Linus Biotechnology Inc. Receives FDA Breakthrough Device Designation for StrandDx™-ASD Exposome Sequencing Diagnostic

NEW YORK, Dec. 7, 2021 -- Linus Biotechnology Inc., a leader in precision exposome sequencing, today announced that the U.S. Food and Drug Administration Center for Devices and Radiological Health has granted the Company’s StrandDx™-ASD diagnostic aid the designation as a Breakthrough Device for Autism Spectrum Disorder (ASD).

The FDA Breakthrough Device designation aims to expedite the review of innovative technologies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Diagnosing ASD can be difficult because there is no FDA-approved molecular biomarker, like a blood test, to identify the disorder. Current ASD diagnosis relies on behavioral observation and it is usually diagnosed at approximately 4 years of age by an experienced professional. However, many children receive a final diagnosis at a much later age and do not receive the benefits of early intervention.

StrandDx™-ASD is based on novel molecular biomarkers developed using Linus Biotechnology’s proprietary exposome and biological response sequencing platform, utilizing a single strand of hair. According to the Breakthrough Device designation label, the intended use of StrandDx™-ASD will extend to patients from birth to 21 years, where the test will assess the likelihood of ASD in children from birth to 18 months old, and aid in diagnosis of ASD in patients aged 18 months to 21 years.

“Now for the first time in the history of medicine we have the prospect that, by studying a single strand of hair, physicians, patients, families and scientists can get the physiological equivalent of a blood-test for autism”, said Dr. Neil Kurtz, MD, physician, psychiatrist and neurologist, and an advisor and director of the Company.

“As our first precision exposome diagnostic, StrandDx™-ASD is being developed to help guide patient care for ASD, a disorder that now affects 1 in 44 children in the U.S. Molecular biomarkers, like StrandDx™-ASD, are a major step forward in precision medicine for autism and illustrate the potential to deploy individualized early intervention”, said Manish Arora, PhD, BDS, MPH, Edith J. Baerwald Professor and Vice Chair of the Department of Environmental Medicine and Public Health at the Icahn School of Medicine at Mount Sinai and co-founder and Chief Scientific Officer of the Company. “This designation is a major milestone for Linus Biotechnology Inc. We look forward to working closely with the FDA to prioritize development of StrandDx™-ASD and moving it forward toward commercialization,” added Dr. Arora.

The Precision Exposome Sequencing Platform described is based on technology developed by Dr. Manish Arora and other faculty members at the Icahn School of Medicine at Mount Sinai and licensed to Linus Biotechnology Inc. Mount Sinai and Mount Sinai researchers, including Manish Arora, have a financial interest in Linus Biotechnology Inc.
About Linus Biotechnology Inc.

Linus Biotechnology is a patient-centric, breakthrough science precision exposome medicine company headquartered in New York, NY. The Company’s program pipeline comprises precision exposome medicine biomarkers and target discovery across disease domains for which historically no molecular endpoints have been available in medical practice or for clinical trials, including CNS (autism spectrum disorder, amyotrophic lateral sclerosis), gastroenterology (inflammatory bowel disease), renal disease and oncology. For more information, visit www.linusbio.com

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. We advance medicine and health through unrivaled education and translational research and discovery to deliver care that is the safest, highest-quality, most accessible and equitable, and the best value of any health system in the nation. The Health System includes approximately 7,300 primary and specialty care physicians; 13 free-standing joint-venture centers; more than 410 ambulatory practices throughout the five boroughs of New York City, Westchester, and Long Island; and more than 30 affiliated community health centers. The Mount Sinai Hospital is ranked in U.S. News & World Report's "Honor Roll" of the top 20 U.S. hospitals and among the top in the nation by specialty: No. 1 in Geriatrics and top 20 in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Neurology/Neurosurgery, Orthopedics, Pulmonology/Lung Surgery, Urology, and Rehabilitation. Mount Sinai Kravis Children's Hospital is ranked in U.S. News & World Report's “Best Children's Hospitals” among the country's best in four out of 10 pediatric specialties. New York Eye and Ear Infirmary of Mount Sinai is ranked among the Top 20 nationally for ophthalmology. The Icahn School of Medicine at Mount Sinai 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 "Honor Roll" Hospital, and No. 14 in the nation for National Institutes of Health funding. Newsweek's “The World's Best Smart Hospitals” ranks The Mount Sinai Hospital as No. 1 in New York and top five globally, and Mount Sinai Morningside as top 20 globally, and “The World’s Best Specialized Hospitals” ranks Mount Sinai Heart as No. 1 in New York and No. 4 globally and the Division of Gastroenterology as No. 3 globally. For more information, visit https://www.mountsinai.org or find Mount Sinai on Facebook, Twitter and YouTube.