Chiesi USA, Inc. announces FDA approval of Bronchitol® (mannitol) inhalation powder

Bronchitol® indicated as add-on maintenance therapy to improve pulmonary function in adult patients with cystic fibrosis (CF)

CARY, NORTH CAROLINA, NOVEMBER 02, 2020 – Chiesi USA, Inc., the U.S. affiliate of Chiesi Farmaceutici S.p.A., an international research-focused healthcare Group (Chiesi Group), received U.S. Food and Drug Administration (FDA) approval of Bronchitol® (mannitol) inhalation powder. Bronchitol is the first and only inhaled dry powder indicated as add-on maintenance therapy to improve pulmonary function in cystic fibrosis (CF) patients 18 years of age and older. It provides a compact, portable option to CF patients. Bronchitol was developed by Pharmaxis Ltd., and Chiesi is now its exclusive distributor in the United States and 11 other countries.

"Our teams have worked tirelessly toward today's FDA approval, and we are thankful that we stayed the course to arrive at this moment," said Ken McBean, Chief Executive Officer of Chiesi USA. "We're thrilled to achieve this important milestone for the U.S. market and congratulate all Chiesi team members and partners who supported the clinical process."

In three large-scale global clinical trials totaling 761 patients aged 18 years and older, Bronchitol use led to a sustained improvement in FEV_1 (Forced Expiratory Volume) versus control. The statistically significant improvement in FEV_1 was observed over the 26-week treatment period in those patients receiving Bronchitol when compared to patients in the control group. The most common adverse reactions, occurring in 3% or more of patients, include cough, hemoptysis, oropharyngeal pain, vomiting, bacteria sputum identified, pyrexia, and arthralgia[1].

"Bronchitol offers a portable and discreet option for CF management, with no routine cleaning or maintenance of the inhaler device required," said Dr. Carmen Dell'Anna, Head, Global Medical Excellence at Chiesi. "We are excited to achieve its approval in the U.S. for adults living with cystic fibrosis."

Bronchitol is currently approved and marketed in Australia, Italy, Germany, Russia and several other countries. With today's FDA approval, Chiesi anticipates launching Bronchitol in the U.S. in March, 2021.

Indication

BRONCHITOL (mannitol) inhalation powder is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis. Use BRONCHITOL only in adults who have passed the BRONCHITOL Tolerance Test.

Important Safety Information

BRONCHITOL is contraindicated in patients with hypersensitivity to mannitol or to any of the capsule components. BRONCHITOL is contraindicated in patients who fail to pass the BRONCHITOL Tolerance Test (BTT).

BRONCHITOL can cause bronchospasm, which can be severe in susceptible patients. Because of the risk of bronchospasm, prior to prescribing BRONCHITOL, patients must pass the BRONCHITOL Tolerance Test (BTT). The BTT must be administered under the supervision of a healthcare practitioner who can treat severe bronchospasm.
Patients who pass the BRONCHITOL tolerance test (BTT) may experience bronchospasm with add-on maintenance therapy with BRONCHITOL. Patients should premedicate with an inhaled short-acting bronchodilator prior to each administration of BRONCHITOL. If bronchospasm occurs, immediately discontinue BRONCHITOL and treat bronchospasm with an inhaled short-acting bronchodilator.
Hemoptysis can occur with BRONCHITOL use. Monitor patients with history of episodes of hemoptysis. If hemoptysis occurs, discontinue use of BRONCHITOL.
Most common adverse reactions (≥3%) include cough, hemoptysis, oropharyngeal pain, vomiting, bacteria sputum identified, pyrexia, and arthralgia.

Please see Full Prescribing Information.

About BRONCHITOL® (mannitol) inhalation powder
BRONCHITOL is a prescription medicine that is used along with other therapies to improve lung function in people 18 years of age and older with cystic fibrosis (CF).

BRONCHITOL is only for adults who have passed the BRONCHITOL Tolerance Test (BTT). Your first dose of BRONCHITOL is given during the BTT by your healthcare provider and tests if BRONCHITOL is right for you. Your healthcare provider will use equipment to monitor you and have medicine ready if you have bronchospasm during the test. If you have bronchospasm during your BTT, then you should not be prescribed BRONCHITOL.

BRONCHITOL should not be used in children and adolescents. It is not known if BRONCHITOL is safe and effective in children under 18 years of age.

Important Safety Information
Do not take BRONCHITOL if you have had an allergic reaction to mannitol or any parts of the BRONCHITOL capsule or if you do not pass the BRONCHITOL Tolerance Test (BTT).

Before you take BRONCHITOL, tell your healthcare provider about all your medical conditions, including if you have ever coughed up blood or had blood in your mucus (sputum); are pregnant or planning on becoming pregnant. It is not known if BRONCHITOL will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while using BRONCHITOL; are breastfeeding or plan to breastfeed. It is not known if BRONCHITOL passes into your breast milk or if it can harm your baby. Talk to your healthcare provider about the best way to feed your baby while using BRONCHITOL.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

BRONCHITOL may cause serious side effects, including sudden breathing problems immediately after inhaling your medicine; coughing up of blood (hemoptysis). Call your healthcare provider or get emergency medical care right away if you cough up a large amount of blood.

The most common side effects of BRONCHITOL include, cough, coughing up of blood, pain or irritation in the back of your mouth and throat and discomfort when swallowing, vomiting, fever, joint pain, bacteria

in your sputum. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of BRONCHITOL. You can ask your healthcare provider or pharmacist for more information.
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Patient Information within the accompanying Full Prescribing Information.

About Chiesi USA
Chiesi USA, Inc., headquartered in Cary, North Carolina, is a specialty pharmaceutical company focused on commercialization of products for the hospital and target office-based specialties. The Company is a wholly-owned subsidiary of family-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 and cystic fibrosis. 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.

References

1. BRONCHITOL® (mannitol) inhalation powder Prescribing Information. 2020.

Contacts

Media: FleishmanHillard, Elizabeth Comtois, (919) 334-3786, elizabeth.comtois@fleishman.com
Chiesi USA: Michael Wasyluk, (919) 678-6611, michael.wasyluk@chiesi.com

PP-BR-0027 V1.0

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