NestléHealthScience

Press release

Nestlé Health Science Makes Latest Move in Breakthrough Microbiome Field

Strategic collaboration with Seres Therapeutics for Clostridium Difficile and IBD pipeline candidates

Epalinges, Switzerland, 11 January 2016 – Consistent with taking a leadership position in the developing microbiome therapy field, Nestlé Health Science has signed an exclusive agreement outside the United States and Canada for Seres Therapeutics' novel class of microbiome therapeutics (Ecobiotics®) in the fields of *Clostridium difficile* infections (CDI, such as SER-109 and SER 262) and Inflammatory Bowel Disease (IBD; such as SER-287 and SER-301). The agreement follows Nestlé Health Science's initial equity investments in US-based Seres Therapeutics (NASDAQ: MCRB) announced in January and July 2015.

Through this agreement, Nestlé Health Science will support the potential future commercialization of the first ever microbiome therapy expected to be launched worldwide: SER 109 is in Phase 2 trials and targets multiple recurrent *Clostridium difficile (C. diff),* a bacterial infection that can affect the digestive system. An additional *C. diff* and two inflammatory bowel disease (IBD) pipeline candidates are also part of the collaboration, including SER-287, the innovative microbiome therapeutic currently in Phase 1 clinical development in IBD. Seres' Ecobiotics® are first-in-field therapies, based upon microbial organisms and target the microbiome, the 100 trillion microorganisms that live within the human body. When unhealthy – or dysbiotic – the microbiome is increasingly understood to be causally related to a range of diseases.

Greg Behar, CEO of Nestlé Health Science and Seres Therapeutics Board member, said: "With this strategic move we demonstrate our intent to be a leader in bringing breakthrough healthcare approaches to market that transform patient outcomes and create value in healthcare system around the world. We are partnering with Seres, a clear leader in advancing their pipeline in the fast evolving microbiome field. We bring our worldwide footprint and capabilities in managing acute care and gastrointestinal (GI) related conditions through our diagnostics, nutritional solutions and innovative pipeline. Moreover, we bring our strong relationships with key opinion leaders, healthcare professionals and patient organizations as well as our experience in clinical development, regulatory and market access in IBD. Together with Seres Therapeutics, we will focus on successfully bringing this pipeline to patients and create innovative therapeutic approaches."

Roger J. Pomerantz, M.D. President, CEO and Chairman of Seres Therapeutics, said, "We are at the forefront of the fast evolving microbiome science and in Nestlé Health Science we have a strategic partner that can help fulfill the potential of Ecobiotics® to transform the treatment paradigm, worldwide, in a number of growing, difficult and expensive to treat conditions."

In the CDI field, SER-109 for recurring *C. diff* in adults (in Phase 2) has received Breakthrough Therapy and Orphan Drug Status designation from the US FDA. SER-262, a follow-on compound is expected to enter clinical trials for the indication of primary *C. diff*, a less severe and more prevalent condition, is also included in the agreement. *C. diff* infections are most prevalent among adults 65 years and older and immune compromised patients who have been treated with broad spectrum antibiotics for the underlying infections. In Europe, the number of reported treated cases in 2015 was 308,000 patients and is expected to grow to 344'000 by 2025. CDI may contribute to 40% of deaths during the three months after diagnosis and is a significant Public Health issue.[1]

In the IBD field, SER-287 for mild-to-moderate ulcerative colitis (UC) has entered Phase 1b clinical trials as announced by Seres in December 2015. Also included in the pipeline is SER-301, currently in pre-clinical development stage for ulcerative colitis and other chronic gastrointestinal disorders. There is growing evidence suggesting that UC is marked by an imbalance of bacteria (dysbiosis) in the gut, and that treating that dysbiosis may lead to a meaningful clinical impact. An estimated 2.5–3 million people in Europe are affected by IBD, with a direct healthcare cost of 4.6–5.6 bn Euros per year.[2]

Under the terms of the agreement, Nestlé Health Science will make an upfront payment of USD 120 million. Seres Therapeutics will be eligible to receive development and approval milestone payments totalling up to USD 660 million, and tiered single to double-digit royalties. The full potential value of the up-front payment, milestones and royalties payable by Nestlé Health Science is over USD 1.9 billion, assuming all products receive regulatory approval and significant revenue targets are met. Seres Therapeutics will be responsible for all development costs associated with Phase 1 and Phase 2 for all four candidates as well as for Phase 3 for SER-109. Nestlé Health Science will participate with 33% in the development costs associated with Phase 3 for three candidates (SER-262; SER-287, SER-301).

*****

About Nestlé Health Science
Nestlé Health Science, a wholly-owned subsidiary of Nestlé, is a health-science company engaged in advancing the role of nutritional therapy to change the course of health for consumers, patients and its partners in healthcare. Nestlé Health Science's portfolio of nutrition solutions, diagnostics, devices and drugs, targets a number of health areas, such as inborn errors of metabolism, pediatric and acute care, obesity care, healthy aging as well as gastrointestinal and brain health. Nestlé Health Science employs around 3,000 people worldwide and is headquartered in Epalinges (near Lausanne), Switzerland. For more information, please visit: www.nestlehealthscience.com.

About Seres Therapeutics
Seres Therapeutics, Inc. is a leading microbiome therapeutics platform company developing a novel class of biological drugs that are designed to treat disease by restoring the function of a dysbiotic microbiome characterized by an increased presence of pathogenic bacterial species, where the natural state of bacterial diversity is imbalanced. Seres' most advanced program, SER-109, has successfully completed a Phase 1b/2 study demonstrating a clinical benefit in patients with recurring Clostridium difficile infection (CDI) and is currently being evaluated in a Phase 2 study in recurring CDI. The FDA has granted SER-109 Orphan Drug, as well as Breakthrough Therapy designations. Seres' second clinical candidate, SER-287, is being evaluated in a Phase 1b study in patients with mild-to-moderate ulcerative colitis (UC).

Forward-Looking Statement
This press release contains "forward-looking statements" regarding the research, development and commercialization of microbiome therapeutic candidates. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed.

Sources:

1. www.multivu.com/assets/60637/documents/60637-CDI-HCP-Report-original.pdf, April 2013
2. www.sciencedirect.com/science/article/pii/S1873994613000305, May 2013

Contact:

Nestlé Health Science
Marie-Françoise Rütimeyer
Head of Communications, Nestlé Health Science
nestlehealthscience.external@nestle.com
Media Tel: + 41 21 924 22 00