

# Seres Therapeutics Announces Broad Agreement with Memorial Sloan Kettering Cancer Center to Develop Microbiome Therapeutics for Hematopoietic Stem Cell Transplantation and Immuno-Oncology Treatment

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## - Agreements provide IP license bolstering Company's strong patent portfolio -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 12, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics platform company, today announced that it has entered into a strategic, multi-year research collaboration with Memorial Sloan Kettering Cancer Center (MSK). The collaboration will support the translation of novel discoveries from MSK laboratories into first-in-field microbiome therapeutics across multiple new cancer indications, where the microbiome may play a critical role.

Seres and MSK have agreed to collaborate in two diverse areas of focus related to the discovery and development of microbiome therapeutics: (1) improving the morbidity and mortality outcomes of patients undergoing Hematopoietic Stem Cell Transplantation (HSCT) for treatment of cancer, by prevention of Transplant-Related Infections and Graft Versus Host Disease (GVHD); and (2) increasing the efficacy and safety of checkpoint inhibitors used for immuno-oncology treatment. Both areas will be targeted using rationally-designed consortia of microbiome bacteria, a technology which Seres has pioneered in other therapeutic areas.

Seres and MSK have agreed to work jointly under a multi-year sponsored research agreement where Seres will collaborate with MSK investigators to study patient samples from MSK clinical studies, generating microbiome metagenomic signatures as well as other clinical data that are expected to aid in the design of novel microbiome therapeutics in these targeted disease states. The agreements also provide Seres with a global license to MSK's intellectual property related to the use of bacterial compositions in treating HSCT patients and related areas, further bolstering Seres' broad existing composition of matter and method of use patent estate.

"MSK scientists have been at the forefront of research into the crucial role of the microbiome in disease, and we believe our combined insights and capabilities could be strongly synergistic and pave the way toward clinically meaningful therapeutic applications for patients with various cancers and serious conditions related to their treatment," said Roger Pomerantz, M.D., President, CEO and Chairman of Seres.

In HSCT, MSK investigators, led by Marcel van den Brink, M.D., Ph.D., have published clinical studies demonstrating a relationship between the diversity and composition of the microbiome in HSCT patients and their increased risk of bacterial infections and GVHD, both of which contribute to overall all-cause mortality.<sup>1,2</sup> Seres is currently developing SER-155, a rationally-designed, preclinical stage therapeutic candidate comprised of *in vitro* cultured bacterial species that aims to improve morbidity and mortality outcomes in HSCT patients.

In the area of immuno-oncology, researchers from Seres and MSK will also work together with the goal of discovering precisely how the microbiome could improve the efficacy and safety of immuno-oncology checkpoint inhibitors. This research builds upon a recent MSK publication which describes, for the first time, the important role of the microbiome in the development of immunological adverse events in patients, and related preclinical work showing that the microbiome can enhance the efficacy of checkpoint inhibitors.<sup>3,4</sup>

"We are looking forward to collaborating with Seres, a global leader in the development of microbiome therapeutics, as we work together to advance our collective insights into meaningful clinical advances for patients. Based upon our research in cancer patients as well as animal models at MSK, we believe there is potential to improve patient outcomes by addressing the critical roles of the microbiome," said Dr. van den Brink.

## **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, where the natural state of bacterial diversity and function 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). For more information, please visit <u>www.serestherapeutics.com</u>. Follow us on Twitter @SeresTx.

## About HSCT

Hematopoietic stem cell transplantation (HSCT) is the transplantation of multipotent hematopoietic stem cells, usually derived from bone marrow, peripheral blood, or umbilical cord blood. The procedure is used as part of the treatment of certain blood cancers. An estimated 22,000 allogeneic HSCT procedures are performed in the US and EU each year. HSCT patients experience elevated mortality risk due to infection, Graft Versus Host Disease (GVHD) and cancer recurrence.

#### About Immuno-Oncology and Checkpoint Inhibitors

Immuno-oncology treatment uses or enhances the patient's own immune system to be able to stop the growth of cancer cells. The composition of a patient's microbiome has been shown to impact this immune response. Several immuno-oncology checkpoint inhibitors, including nivolumab (Opdivo®), ipilimumab (Yervoy®) and pembrolizumab (Keytruda®) are FDA approved and indicated to treat various cancers. While immuno-oncology

treatment can lead to profound clinical responses, these therapies are effective in a minority of patients who use them. Also, the clinical utility of immuno-oncology products can be limited by serious immune mediated adverse events observed in some patients.

#### **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 without limitation statements regarding the potential benefits of Seres' collaboration with MSK, the results of clinical studies, the impact of the microbiome on various forms of cancer and the ability for Seres to design Ecobiotic® therapeutic candidates.

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, which may not be available; our limited operating history; the unpredictable nature of our early stage development efforts for marketable drugs; the unproven approach to therapeutic intervention of our microbiome therapeutics; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; potential delays in enrollment of patients which could affect the receipt of necessary regulatory approvals; potential delays in regulatory approval, which would impact the ability to commercialize our product candidates and affect our ability to generate revenue; any fast track or Breakthrough Therapy designation may not lead to faster development, regulatory approval or marketing approval; our possible inability to receive orphan drug designation should we choose to seek it; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; our lack of experience in manufacturing our product candidates; the potential failure of our product candidates to be accepted on the market by the medical community; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; potential competition from biosimilars; failure to obtain marketing approval internationally; post-marketing restrictions or withdrawal from the market; anti-kickback, fraud, abuse, and other healthcare laws and regulations exposing us to potential criminal sanctions; recently enacted or future legislation; compliance with environmental, health, and safety laws and regulations; protection of our proprietary technology; protection of the confidentiality of our trade secrets; changes in United States patent law; potential lawsuits for infringement of third-party intellectual property; our patents being found invalid or unenforceable; compliance with patent regulations; claims challenging the inventorship or ownership of our patents and other intellectual property; claims asserting that we or our employees misappropriated a third-party's intellectual property or otherwise claiming ownership of what we regard as our intellectual property; adequate protection of our trademarks; ability to attract and retain key executives; managing our growth could result in difficulties; risks associated with international operations; potential system failures; the price of our common stock may fluctuate substantially; our executive officers, directors, and principal stockholders have the ability to control all matters submitted to the stockholders; a significant portion of our total outstanding shares are eligible to be sold into the market in the near future; unfavorable or lacking analyst research or reports; and we may be subject to securities class action litigation. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 14, 2016 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.

## References

<sup>1</sup> Jenq R et al., Intestinal blautia is associated with reduced death from graft-versus-host disease. Biology of Blood and Marrow Transplantation, 2015.

<sup>2</sup> Taur Y et al., The effects of intestinal tract bacterial diversity on mortality following allogeneic hematopoietic stem cell transplantation. *Blood*, 2014.

<sup>3</sup> Vetizou et al., Anticancer immunotherapy by CTLA-4 blockade relies on the gut microbiota. Science, 2015.

<sup>4</sup> Dubin K et al., Intestinal microbiome analyses identify melanoma patients at risk for checkpoint-blockade-induced colitis. *Nature*, 2016.

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