ReNetX Bio Completes Enrollment of RESET Study of AXER-204 for Chronic Spinal Cord Injury

New Haven, Conn., Nov. 10, 2021 -- ReNetX Bio, Inc., a privately held, clinical-stage company committed to reversing disease and damage for patients suffering from central nervous system (CNS) disorders, announces successful completion of patient enrollment in Part 2 of the RESET study.

The RESET study (Part 2) is a multiple dose, double-blind, placebo-controlled study to confirm safety and tolerability, and to investigate the efficacy of AXER-204 with chronic cervical spinal cord injury. According to the National Spinal Cord Injury Statistical Center, there are 300,000 people in the US living with chronic spinal cord injury, and 60% of those individuals have a cervical level injury resulting in quadriplegia. The lifelong cost of spinal cord injury is over $5M per patient depending on age and severity of injury, with no treatments available to date.

A total of 24 participants received AXER-204 in Part 1 of the trial which entailed evaluating single ascending doses of AXER-204. Part 2 of the trial comparing multiple doses of AXER-204 with placebo enrolled 27 participants at six major spinal cord injury treatment and rehabilitation centers in the United States. The primary effectiveness endpoint is International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) Upper Extremity Motor Score (UEMS), the internationally recognized standard of SCI measure that reflects the function of key muscle groups in the hands and arms. The company has powered the study for proof of concept and anticipates unblinding and reporting top line data in Q2/Q3 of 2022.

“We are pleased that the RESET study has successfully reached the completion of enrollment,” said Dr. Gil Block, MD, PhD, Chief Medical Officer. “The enthusiasm for the study from patients and our top tier investigators has been outstanding, and I’m proud of the quality of the study execution. We want to thank the participants, their families and caregivers, staff, and investigators for their participation in this study, and for contributing to our understanding of AXER-204 as we work to address this significant unmet medical need.”

“We’re also excited to have the opportunity to gather critical data from people with chronic cervical spinal cord injury utilizing key scales and measures and to support the International Spinal Cord Injury Biobank (ISCIB). Continuing to gather data on patients in this population is an important initiative and will support additional development of restorative therapies,” said Dr. George Maynard, President & CSO.

“This is the very first therapy developed for patients suffering from paralysis associated with chronic spinal cord injury. This study also lays the foundation for AXER-204 as a targeted approach to broadly address axonal damage across other conditions from multiple sclerosis to stroke to optic nerve injury,” said CEO Erika Smith.

About the RESET Study: For more information, see ClinicalTrials.gov
About ReNetX Bio, Inc.: For more information, please visit www.renetx.com

This study is supported by Wings for Life Foundation and the National Institute of Neurological Disorders and Stroke of the National Institutes of Health under Award Number R44NS118974.