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Airiver Medical Receives IDE Approval from the FDA for Pivotal Clinical Study of the Airiver Pulmonary Drug Coated Balloon to Treat Benign Central Airway Stenosis

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

BROOKLYN PARK, Minn. (August 27, 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 Pulmonary Drug Coated Balloon (DCB) to treat central airway stenosis. This is the company's first IDE study submission and approval.

The study will enroll up to 200 patients suffering from central airway stenosis and is being conducted across the country to assess the safety and efficacy of the Airiver DCB which combines standard balloon dilation to open the respiratory tract with proprietary drug delivery designed to maintain symptom relief and prevent recurrence. The proprietary coating allows for very localized paclitaxel delivery to the stenosis, while limiting levels in the surrounding healthy tissue. The trial is testing the Airiver DCB against standard of care bare balloon dilation.

"As it stands, there is no optimal treatment of recurrent airway stenosis available as part of today's treatment paradigm," said Lixiao Wang, founder, chief executive officer and chief technology officer for Airiver Medical. "Securing IDE approval for this study is extremely exciting because the Airiver DCB has the potential to establish a new minimally invasive and durable treatment option preventing recurrence for patients suffering from this serious condition, which has not yet been accomplished."

Central airway stenosis, otherwise defined as airway narrowing, is often associated with prolonged intubation, tracheostomy, stenting, tuberculosis or lung transplant. There are approximately 100,000 tracheo-bronchial stenting and dilation procedures performed annually within the United States. The study will serve as the basis for Airiver Medical's regulatory submission to the FDA and eventual commercialization of the Airiver Pulmonary DCB in the U.S.

The Airiver DCB is an investigational device for the use of treating benign central airway stenosis. 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.