# Seres Therapeutics, Nestlé Health Science Announce SER-109 Co-Commercialization License Agreement

July 1, 2021

- Companies Agree to Jointly Commercialize SER-109 Investigational Microbiome Therapeutic to Treat Recurrent *C. difficile* Infection, Leading the Way for Entirely New Treatment Modality
- Deal calls for more than $500 million in upfront and contingent milestone payments
- Seres Therapeutics to conduct a conference call at 8:30 a.m. ET

CAMBRIDGE, Mass. & LAUSANNE, Switzerland--(BUSINESS WIRE)--Jul. 1, 2021-- Seres Therapeutics, Inc. (Nasdaq: MCRB), a leading microbiome therapeutics company, announced today that it has entered into an agreement with Nestlé Health Science to jointly commercialize SER-109, Seres' investigational oral microbiome therapeutic for recurrent *Clostridioides difficile* infection (CDI), in the United States (U.S.) and Canada. If approved, SER-109 would become the first-ever FDA-approved microbiome therapeutic.

Under the terms of the agreement, Nestlé Health Science will utilize its global pharmaceutical business Aimmune Therapeutics and will assume the role of lead commercialization party. Seres will receive license payments of $175 million up front, and an additional $125 million upon FDA approval of SER-109. The agreement also includes sales target milestones which, if achieved, could total up to $225 million. Seres will be responsible for development and pre-commercialization costs in the U.S. Upon commercialization, Seres will be entitled to an amount equal to 50% of the commercial profits.

The agreement to co-commercialize SER-109 in the U.S. and Canada represents the expansion of an existing strategic collaboration between the companies. Nestlé Health Science already has commercial rights to Seres' investigational treatments for CDI and inflammatory bowel disease outside of the U.S. and Canada, and with this expansion, Nestlé Health Science becomes Seres' global collaborator in SER-109.

A leading cause of hospital-acquired infections in the U.S., CDI is associated with debilitating diarrhea and claims the lives of more than 20,000 Americans each year. SER-109 is comprised of purified Firmicutes spores, based on their modulatory role in the life cycle of *C. difficile* and disease pathogenesis. The bacterial consortium in SER-109 rapidly repopulates the microbiome in the gut to produce compositional and functional changes that are critical to a sustained clinical response.

"Nestlé Health Science has been a terrific collaborator in our quest to develop a new treatment option for patients suffering from recurrent *C. difficile* infection, and their support over the past few years has been critical in advancing SER-109 to address this unmet need," Seres Therapeutics CEO, Eric Shaff, said. "We conducted a competitive process to select a collaborator for SER-109. As we prepare for potential approval and commercialization, we are eager to embark side-by-side on our next phase with a company that believes as fervently as we do in the potential of this transformative approach to reduce the recurrence of CDI."

"We are excited to expand our existing collaboration with Seres Therapeutics at this pivotal time, given the promise SER-109 holds for patients trapped in the debilitating cycle of recurrent *C. difficile* infection," CEO of Nestlé Health Science, Greg Behar, added. "Nestlé Health Science is focused on the fast-developing areas of gut health, food allergies and metabolic health within our global pharmaceutical business, Aimmune Therapeutics. We look forward to leveraging Aimmune's existing, fully integrated commercial infrastructure and capability to launch this important medicine, once approved."

Nestlé Health Science continues to make significant investments in innovation while leveraging leading-edge science. Its pharma arm, Aimmune Therapeutics, has a strong presence in the field of gastroenterology, allowing it to lead the commercialization of SER-109 while providing Seres the ability to retain a strategic role and actively participate in the launch.

SER-109 Clinical & Regulatory Milestones

- In August 2020, Seres announced that SER-109 had met the primary endpoint from the pivotal Phase 3 ECOSPOR III study, showing a highly statistically significant reduction in the rate of CDI recurrence compared to placebo at 8 weeks, with an absolute reduction of 27% and a relative risk reduction of 68%. In a separate measure, approximately 88% of patients achieved sustained clinical response at week 8.
- The Company expects that the ECOSPOR III efficacy results should support a BLA filing as a single pivotal trial once the SER-109 safety database includes at least 300 treated subjects monitored for 24 weeks, based on feedback from the FDA.
- A SER-109 open-label study is ongoing and continues to contribute to the SER-109 safety database. Completion of target enrollment is anticipated in Q3 of 2021.

Responsibility for oversight of activities to support SER-109 will be governed by a Joint Steering Committee composed of an equal number of members from each company. Seres is responsible for the manufacturing and supply of SER-109 for all geographies contemplated in the collaboration in addition to ex-North America. Seres will lead medical affairs activities pre-launch and Aimmune Therapeutics will lead commercialization and medical affairs activities post-launch.

**Conference Call Information**

Seres' management team will host a conference call today, July 1, 2021, at 8:30 a.m. ET. To access the conference call, please dial 844-277-9450 (domestic) or 336-525-7139 (international) and reference the conference ID number 5382249. To join the live webcast, please visit the "Investors and News" section of the Seres website at www.serestherapeutics.com.

A webcast replay will be available on the Seres website beginning approximately two hours after the event and will be archived for at least 21 days.

**About Seres Therapeutics**
Seres Therapeutics, Inc., (Nasdaq: MCRB) is a leading microbiome therapeutics company developing a novel class of multifunctional bacterial consortia that are designed to functionally interact with host cells and tissues to treat disease. Seres' SER-109 program achieved the first-ever positive pivotal clinical results for a targeted microbiome drug candidate and has obtained Breakthrough Therapy and Orphan Drug designations from the FDA. The SER-109 program is being advanced for the treatment of recurrent *C. difficile* infection and has potential to become a first-in-class FDA-approved microbiome therapeutic. Seres' SER-287 program has obtained Fast Track and pediatric Orphan Drug Designations from the FDA and is being evaluated in a Phase 2b study in patients with active mild-to-moderate ulcerative colitis. Seres is evaluating SER-301 in a Phase 1b study in patients with ulcerative colitis and SER-155 in a Phase 1b study to address gastrointestinal infections, bacteremia and graft-versus-host disease. For more information, please visit www.serestherapeutics.com.

**About Nestlé Health Science and Aimmune Therapeutics**
Nestlé Health Science, a leader in the science of nutrition, is a globally managed business unit of Nestlé. We are committed to redefining the management of health, offering an extensive portfolio of science-based consumer health, medical nutrition, pharmaceutical therapies, and vitamin and supplement brands. Our extensive research network provides the foundation for products that empower healthier lives through nutrition. Headquartered in Switzerland, we have more than 7,000 employees around the world, with products available in more than 140 countries. www.nestlehealthscience.com

Aimmune Therapeutics, Inc., a Nestlé Health Science Company, is a biopharmaceutical company developing and commercializing treatments for potentially life-threatening gastrointestinal, metabolic, and food-mediated allergic conditions. www.aimmune.com

**Forward-looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including our development plans; the timing and results of the SER-109 safety data; the ability of our clinical trials to support approval of SER-109; the size of the market for SER-109; our ability to achieve the targets and receive any milestones payments from Nestlé Health Science; Nestlé Health Science's obligation to share responsibility and costs for the commercialization of SER-109; and the potential benefits of our collaboration with Nestlé Health Science.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our limited operating history; the impact of the COVID-19 pandemic; our unproven approach to therapeutic intervention; the lengthy, expensive and uncertain process of clinical drug development; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates and develop and commercialize our product candidates, if approved; and our ability to retain key personnel and to manage our growth. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on May 4, 2021, and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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