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NIPRO CORPORATION

Announcement of Spryte Medical, a US Affiliate of NIPRO, Completion of Subject Enrollment in the "INSYTE" US Pivotal Trial evaluating the nOCT Imaging System during Brain Aneurysm Treatment

NIPRO CORPORATION (Head office: Settsu, Osaka; President: Tsuyoshi Yamazaki) is pleased to announce that Spryte Medical (Head office: Massachusetts, USA; hereinafter "Spryte"), an equity-method affiliate of NIPRO, has completed subject enrollment in the "INSYTE" US Pivotal Trial evaluating the nOCT Imaging System during brain aneurysm treatment.

Spryte issued a press release as follows.

Spryte Medical Completes INSYTE Trial Enrollment

FDA-approved IDE study of the company's neuro-optical coherence tomography nOCT Imaging System completes enrollment, representing a significant step toward regulatory submission for diagnostic use in intracranial aneurysm treatment

Bedford, MA — July 22,2026 — **Spryte Medical**, a leader in neuro intravascular imaging, today announced the completion of subject enrollment of the INSYTE Trial, a key milestone in the clinical development of its proprietary nOCT Imaging System. With enrollment now complete, the company is advancing toward a U.S. Food and Drug Administration (FDA) submission an indication for use of the system during endovascular treatment of intracranial aneurysms.

The INSYTE Trial — **Intravascular Neuro OCT Imaging System for AneurYsm Treatment Evaluation** — is a U.S. Food and Drug Administration (FDA)–approved Investigational Device Exemption (IDE).The study is designed to determine the system's ability to safely and effectively generate high-resolution intravascular images during aneurysm treatment procedures and subsequent follow-up evaluation. The study represents the first FDA-approved clinical trial evaluating an intravascular optical imaging platform developed specifically for use within the neurovasculature..

Sixty-five subjects were enrolled in 5 months by 16 investigators across 8 centers in 3 countries. This participation reflects a strong commitment by the neurointerventional teams to complete this pioneering evaluation of intravascular imaging in the treatment of brain aneurysms.

"Completing enrollment in the INSYTE Trial is a major achievement for Spryte Medical and reflects years of collaboration among physicians, clinical partners, engineers, and regulatory stakeholders," said **David W. Kolstad, Chief Executive Officer of Spryte Medical.** "We are excited to take the next step toward an FDA submission and ultimately bring this technology to neurointerventional teams across the United States."

With enrollment complete, Spryte Medical will focus on trial completion activities, and preparation of its initial FDA submission. If marketing authorization is received, the nOCT Imaging System would provide neurointerventionalists in the US with access to real-time intravascular imaging capabilities designed to significantly improve visualization of vessel anatomy, device-tissue interactions, and brain vessel wall pathology.

"I have observed firsthand the unique insights that intravascular neuro-OCT imaging can provide into vascular disease, vessel wall and device-tissue interface. I am excited about the higher levels of precision and confidence this will provide us, helping us to deliver the best possible treatment for our patients," said **Ricardo Hanel, MD, PhD, Neurosurgeon at Baptist Health Jacksonville, Co-Principal Investigator of the INSYTE Trial.**

Demetrius Lopes, MD, Neurosurgeon at Advocate Health and Co-Principal Investigator of the INSYTE Trial stated, "This first phase was remarkable in so many ways. I am just as excited as we enter the second phase of the INSYTE trial, performing nOCT imaging of these patients in their follow-up sessions. For the first time we will have a detailed longitudinal view of aneurysm treatment, therapeutic device response and healing. I am confident this next phase will further expand our understanding of neurovascular disease healing across a range of device and antiplatelet regimens."

The nOCT Imaging System is an investigational device and is not commercially available in the United States. Its safety and effectiveness have not yet been established.

About the INSYTE Trial

The INSYTE Trial is a prospective, single-arm, unblinded, multicenter trial evaluating the Spryte Medical nOCT Imaging System for use during endovascular treatment and follow-up of intracranial aneurysms. The trial focuses on safety and imaging performance to support diagnostic assessment in the neurovasculature. Details of the study are available on ClinicalTrials.gov.

About Spryte Medical :

Spryte Medical is an intravascular imaging, AI, and data company headquartered in Bedford, MA. The unique imaging and data platform is purpose-built to accelerate understanding of target diseases, facilitate the development of novel therapies, and to provide information for optimal treatment delivery for the benefit of patients worldwide.