

NIPRO CORPORATION Announces Completion of Patient Enrollment in the GREAT U.S. Pivotal Trial Evaluating the Golazo™ Peripheral Atherectomy System

Completion of enrollment in the GREAT trial marks an important milestone toward FDA 510(k) submission.

Osaka, Japan, October 1, 2026 – NIPRO CORPORATION today announced that its U.S. subsidiary, Nipro Vascular Innovations Americas, Inc. (NVIA), has completed enrollment in the GREAT pivotal trial evaluating the investigational Golazo Peripheral Atherectomy System for the treatment of symptomatic lower-extremity peripheral artery disease (PAD). A total of 158 subjects were enrolled in the study. Completion of enrollment represents an important milestone in the clinical development of Golazo and advances the program toward a planned 510(k) Premarket Notification submission to the U.S. Food and Drug Administration (FDA). The company is targeting a commercial availability in the United States in 2028, subject to successful completion of the study and regulatory review.

The GREAT Trial (Golazo Peripheral Atherectomy System for a Safe and Effective Atherectomy) is an Investigational Device Exemption (IDE) pivotal study approved by the FDA and designed to evaluate the safety and effectiveness of the Golazo Peripheral Atherectomy System in patients with symptomatic lower-extremity PAD. The prospective, multicenter, single-arm study enrolled 158 subjects across participating clinical centers in the United States and includes follow-up evaluations at 30 days and six months following treatment.

Peripheral artery disease is a condition in which blood flow to the lower extremities is reduced due to narrowing or blockage of arteries, most commonly caused by atherosclerosis. Although balloon angioplasty and stent implantation are widely used treatment options, complex lesions with significant fibrotic or calcified plaque may present challenges for conventional endovascular treatment. Atherectomy is used to remove or reduce plaque burden and facilitate vessel preparation prior to definitive therapy.

The investigational Golazo Peripheral Atherectomy System is a rotational, front-cutting atherectomy catheter intended for the removal of both fibrocalcific and viscoelastic plaque. Excised plaque is collected within the catheter and removed from the body.

“Completing enrollment in the GREAT Trial represents a significant milestone for NVIA and reflects the dedication of our investigators, participating clinical sites, and employees,” said Jack Hoshino, President and CEO of Nipro Vascular Innovations Americas. “As we move into the follow-up and data analysis phase of the study, we remain focused on building a robust clinical evidence package to support our planned FDA submission and ultimately bring Golazo to physicians treating patients with peripheral artery disease.”

“Effective plaque modification and vessel preparation remain important goals in the treatment of peripheral artery disease,” said Robert E. Beasley, MD, Principal Investigator of the GREAT Trial. “With enrollment now complete, we look forward to evaluating the complete clinical dataset and assessing the safety, handling characteristics, and procedural performance of the Golazo system across a broad range of lesion types.”

Completion of enrollment marks an important step toward the future availability of Golazo in the United States. NVIA intends to submit a 510(k) Premarket Notification to the FDA including the analysis of study endpoints for the full study cohort. Through continued innovation in vascular care, NIPRO remains committed to expanding treatment options for healthcare professionals and patients worldwide while supporting the advancement of endovascular therapy.

About the GREAT Trial

The GREAT Trial (ClinicalTrials.gov Identifier: NCT06321575) is a prospective, multicenter, single-arm FDA IDE pivotal study evaluating the safety and effectiveness of the Golazo Peripheral Atherectomy System in patients with symptomatic lower-extremity peripheral artery disease. The study enrolled 158 subjects and includes protocol-required follow-up assessments at 30 days and six months after treatment.

Investigational Device Statement

CAUTION: The Golazo Peripheral Atherectomy System is an investigational device and is limited by United States law to investigational use only. The device has not been approved or cleared by the U.S. Food and Drug Administration, and its safety and effectiveness have not been established for commercial distribution.

About NIPRO CORPORATION

NIPRO is a global healthcare company committed to improving patient outcomes through medical technologies, pharmaceutical solutions, PharmaPackaging, and regenerative medicine. Guided by its promise of helping people live longer and better lives, NIPRO partners with healthcare professionals around the world to deliver safe, reliable, and practical solutions that advance patient care.

About Nipro Vascular Innovations Americas

Nipro Vascular Innovations Americas, Inc., a NIPRO company headquartered in Bedford, Massachusetts develops innovative vascular technologies designed to advance endovascular therapy, improve procedural efficiency, and support better patient outcomes worldwide.

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