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Airiver Medical Secures IDE Approval from the FDA for Pivotal Clinical Study of the Airiver Drug Coated Balloon for Patients with Chronic Rhinosinusitis

The nationwide study will assess the safety and efficacy of the technology that combines standard balloon dilation to open the nasal passageways with drug delivery designed to maintain symptom relief

BROOKLYN PARK, Minn. (December 9, 2025) – Airiver Medical, a clinical stage company developing technologies to help patients who suffer from certain respiratory tract conditions, received investigational device exemption (IDE) approval from the U.S. Food and Drug Administration (FDA), enabling the company to begin a pivotal clinical trial of the Airiver ESSpand Sinus Drug Coated Balloon (DCB) in patients with chronic rhinosinusitis (CRS).

The study will enroll up to 300 patients suffering from CRS with and without nasal polyps and is being conducted across the country to assess the safety and efficacy of the ESSpand DCB as an adjunct to endoscopic sinus surgery (ESS). The ESSpand DCB is designed to maintain symptom relief and prevent scarring and renarrowing of drainage passageways by applying a thin layer of a proprietary paclitaxel drug coating to the targeted tissue contemporaneously with balloon dilation of the restricted sinus drainage passageways. The study is intended to serve as the basis for Airiver Medical's regulatory submission to the FDA and eventual commercialization of the ESSpand DCB in the U.S.

"Securing IDE approval for this study means we are one step closer to being able to offer chronic rhinosinusitis patients a treatment option that has the potential to finally give them the long-term relief they've been waiting for with fewer treatments," said Lixiao Wang, founder, chief executive officer and chief technology officer for Airiver Medical.

CRS is defined as long-term (present for a minimum of three months despite intervention) symptomatic inflammation of the nose and paranasal sinuses. CRS is one of the most common chronic medical conditions in the world. For many CRS sufferers, medication alone is not enough, and they may choose to undergo surgery. Despite this initial surgery, symptoms often return and many patients undergo at least one additional surgery.

The Airiver DCB is an investigational device. The Airiver DCB has not received marketing authorization from the FDA and is not available for sale in the United States.

About Airiver Medical

Airiver Medical is a clinical stage company developing technologies to help patients who suffer from certain respiratory tract conditions. The company aims to improve the current standard of care for central airway stenosis and chronic rhinosinusitis. Airiver Medical's Drug Coated Balloon could offer a

new solution for these conditions, potentially creating sustained patency, better outcomes and fewer treatments.

For more information, please visit www.airiver.com.