



Enterome's EB8018, a first-in-class drug candidate targeting Crohn's disease, successfully completes Phase I study in healthy volunteers

EB8018 is an oral small molecule targeting the host-microbiome interaction by blocking FimH

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ENTEROME SA, a pioneer of innovative therapies for microbiome-related diseases, is pleased to announce the successful completion of the first Phase 1 clinical study with its lead candidate EB8018, a small molecule designed to block FimH, as a potential new orally-administered treatment for Crohn's disease.

EB8018 was found to be well tolerated in healthy volunteers across a wide range of doses tested. The compound also demonstrated a pharmacokinetic (PK) profile consistent with it being a gut-restricted molecule that is soluble in the gut and thereby able to act on its target in the gut microbiome. EB8018 also exhibited minimal absorption into the blood potentially limiting interactions with other drugs that are absorbed into the blood stream. The results from the study will be presented at an upcoming medical congress.

Enterome is in the process of initiating a Phase 1b trial of EB8018 in patients with Crohn's Disease who have active inflammation of the gut. This study will investigate the safety, PK and preliminary signals of efficacy of EB8018. The results from these studies are expected to provide information that will support the design of a Phase 2 clinical proof-of-concept trial with EB8018 that is planned to start in 2018.

The Phase 1 study was designed to determine the safety and tolerability profile of single and multiple doses of EB8018 in healthy subjects. The study also assessed 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 potential non-invasive microbiome biomarker to identify patients that may benefit from treatment with EB8018.

Jai Patel, Enterome's Chief Medical Officer, said: *"The outcome of the first-in-human trial with EB8018 is an encouraging step towards demonstrating its clinical potential in patients with active Crohn's Disease. EB8018 is a first-in-class, orally-administered investigational medicine that is targeted at disarming specific bacteria in the gut that cause inflammation, without disrupting the microbiome. It represents a novel, non-biologic, non-steroidal, non-immunomodulatory approach for the treatment of Crohn's Disease. We are now preparing to test EB8018 in Crohn's patients with a view to a larger scale clinical proof-of-concept trial next year."*

About Crohn's disease, FimH and EB8018

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 is targeting the FimH adhesin, which is over-expressed on the surface of bacteria that bloom in patients with Crohn's Disease. Blocking the FimH adhesin has been shown to reduce or inhibit the local inflammation in the gut wall triggered by the microbiome. Research studies have demonstrated an imbalance of bacteria in the microbiomes of patients with Crohn's Disease, with a significant increase of pro-inflammatory bacteria, a reduction of anti-inflammatory bacteria as well as a reduction in the diversity of bacterial species. The pro-inflammatory bacteria trigger inflammation in the gut wall by inducing local production of cytokines by activating TLR-4 and subsequent invasion of the gut wall through CEACAM6 and GP-2 receptors, which are strongly upregulated in the ileocecal region of the gut wall in patients with Crohn's Disease.

EB8018 is an orally administered, gut-restricted small molecule drug with minimal absorption into the bloodstream. It is designed to prevent local cytokine production in the gut wall by selectively disarming the virulent FimH-expressing bacteria without disrupting the gut microbiome. It represents a novel, non-biologic, non-steroidal, non-antibiotic, non-immunomodulatory approach for the treatment of Crohn's disease. Enterome in-licensed EB8018 from Vertex Pharmaceuticals Inc.

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.

Enterome also has a 50/50 joint venture with Nestlé Health Science, called Microbiome Diagnostics Partners (MDP), focused initially on the development of novel microbiome-based diagnostics for IBD and liver diseases.

The Company was established in 2012 in Paris (France) to develop the discoveries made by the INRA metagenomic platform, and is backed by leading venture capital investors (Seventure Partners, Lundbeckfonden Ventures, Health for Life Capital et Omnes Capital) and strategic investors (Nestlé Health Science, BMS, Shire et INRA Transfert).

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

Contact

Enterome

Pierre Belichard, CEO
Tel. +33 1 75 77 27 87

Public Relations

Mark Swallow / Marine Perrier / David Dible
Citigate Dewe Rogerson
Tel. +44 207 638 9571 / enterome@citigatedr.co.uk