



Enterome starts Phase I clinical trial with its lead candidate EB8018 to treat Crohn's disease

EB8018 is a first-in-class oral small molecule targeting the host-microbiome interaction by blocking FimH

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Enterome SA, a pioneer in the development of pharmaceuticals and diagnostics based on the gut microbiome, is pleased to announce the launch of a Phase 1 clinical study with its lead small molecule drug candidate EB8018, a small molecule designed to block FimH, as a potential new treatment for Crohn's disease.

Crohn's disease is a chronic inflammatory disease of the gastrointestinal tract. Emerging evidence suggests that the microbiome plays an important role in triggering an abnormal mucosal immune response in patients with Crohn's disease.

Enterome has identified the FimH adhesin from overabundant *E. coli* species as a potential novel target to block inflammation in Crohn's disease through application of its metagenomics platform to the microbiomes of patients suffering from Crohn's disease. Independent studies have also demonstrated an imbalance of the microbiomes of such patients with a significant increase of *E. coli* with invasive properties, termed adherent-invasive *E. coli* (AIEC). These AIEC bacteria attach to the gut wall of susceptible patients via the fimbrial adhesion protein FimH, and subsequently trigger inflammation by inducing local production of cytokines and invasion of the gut wall through activation of TLR4 and CEACAM6 receptors which are strongly upregulated in the ileum of Crohn's disease patients.

EB8018 is an oral and non-systemic small molecule drug that is designed to block FimH thereby preventing local cytokine production and the entry of AIEC into the gut wall by selectively disarming the virulent bacteria without disrupting the gut microbiome. It represents a novel, non-biologic, non-steroidal, non-antibiotic, non-immunomodulatory and local approach for the treatment of Crohn's disease. Enterome in-licensed EB8018 from Vertex Pharmaceuticals Inc.

The phase 1 clinical study is designed to determine the safety and tolerability profile of single and multiple doses of EB8018 in healthy subjects. The study will also assess the pharmacokinetic profile of single and multiple doses of EB8018 and the effects of EB8018 on the healthy gut microbiome.

In parallel with the phase 1 study, Enterome is developing a non-invasive microbiome biomarker to identify patients that may benefit from treatment with EB8018.

Pierre Belichard, CEO of Enterome, said: *"We are delighted to have started the clinical development of our lead drug candidate EB8018. This represents an important milestone for Enterome and validation of our capability to identify novel targets derived from the microbiome that we can use to develop small molecule drug candidates originating either from our internal resources or via in-licensing, as is the case with EB8018. We look forward to reporting the results from the phase 1 study later in 2017."*

About Enterome

Enterome is pioneering the development of novel pharmaceuticals and diagnostics to support personalized therapies in microbiome-related diseases such as Inflammatory Bowel Disease (IBD), cancer and metabolic diseases.

Enterome is also leading the development of new industry standards in gut microbiome quantitative and functional analysis. This technology leadership allows Enterome to open up the new field of therapeutic target discovery in the microbiome in order to address significant unmet medical needs.

Enterome has established partnerships with leading pharmaceutical companies and academic research institutes, including Johnson & Johnson Innovation/Janssen Biotech, Takeda and Abbvie in inflammatory bowel and gastro-intestinal diseases; Bristol-Myers Squibb in immuno-oncology; and the Mayo Clinic and Geisinger hospitals in metabolic disorders.

The Company was established in 2012 in Paris (France) to develop the discoveries made by the INRA metagenomic platform. The Company has raised a total of €32 million from leading venture capital investors (Seventure Partners, Lundbeckfonden Ventures, Health for Life Capital & Omnes Capital) and strategic investors (Nestlé, Shire & INRA Transfert).

Additional information about Enterome is available through its website : www.enterome.com.

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