



Tacitus Therapeutics Launches in Collaboration with Mount Sinai to Develop Stem Cell Therapies for Life-Threatening Diseases

Tacitus Therapeutics exclusively licenses technology for expansion, differentiation and engineering of hematopoietic stem cells for use in therapeutic applications

NEW YORK, Jan. 9, 2020 – Tacitus Therapeutics, a clinical-stage company, has launched in collaboration with the Mount Sinai Health System to develop stem cell therapies initially targeting blood cancers and related clotting disorders. Their first therapy, HSC100, currently is being investigated in a Phase I clinical trial¹.

Tacitus is building upon technology developed by and exclusively licensed from Mount Sinai. Based on research by scientific co-founders Ronald Hoffman, M.D., and Camelia Iancu-Rubin, Ph.D., the technology includes proprietary cell expansion, differentiation and engineering methods. Together, these methods manufacture healthy cells that overcome the limitations of traditional allogeneic, or donor, cell transplantations.

Blood cancers comprise about 10% of new cancer cases in the U.S. each year, and almost 60,000 people die from blood cancer complications annually. Most blood cancers start in the bone marrow, where blood is produced. A common therapy for such blood cancers is a hematopoietic stem cell (HSC) treatment or, as more commonly referred to, bone marrow transplantation. In this process, doctors infuse healthy HSCs into the patient's bloodstream, where they migrate to the bone marrow to grow or engraft.

HSCs for this process can be collected from bone marrow, circulating blood, or umbilical cord blood (CB) of healthy donors. While HSC transplants are common, significant barriers to success exist, including high levels of graft-versus-host disease, low numbers of healthy cells obtained from CB, and increased risk of bleeding due to delayed megakaryocyte, or platelet, engraftment.

Hoffman and Iancu-Rubin are pioneers of bone marrow cell therapy treatments, and development of this technology was enabled by the New York State Stem Cell Science program, NYSTEM. As a New York State Department of Health initiative, NYSTEM awarded a \$1 million grant to Hoffman in 2010 that supported the original research underpinning this platform technology. In 2015, NYSTEM awarded Hoffman and Iancu-Rubin an \$8 million grant to translate the technology from the laboratory into the clinic, where it is currently in clinical trial¹.

Hoffman also serves as Director of the Myeloproliferative Disorders Research Program and Professor of Medicine (Hematology and Medical Oncology) at the Icahn School of Medicine at Mount Sinai, and Iancu-Rubin is Associate Professor of Pathology at the Icahn School of Medicine and Director of the Cellular Therapy Laboratory at Mount Sinai Hospital.

"Promising discoveries by Mount Sinai scientific thought leaders may lead to new, essential cell-based therapies that will broadly benefit patients," said Erik Lium, Executive Vice President and Chief Commercial Innovation Officer, Mount Sinai Innovation Partners. "We're pleased to be collaborating with Tacitus to launch the next stage of development for these technologies."

“Tacitus is committed in its mission to advance next-generation cell therapies with curative potential,” said Carter Cliff, CEO of Tacitus. “Based on our founders’ solid foundation of research, we are translating these discoveries into broad clinical practice as we look to dramatically improve the standard of care for patients with life-threatening conditions.”

About HSC100

HSC100 is an investigational therapy based on allogeneic hematopoietic stem cells (HSC) expanded from umbilical cord blood. HSC100 is being investigated currently in an open-label Phase I clinical trial¹ in the United States for treatment of hematological malignancies. The success of unmanipulated cord blood as a source of stem cells has been hampered by the small number of stem cells present in a single cord, leading to delayed engraftment and frequent graft failure. Our proprietary technology includes the use of an epigenetic modifier, valproic acid, to expand the number and the quality of HSCs found in cord blood collections. For more information on HSC100 clinical trials, please visit www.clinicaltrials.gov.

¹ClinicalTrials.gov identifier NCT03885947.

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About Tacitus Therapeutics

Tacitus Therapeutics is a clinical-stage biotechnology company developing advanced medicines for treatment of blood cancers, immune disorders and other intractable disease conditions. Our mission is to pioneer best-in-class therapies using proprietary cell expansion, differentiation and engineering platform technologies that overcome the limitations of traditional cell transplantation. Initial targets include a lead clinical program (HSC100) investigating the treatment of blood cancers, followed by preclinical programs to address clotting disorders and other serious unmet medical needs. For additional information, please visit www.tacitustherapeutics.com.

About Mount Sinai Health System

The Mount Sinai Health System is New York City's largest integrated delivery system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai's vision is to produce the safest care, the highest quality, the highest satisfaction, the best access and the best value of any health system in the nation. The Health System includes approximately 7,480 primary and specialty care physicians; 11 joint-venture ambulatory surgery centers; more than 410 ambulatory practices throughout the five boroughs of New York City, Westchester, Long Island, and Florida; and 31 affiliated community health centers. The Icahn School of Medicine is one of three medical schools that have earned distinction by multiple indicators: ranked in the top 20 by U.S. News & World Report's "Best Medical Schools", aligned with a U.S. News & World Report's "Honor Roll" Hospital, No. 12 in the nation for National Institutes of Health funding, and among the top 10 most innovative research institutions as ranked by the journal Nature in its Nature Innovation Index. This reflects a special level of excellence in education, clinical practice, and research. The Mount Sinai Hospital is ranked No. 14 on U.S. News & World Report's "Honor Roll" of top U.S. hospitals; it is one of the nation's top 20 hospitals in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Geriatrics, Gynecology, Nephrology, Neurology/Neurosurgery, and Orthopedics in the 2019-2020 "Best Hospitals" issue. Mount Sinai's Kravis Children's Hospital also is ranked nationally in five out of ten pediatric specialties by U.S. News & World Report. The New York Eye and Ear Infirmary of Mount Sinai is ranked 12th nationally for Ophthalmology, Mount Sinai St. Luke's and Mount Sinai West are ranked 23rd nationally for Nephrology and 25th for Diabetes/Endocrinology, and Mount Sinai South Nassau is ranked 35th nationally for Urology. Mount Sinai Beth Israel, Mount Sinai St. Luke's, Mount Sinai West, and Mount Sinai South Nassau are ranked regionally. For more information, visit www.mountsinai.org or find Mount Sinai on Facebook, Twitter and YouTube.

About Mount Sinai Innovation Partners (MSIP)

MSIP is responsible for driving the real-world application and commercialization of Mount Sinai discoveries and inventions and the development of research partnerships with industry. Our aim is to translate discoveries and inventions into health care products and services that benefit patients and society. MSIP is accountable for the full spectrum of commercialization activities required to bring Mount Sinai inventions to life. These activities include evaluating, patenting, marketing and licensing new technologies building research, collaborations and partnerships with commercial and nonprofit entities, material transfer and confidentiality, coaching innovators to advance commercially relevant translational discoveries, and actively fostering an ecosystem of entrepreneurship within the Mount Sinai research and health system communities. For more information, please visit www.ip.mountsinai.org or find MSIP on [LinkedIn](#), [Twitter](#), [Facebook](#), [Medium](#), and [YouTube](#).

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