



Gradalis Announces Research Alliance with Mount Sinai

DALLAS, December 19, 2016 – Gradalis, Inc. a clinical stage cellular immunotherapy company, developing Vigil® Engineered Autologous Tumor Cell (EATC) therapy, today announced the establishment of a research alliance with the Icahn School of Medicine at Mount Sinai to advance the scientific understanding of Vigil EATC treatment. Under the terms of the agreement, Gradalis will provide funding and clinical samples for research to understand the nature of immune response generated to the Vigil engineered autologous tumor cell therapy.


The research collaboration will be jointly headed by Gradalis' Chief Scientific Officer, John Nemunaitis, MD, and by Seunghee Kim-Schulze, PhD, Assistant Professor of Medicine and Facility Director, Human Immune Monitoring Core at The Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai.

"We are extremely pleased to collaborate with the world class Immune Monitoring program at Mount Sinai," said Sunil Joshi, President and Chief Executive Officer of Gradalis. "This research collaboration will help us elucidate further the robust ELISPOT response observed in the Vigil EATC clinical trials, and characterize the nature of the immune response."

"We are pleased to collaborate on this important project with Gradalis," said Miriam Merad, Professor of Oncological Science, Medicine (Hem/Onc Division) and Immunology, The Tisch Cancer and Precision Immunology Institutes at the Icahn School of Medicine at Mount Sinai. "Over the last few years, we have invested heavily in the latest technology to assist companies like Gradalis develop a deeper understanding of the immune mechanisms underlying their technologies. We look forward to leveraging our collective experience in helping Gradalis better understand the nature of the immune response generated to Vigil EATC."

This collaboration will span multiple clinical trials including the recently completed First in Human study and Ovarian Phase 2A study. Additional collaboration effort may be initiated to support ongoing registrational clinical trials in Ewing's sarcoma and ovarian cancer, as well as trials exploring the combination of Vigil and PD-1/PDL-1 inhibitors in non-small cell lung cancer (NSCLC), melanoma and triple negative breast cancer.

About Vigil EATC

 Vigil is an investigational cellular immunotherapy technology that combines the concepts of genetic engineering with the science of immuno-oncology to enable an immune response to cancer cells. A patient's tumor cells are engineered with a plasmid carrying the gene vector for shRNA Furin and GM-CSF to elicit a systemic T-cell directed immune response when administered to the patient through intradermal injections. By utilizing the patient's own tumor as the antigen source, Vigil EATC is designed to elicit an immune response that is specifically targeted and broadly relevant to each patient's unique tumor antigens. Vigil EATC is being studied in Ewing's sarcoma and ovarian cancer as a single agent, and in breast cancer, non-small cell lung cancer and melanoma

in combination with PD-L1 inhibitors. More information about these studies can be found on www.vigilclinicaltrials.com.

About Gradalis



Gradalis is a fully integrated biotechnology company based in Dallas, Texas, that focuses on the development, manufacturing, and commercialization of novel proprietary personalized cellular immunotherapies to treat cancer. Gradalis operates a cGMP manufacturing facility in Carrollton, Texas. For more information about Gradalis, Inc., please visit www.gradalisinc.com.

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About the Mount Sinai Health System

The Mount Sinai Health System is an integrated health system committed to providing distinguished care, conducting transformative research, and advancing biomedical education. Structured around seven hospital campuses and a single medical school, the Health System has an extensive ambulatory network and a range of inpatient and outpatient services—from community-based facilities to tertiary and quaternary care.

The System includes approximately 7,100 primary and specialty care physicians; 12 joint-venture ambulatory surgery centers; more than 140 ambulatory practices throughout the five boroughs of New York City, Westchester, Long Island, and Florida; and 31 affiliated community health centers. Physicians are affiliated with the renowned Icahn School of Medicine at Mount Sinai, which is ranked among the highest in the nation in National Institutes of Health funding per investigator. The Mount Sinai Hospital is in the “Honor Roll” of best hospitals in America, ranked No. 15 nationally in the 2016-2017 “Best Hospitals” issue of U.S. News & World Report. The Mount Sinai Hospital is also ranked as one of the nation’s top 20 hospitals in Geriatrics, Gastroenterology/GI Surgery, Cardiology/Heart Surgery, Diabetes/Endocrinology, Nephrology, Neurology/Neurosurgery, and Ear, Nose & Throat, and is in the top 50 in four other specialties. New York Eye and Ear Infirmary of Mount Sinai is ranked No. 10 nationally for Ophthalmology, while Mount Sinai Beth Israel, Mount Sinai St. Luke's, and Mount Sinai West are ranked regionally. Mount Sinai’s Kravis Children’s Hospital is ranked in seven out of ten pediatric specialties by U.S. News & World Report in “Best Children's Hospitals.”

For more information, visit <http://www.mountsinai.org> or find Mount Sinai on [Facebook](#), [Twitter](#) and [YouTube](#).

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