "non-self," they tap into pre-existing pools of effector-memory CD8 T cells primed by gut bacteria, enabling rapid, strong, and durable anti-tumor responses while avoiding the self-tolerance that limits many cancer immunotherapies. 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. In clinical testing to date they have been shown to be extremely well tolerated, especially compared to other potent immunotherapies.

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 in more than **230 patients across solid tumors and haematological malignancies**, showing correlation between clinical efficacy and induced immunogenicity and a very favourable safety profile with **no systemic adverse events**, activating large quantities of endogenous memory T-cells without inducing CRS.

For more information, please contact:

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