ENGINEERING STROKE SOLUTIONS

PRESS RELEASE

Acandis Receives Regulatory Approval to Launch SONIC Pivotal Clinical Investigation Evaluating the SILANCE® Stent for the Treatment of Idiopathic Intracranial Hypertension (IIH)

Pforzheim, Germany – [August 5, 2026]

Acandis GmbH, a leading Germany medical technology company specialising in devices for neurovascular interventions, announced today that it has received approval from the German Federal Institute for Drugs and Medical Devices (BfArM) to initiate the SONIC clinical investigation in Germany. The pivotal, prospective, multicentre clinical investigation will evaluate the SILANCE® Stent for the treatment of patients with **idiopathic intracranial hypertension (IIH) associated with symptomatic cerebral venous sinus stenosis**. The first site initiation is scheduled for September 2026.

Fig. 1: SONIC Clinical Investigation
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The **SONIC study** (ClinicalTrials.gov Identifier: NCT07561268) is designed to evaluate the clinical benefit, performance, and safety of the SILANCE® Stent, a novel laser-cut, self-expanding nitinol stent specifically developed for venous sinus stenting. A total of **99 patients** will be enrolled across approximately **20 European neurovascular centres** with an emphasis on Germany. The study is led by **PD Dr. med. Hannes Nordmeyer**, an internationally recognised interventional neuroradiologist and expert in the treatment of cerebral venous sinus stenosis.

Cerebral venous sinus stenosis is increasingly recognised as closely associated with **IIH**, a condition that may lead to severe headaches, visual impairment, papilledema and pulsatile tinnitus. While venous sinus stenting has become an established treatment option for patients who remain symptomatic despite medical therapy, currently available devices are primarily carotid stents used off-label and are not optimised for the specific anatomical requirements of the cerebral venous system.

The SILANCE® Stent has been purpose-built to address these challenges. Its laser-cut closed-cell design, atraumatic stent ends and low-profile **3F delivery system** are designed to facilitate safe navigation through the tortuous venous anatomy while minimising procedural risks. As a result, the SILANCE® Stent represents the next generation of dedicated devices engineered to meet the unique anatomical and procedural demands of the cerebral venous system.

"Venous sinus stenting has become an increasingly important treatment option for patients suffering from idiopathic intracranial hypertension," said PD Dr. Hannes Nordmeyer. "The SILANCE® Stent has been specifically engineered for this indication and combines a low-profile delivery system with a design tailored to the unique anatomy of the cerebral venous sinuses. We believe this dedicated approach has the potential to further improve procedural safety and treatment outcomes."

The **primary objective** of the SONIC study is to evaluate the clinical benefit, performance and safety of the SILANCE® Stent. The primary clinical endpoint is the disappearance or significant improvement of IIH-related symptoms six months after treatment, while the primary performance endpoint evaluates the reduction of the transstenotic venous pressure gradient following stent implantation. Safety will be assessed by the rate of major adverse events.

"The approval of the SONIC study represents another important milestone in Acandis' commitment to advancing neurovascular innovation," said **Dr. Andreas Schüßler**, Founder and CEO of Acandis GmbH. "Together with our ongoing RESOLVE study evaluating the SiREX® Stent for the treatment of pulsatile tinnitus, the SONIC study expands our clinical research portfolio to encompass the two major clinical manifestations of symptomatic cerebral venous sinus stenosis. While RESOLVE focuses on pulsatile tinnitus, SONIC addresses idiopathic intracranial hypertension, making Acandis the first company in Europe to initiate dedicated pivotal clinical investigations for both major indications associated with symptomatic cerebral venous sinus stenosis. This underscores our commitment to pioneering dedicated venous sinus stenting technologies and generating the clinical evidence needed to establish this emerging field of neurovascular therapy."

Recruitment is expected to continue over approximately 24 months, followed by a 12-month clinical follow-up. The SONIC study is expected to generate robust clinical evidence supporting the use of dedicated venous sinus stenting in patients with idiopathic intracranial hypertension and further advance this emerging field of neurovascular therapy.

About Acandis GmbH

Acandis GmbH, headquartered in Pforzheim, Germany, develops and manufactures medical devices for the treatment of neurovascular diseases. The company focuses on advancing minimally invasive technologies that improve outcomes for patients suffering from complex cerebrovascular conditions.

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