# Enterome's Immunotherapy EO2463 Shows Early Clinical Response in Newly Diagnosed Follicular Lymphoma Suggesting a Potential Alternative to 'Watchful Waiting'

- ***46% objective response rate, with 15% complete responses and 31% partial responses in patients with early-stage follicular lymphoma reported at the ASH 2024 meeting.***
- ***Well-tolerated treatment with no severe adverse events.***
- ***Early CD8+ T cell expansion may predict positive clinical outcomes.***
- ***Findings support EO2463 as a proactive treatment option for asymptomatic patients who typically go untreated.***

**Paris, France – December 10, 2024**

**Enterome, a clinical-stage company developing first-in-class immunomodulatory drugs for cancer based on its unique Mimicry platform**, today announced new clinical data from the ongoing Phase 1/2 'SIDNEY' trial evaluating EO2463 in patients with indolent Non Hodgkin Lymphoma.

The data were presented in two posters at the 66th American Society of Hematology (ASH) Annual Meeting and Conference by Dr. Villasboas Bisneto, M.D., hematologist and oncologist at Mayo Clinic, and Dr. Stephen Smith, M.D., hematologist and oncologist at Fred Hutchinson Cancer Center.

Enterome is also holding a webinar on December 12, 2024 for external audiences in order to run through the data sets. See details at the end of this release.

The Phase 1/2 SIDNEY trial (EONHL1-20) investigates EO2463, an off-the-shelf immunotherapy targeting four B cell antigens and based on Enterome's OncoMimic™ peptides, in patients with frequent forms of indolent Non-Hodgkin Lymphoma. In Cohort 2 of the SIDNEY trial, patients with newly diagnosed, asymptomatic follicular lymphoma, received EO2463 monotherapy as an alternative to the standard "watch-and-wait" approach. With most patients still on study treatment, an objective response rate of 46% has been observed in the first 13 patients, including 15% complete responses and 31% partial responses. Consistent with observations from the safety lead-in cohort, the treatment was well tolerated, with no severe adverse events, suggesting EO2463 may offer a safe treatment option for patients with early-stage disease.

A biomarker analysis was conducted in Cohort 1 (EO2463 in monotherapy and in combination with lenalidomide/rituximab, in patients with relapsed/refractory disease) to explore whether early $CD8^+$ T cell expansion in response to EO2463 administration could serve as a predictor of later clinical benefit. The current assessment indicates that the biomarker as applied (measuring fast

expansion of EO2463 specific CD8 T cells) can predict for clinical response, both for EO2463 monotherapy, and for EO2463 in combination with lenalidomide + rituximab.

**Jan Fagerberg, Chief Medical Officer of Enterome**, commented, "These new data provide encouraging indications that EO2463 can safely induce meaningful responses in patients with newly diagnosed follicular lymphoma typically managed with observation alone, addressing an important unmet need. Additionally, our biomarker findings open up possibilities for precision immunotherapy by identifying patients most likely to benefit early in their treatment course."

**Pierre Bélichard, CEO of Enterome**, added, "These promising results from Cohort 2 in the SIDNEY trial mark an important step in our commitment to providing early therapeutic options for patients who would usually not receive immediate treatment due to the absence of safe and effective therapies. We look forward to advancing EO2463 through the SIDNEY trial and to expanding our work with OncoMimics™ immunotherapies in other blood cancer types."

**Details of the poster presentations:**

**Abstract #1616**

- **Title**: *EO2463 Peptide Immunotherapy in Patients with Indolent NHL: A Phase 1 Exploration of a Response Biomarker for EO2463 Monotherapy and EO2463 in Combination with Lenalidomide/Rituximab*
- **Presenting Author:** Jose Caetano (JC) Villasboas, MD Mayo Clinic
- **Session: 622**. Lymphomas: Translational – Non-Genetic: Poster I

**Abstract #4395**

- **Title**: *EO2463 Peptide Immunotherapy in Patients with Newly Diagnosed Asymptomatic Follicular Lymphoma Results in Monotherapy Objective Clinical Responses Linked with Anti-Peptide Specific CD8 Memory T Cell Responses: The EONHL1-20/SIDNEY Study*
- **Presenting Author:** Dr. 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: Poster III

**About EONHL1-20/SIDNEY:**

SIDNEY (EONHL1-20) is a Phase 1/2 multicenter, open-label, first-in-human study of EO2463 as a monotherapy and in combination with lenalidomide and/or rituximab for the treatment of patients with iNHL. The study aims to assess the safety, tolerability, immunogenicity, and preliminary efficacy of EO2463 monotherapy and combination therapy in approximately 60 patients with follicular lymphoma (FL) and marginal zone lymphoma (MZL).

For more information on the study, visit www.Clinicaltrials.gov, reference: NCT04669171.

**About EO2463:**

EO2463 is an innovative, off-the-shelf immunotherapy candidate that combines four synthetic OncoMimic™ 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). EO2463 also includes the helper peptide (CD4+ epitope) universal cancer peptide 2 (UCP2).

The unique ability of EO2463 immunotherapy to selectively target multiple B cell markers enables the destruction of malignant B lymphocytes that are abundant in iNHL. 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.

**Details of the webinar, please register at enterome@vigoconsulting.com to attend.**

**Date:** 12 December 2024

**Time:** 7.30am-8.30am PT / 9.30am-10.30am Central US time / 3.30pm-4.30pm UK / 4.30pm-5.30pm CET

**Presenters:**

Jose Caetano (JC) Villasboas, MD Mayo Clinic

Pierre Belichard PhD, CEO, Enterome

Laurent Chene PhD, Head of Drug Discovery, Enterome

Jan Fagerberg, MD, PhD, CMO Enterome

**Registration link: HERE**

**(https://storm-virtual-uk.zoom.us/webinar/register/WN_jTBLmm7ZRBK6KLvtG3I6Lw)**

**Webinar ID**

**822 5290 4200**

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**About Enterome**

Enterome is a clinical-stage biopharmaceutical company developing breakthrough immunomodulatory drugs for the treatment of cancer. 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 drug candidates are based on synthetically produced, commensal-derived peptides that modulate the immune system by closely mimicking the structure of specific antigens.

The company's oncology pipeline includes the following OncoMimics™ peptide-based immunotherapies:

- EO2463, currently in the Phase 2 'SIDNEY' clinical trial for indolent non-Hodgkin lymphomas, has shown a favorable safety profile with promising early signs of efficacy;
- EO2401, administered in combination with nivolumab and bevacizumab, has demonstrated clinical activity in approximately one-third of patients with recurring glioblastoma in the completed Phase 1/2 'ROSALIE' study;
- EO4010 is being evaluated in metastatic colorectal cancer in the Phase 1/2 'AUDREY' study.

Enterome 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 through pharmaceutical partnerships.

For more information, please visit the company's website at: **www.enterome.com**