



Enterome signs global licensing, co-development and co-promotion agreement with Takeda for the treatment of Crohn's disease

EB8018, the lead investigational candidate, targets Crohn's disease with potential for other GI disorders

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ENTEROME SA, a clinical-stage biotech company developing innovative therapies to treat microbiome-associated diseases with a focus on auto-immune disease and cancer, has entered into a global licensing, co-development and co-promotion agreement with Takeda Pharmaceutical Company Limited ("Takeda"). The agreement covers Enterome's lead investigational drug candidate EB8018 in patients with Crohn's disease, with the potential to expand to other gastrointestinal (GI) disorders and liver diseases.

"We are delighted to sign this agreement for EB8018, our most advanced candidate that represents a non-antibiotic, non-steroidal, non-immunomodulatory approach for the treatment of GI disorders including Crohn's disease," said **Pierre Belichard**, CEO of Enterome. *"We believe we have a world-class partner in Takeda to deliver the best development and commercialization strategy for EB8018 based on their extensive expertise and focus in Crohn's disease and GI disorders. We are very excited about the potential of EB8018 and look forward to deepening our relationship with Takeda as we advance this novel candidate through clinical development."*

Enterome will receive an upfront payment of \$50 million and a commitment from Takeda to make a future equity investment in the Company. Enterome is also eligible to receive up to \$640 million for achieving specified clinical development, regulatory and commercial milestones with EB8018. In addition, Enterome and Takeda will co-develop EB8018 under the joint agreement and, if approved, the product will be co-promoted in the US under a profit/cost sharing structure. Takeda will receive an exclusive license to commercialize EB8018 outside of the US, and Enterome will be eligible to receive royalties on net sales generated in these territories.

"At Takeda, we are continually exploring diverse modalities with the hope to deliver medicines that break the loop of unpredictable disruption that people living with GI disorders experience every day," said **Asit Parikh**, M.D., Ph.D., Head, Gastroenterology Therapeutic Area Unit at Takeda. *"We are excited to partner again with Enterome on such a novel approach and work together to advance EB8018 through clinical development."*

EB8018 is a novel, first-in-class, orally administered, gut-restricted small molecule designed to selectively disarm virulent bacteria in the gut that can cause inflammation without disrupting the local microbiome. EB8018 inhibits FimH-mediated inflammation induced by interaction of pathogenic pro-inflammatory bacteria to receptors in the gut wall, thereby potentially reducing the production of inflammatory cytokines including TNF. FimH was validated as a novel microbiome-derived therapeutic target by Enterome through application of its proprietary metagenomics platform, EB8018 was originally discovered by Vertex Pharmaceuticals, Inc.

EB8018 successfully completed a Phase 1a trial, where the study results demonstrated that administration of EB8018 in the dose range examined was safe and exhibited minimal blood absorption.

A Phase 1b study to evaluate safety, tolerability, pharmacokinetic profile and preliminary efficacy signals of EB8018 when given to patient volunteers with active Crohn's disease is underway.

The global agreement is the second collaboration between Enterome and Takeda. In 2016, the two companies entered a strategic drug discovery collaboration focused on microbiome targets across multiple GI disorders, including inflammatory bowel disease and motility disorders.

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About Enterome

Enterome is a clinical-stage company pioneering the development of novel pharmaceuticals based on its leading knowledge of the interaction between the immune system and the gut microbiome. Enterome is advancing a pipeline of small molecule and peptide candidates to treat microbiome-associated diseases with a focus on auto-immune disease and cancer: these include EB8018, a selective FimH blocker, in a Phase 1b clinical trial for Crohn's disease (partnered with Takeda); and EO2401, an innovative Microbiome antigen-based therapeutic ("onco-mimic"), which is expected to enter clinical trial in glioblastoma patients in 2019.

The Company's strategic drug discovery is driven by its proprietary metagenomics platform enabling the identification of new targets and therapeutic candidates derived from the microbiome. The Company's approach is based on a "drugs from bugs" philosophy and is expected to facilitate the use of recognised development and regulatory pathways for its candidates.

Enterome's partners include Takeda, Bristol-Myers Squibb and Johnson & Johnson Innovation/Janssen Biotech.

The Company is backed by leading venture capital investors (Seventure Partners, Lundbeckfonden Ventures, Health for Life Capital, Omnes Capital and Principia) and strategic investors (BMS, Nestlé Health Science, Shire and INRA Transfert).

Additional information about Enterome is available at: www.enterome.com