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First Adaptive Hemorrhagic Stroke Trial Completes Enrollment

Trial sponsor, NICO Corporation, hopes to show functional recovery for the most deadly, costly stroke

INDIANAPOLIS (October 6, 2022) – NICO Corporation announced today that enrollment is now complete for the ENRICH (Early MiNimally-invasive Removal of ICH) randomized controlled trial. The trial compares medical and economic outcomes between *early surgical intervention* of intracerebral hemorrhage (ICH) with minimally invasive parafascicular surgery (MIPS) to current guideline-directed medical management. ENRICH is the first ICH trial using the natural folds of the brain (trans-sulcal) to *access and surgically address* hemorrhages *within 24 hours of onset*. It is also the first trial to adaptively enroll patients based on ICH location to maximize the likelihood of patient benefit.

ENRICH utilizes a MIPS approach that uniquely integrates advanced imaging technologies with the NICO BrainPath® for non-disruptive navigable access using a parafascicular route to the ICH and the automated Myriad® to pursue the goal of maximum clot evacuation. The goal of the trans-sulcal MIPS approach is to allow surgeons to access and remove the hemorrhage more quickly – providing an opportunity for improved recovery.

"Historically, supratentorial intracerebral hemorrhage is a disease where all earlier surgical trials have failed to meet their primary endpoints, these studies, however, paved the way for future successes by providing specific metrics needed to impact functional outcomes," said Dr. Gustavo Pradilla of Emory University, co-principal investigator of the ENRICH trial.

Intracerebral hemorrhage, or hemorrhagic stroke, is the deadliest, most costly, and most debilitating form of stroke. As many as half of ICH patients die within 30 days, and there is no current proven therapy to treat the disease. ICH costs the U.S. more than $12 billion annually. More than 120,000 people are diagnosed with an ICH annually in the U.S. and 2.1 million people worldwide. The incidence of ICH is expected to rise due to the aging population and increased use of anticoagulants.

The ENRICH multi-center trial is led by the Emory Stroke Center of Emory University hospitals and Marcus Stroke & Neuroscience Center of Grady Memorial Hospital in Atlanta. The trial leverages multi-disciplinary teams, including stroke neurology, neurosurgery, and neuro-critical care at 33 sites that include major medical and academic centers, as well as large community hospitals. NICO has invested $10 million and more than five years in the trial, initiated in January 2017. Results are expected to be announced in Q1 2023 after the final 180-day patient follow-up period concludes.

In May, the American Heart Association-American Stroke Association announced changes to the stroke guidelines to include minimally invasive surgery approaches like MIPS when treating ICH. "We are thrilled that ENRICH is now fully enrolled and want to express our sincere gratitude to all patients and healthcare providers

involved in this groundbreaking adaptive trial," said Jim Pearson, president and CEO of NICO Corporation, sponsor of the ENRICH trial. "We are hopeful the trial results will reinforce the recent changes to ICH guidelines and further define the role of MIPS in treating patients who suffer from ICH."

NICO currently holds over 250 issued or pending patents, with 60 focusing solely on safe and repeatable non-disruptive trans-sulcal access through eloquent areas of the brain with BrainPath. NICO's patents also cover efficient removal of clots formed by brain bleeds down a small corridor using the automated Myriad. It is the first and only company in the world to develop and patent technologies to create an entirely new minimally invasive surgical market in neurosurgery for subcortical and skull base lesions, including ICH. Its technologies have been featured in more than 180 peer-reviewed published papers with over 550 unique authors from major academic centers. For more information, visit NICOneuro.com, and follow the latest news on LinkedIn and Twitter.

For more information about the ENRICH trial or patient selection criteria, visit ClinicalTrials.gov or EnrichTrial.com.