PRESS RELEASE

Chiesi Announces FDA Acceptance of New Drug Application for its Triple Combination Inhaler for the Maintenance Treatment of Asthma

- Asthma remains a significant health burden in the U.S., with more than 60% of adults continuing to experience frequent symptoms despite the availability of many treatments.[1]
- Chiesi's single inhaler triple therapy (beclomethasone dipropionate/formoterol fumarate/glycopyrrolate) is designed for the maintenance treatment of asthma in adults, aiming to lower the burden of uncontrolled asthma in the U.S.
- Chiesi's single inhaler triple therapy was the first approved in its class outside of the U.S. – and currently commercialized in nearly 50 countries – and its NDA submission signals the company's expansion of its more than 45 years of leading respiratory expertise to the U.S. market.

Cary, N.C., October 15, 2025—Chiesi USA, Inc. (key-A-zee), a biopharmaceutical company that supports patients in living their best possible lives through life-changing or lifesaving innovations, today announced that the U.S. Food and Drug Administration has accepted the company's New Drug Application (NDA) for its investigational maintenance treatment of asthma in adults. Chiesi's inhaler delivers three active ingredients in a single device, referred to as a single inhaler triple therapy (SITT). Already approved in nearly 50 countries, this product is marketed outside of the U.S. under the brand name TRIMBOW®.

"The FDA's acceptance of Chiesi's New Drug Application for our fixed-dose triple combination inhaler represents another important step in our journey to delivering solutions that address respiratory needs and reduce the burden that persists for people living with asthma, their caregivers, and the healthcare system in the U.S.," said Martin Marciniak, Vice President of U.S. Medical Affairs at Chiesi. "Respiratory care is in our DNA--we have created medicines in this area for more than four decades, and transformed respiratory care by creating and commercializing the first triple therapy for asthma outside the U.S. We are bringing our respiratory expertise to the U.S. to help even more people live healthier lives."

Chiesi's inhaler delivers three active ingredients, beclomethasone dipropionate (BDP), an inhaled corticosteroid; formoterol fumarate (FF), a long-acting beta-agonist (LABA); and glycopyrrolate (G), an anticholinergic in a single device, referred to as a fixed dose triple combination inhaler. It is administered as twice daily in a pressurized metered-dose inhaler (pMDI). The NDA is supported in part by data from the TRIMARAN and TRIGGER studies, which are double-blind, parallel group, randomized, active-controlled Phase 3 trials. These studies evaluated the safety and efficacy of the triple inhaler ingredients (BDP/FF/G) in more than 2,500 patients with uncontrolled asthma.[2]

"Among the 28 million people in the U.S. who have asthma, many experience symptoms that disrupt daily life and have lasting effects on their lung health and function--and tragically, nine people die from asthma complications every day[3]," said Kenneth Mendez, President and CEO of the Asthma and Allergy Foundation of America. "New treatment options offer the potential for improved asthma management. Expanding choices means more opportunities for patients and their care teams to find solutions that meet individual needs and improve quality of life."

Chiesi's single inhaler triple therapy pressurized metered dose inhaler was the first approved in its class outside of the U.S. and is commercialized in nearly 50 countries, including the European Union, the United Kingdom and China.

About Asthma

Asthma is a chronic, inflammatory respiratory disease that causes inflammation in the airways. People who have asthma can experience symptoms such as shortness of breath, wheezing, coughing and chest tightness – often every day for those with severe cases.[4]

More than 25 million people in the U.S. live with asthma, and for many adults, symptoms remain difficult to manage even with existing treatments.[5] In fact, an estimated 60% of adults with asthma continue to experience frequent symptoms, which can lead to trips to the emergency room, interruption to daily activities, missed work, and a lower quality of life.[1]

Severe asthma attacks can be life-threatening. Centers for Disease Control and Prevention (CDC) data show that more than 3,600 adults die from asthma each year in the U.S., which is an average of nine deaths per day.[6] Asthma also places a major burden on the healthcare system and economy, costing the U.S. an estimated $82 billion annually.[7]

About beclomethasone dipropionate/formoterol fumarate/glycopyrrolate
Beclomethasone dipropionate/formoterol fumarate/glycopyrrolate is an investigational, triple combination inhaler under FDA review in the U.S. for maintenance treatment of asthma in adults. It contains three active ingredients: beclomethasone dipropionate (BDP), an inhaled corticosteroid; formoterol fumarate (FF), a long-acting beta-agonist (LABA); and glycopyrrolate (G), an anticholinergic. It is administered as twice-daily, fixed-dose therapy in a pressurized metered-dose inhaler (pMDI) using a particle formulation designed for deep lung deposition. Chiesi's robust clinical trial program evaluated the safety and efficacy of BDP/FF/G in more than 2,500 patients with uncontrolled asthma. It was the world's first fixed triple combination in a single inhaler and is commercialized in nearly 50 countries outside of the U.S., including the United Kingdom, the European Union and China.

About Chiesi USA
Chiesi USA, Inc., headquartered in Cary, North Carolina, is a specialty pharmaceutical company focused on the commercialization of products for the hospital and target office-based specialties. Chiesi USA is a wholly owned subsidiary of privately-owned Chiesi Farmaceutici S.p.A, a global R&D-focused pharmaceutical company based in Parma, Italy. In the United States, the company delivers therapies and enhances care for patients in the areas of acute cardiology, neonatology, cystic fibrosis and rare diseases. Recognized as a Certified B Corporation™, Chiesi is dedicated to improving the health and well-being of its communities through its employee-led corporate social responsibility program, Chiesi in the Community. Innovation, collaboration and impact are the cornerstones of the Chiesi culture. For more information, visit www.chiesiusa.com.

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