

Chiesi USA, Inc. announces Commercial Availability of Bronchitol® (mannitol) inhalation powder for improvement in pulmonary function in adult patients with cystic fibrosis

Phase 3 clinical trial data published in the Journal of Cystic Fibrosis

CARY, N.C., March 17, 2021 (GLOBE NEWSWIRE) -- [Chiesi USA, Inc.](#), the U.S. affiliate of Chiesi Farmaceutici, an international research-focused healthcare Group (Chiesi Group), today announced the launch of FDA-approved Bronchitol® (mannitol) inhalation powder, an add-on maintenance therapy to improve pulmonary function in cystic fibrosis (CF) patients 18 years of age and older. Bronchitol is the first and only dry powder inhaled mucoactive agent* providing a compact, portable option for patients.

Additionally, data from the global Phase 3 study evaluating the efficacy and safety of inhaled dry powder mannitol in adults with CF has been published online in the [Journal of Cystic Fibrosis](#). In the multicenter, double-blind, randomized, parallel-group, controlled study of 423 adults with CF, subjects received either mannitol 400mg or mannitol 50mg (control), twice-daily via dry powder inhaler for 26 weeks. Authors concluded that mannitol 400mg inhaled twice-daily via a dry powder inhaler statistically significantly improved lung function (FEV₁) compared with control, with this improvement supported by sensitivity analyses. Most common adverse reactions (≥3%) include cough, hemoptysis, oropharyngeal pain, vomiting, bacteria sputum identified, pyrexia and arthralgia.

“Chiesi USA has a longstanding commitment to advancing treatments and patient care programs among the CF community, and we are thrilled to add Bronchitol to our comprehensive offering,” said Jon Zwinski, General Manager and Chief Executive Officer of Chiesi USA. “We are excited to bring the first dry powder inhaled mucoactive agent* to the U.S. for adults with CF, delivered by a portable device that doesn’t require routine maintenance or cleaning.”

Bronchitol was developed by Pharmaxis Ltd., and Chiesi is now its exclusive distributor in the United States and 11 countries in Europe. Bronchitol is also approved and marketed in Australia, Europe, Russia, and several other countries.

*The precise mechanism of action of BRONCHITOL in improving pulmonary function in CF patients is unknown. Data suggest that BRONCHITOL may impact sputum properties, however, a causal relationship between changes in sputum properties and pulmonary function have not been demonstrated.

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.

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-0162 V1.0

PDF available: <https://prdesk.globenewswire.com/api/ResourceLibraryFile/DownloadFile?source=ml&Id=a82ae709-352d-42da-8ff6-35221f7d3093>

Attachment Preview:

4067681_WireRelease_Preview.pdf.pdf

File Size: 94.96 KB

File Type: PDF

File Name: 4067681_WireRelease_Preview.pdf.pdf

[\[Preview \]](#)