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FDA approves Novartis TOBI® Podhaler™ for certain cystic fibrosis patients, the first and only dry powder inhaled antibacterial in US

Mar 23, 2013

- - TOBI Podhaler is portable and requires no nebulizer, refrigeration or power source to deliver the medicine
- - TOBI Podhaler is indicated for certain cystic fibrosis (CF) patients with Pa and shortens treatment time by about 70% compared to nebulized TOBI®
- - CF affects about 30,000 children and adults in the US with an average daily treatment burden of approximately 2 hours for CF therapies

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EAST HANOVER, N.J., March 22, 2013 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has approved TOBI® Podhaler™ (tobramycin inhalation powder) 28 mg per capsule for the management of cystic fibrosis (CF) patients with Pseudomonas aeruginosa (Pa) bacteria in the lungs. Pa is the leading cause of loss of lung function in CF patients. It is not known if TOBI Podhaler is safe and effective in patients under six years of age, in those with lung function outside of a certain range, or in those whose lungs contain bacteria called Burkholderia cepacia.

To view the multimedia assets associated with this release, please click: http://www.multivu.com/mnr/58560-novartis

TOBI Podhaler is a new, non-nebulized formulation and delivery system of tobramycin, the same active ingredient as in TOBI® (tobramycin inhalation solution, USP) 300 mg/5 mL, which has been on the market for approximately 15 years. TOBI Podhaler is the first and only FDA-approved dry powder inhaled antibacterial for Pa in the US. It delivers tobramycin into the patient's lungs via a pocket-sized dry powder inhaler and offers better portability than TOBI, which is administered using a nebulizer. In a Phase III study, TOBI Podhaler shortened administration time for patients by approximately 70% compared to TOBI, saving about 13 hours per treatment cycle. This does not include the time saved on setting up and maintaining the nebulizer and compressor.

TOBI Podhaler does not need to be stored in a refrigerator and, unlike nebulized Pa treatments, does not require a power source to operate the delivery device. While the nebulizer used to administer TOBI must be disinfected in boiling water for 10 minutes every other treatment day, the disposable Podhaler device must only be wiped clean with a dry cloth after each use and is then replaced weekly.

"This is good news for the CF community," said Robert J. Beall, Ph.D., President and CEO, Cystic Fibrosis Foundation. "Managing daily CF treatments is a challenge for people with CF. TOBI Podhaler helps relieve that burden by shortening the time it takes to administer the medicine and making it easy for people with CF to take their treatment with them wherever they need to g¢4'

The new TOBI Podhaler dry powder formulation was developed using proprietary Novartis PulmoSphere™ technology. This technology enables the creation of hollow porous particles of tobramycin that can be delivered as a dry powder rather than as a nebulized solution.

"TOBI Podhaler is an example of how Novartis is utilizing innovative technologies to better meet the needs of patients. By eliminating the need for a nebulizer to deliver tobramycin and providing a small, lightweight design, TOBI Podhaler reduces administration time and improves portability for patients on-the-go," said Andre Wyss, President of Novartis Pharmaceuticals Corporation. "It also underscores our long-term commitment to the cystic fibrosis community."

TOBI Podhaler was studied in a Phase III clinical program involving 674 CF patients aged six years and older with Pa in their lungs, of whom 425 patients received at least one dose of TOBI Podhaler. Two trials evaluated the efficacy of TOBI Podhaler vs. placebo, while a third trial assessed the safety of TOBI Podhaler vs. TOBI. All studies evaluated TOBI Podhaler at the approved dose of 112 mg twice daily (the contents of four 28 mg capsules per dose) in cycles of 28 days on, immediately followed by 28 days off treatment. Results of the efficacy studies showed that TOBI Podhaler improved lung function compared to placebo.

The safety of TOBI Podhaler was evaluated in 425 patients who received at least one dose of TOBI Podhaler, including 273 who were exposed across three cycles. In the two placebo-controlled efficacy trials, adverse reactions reported more commonly with TOBI Podhaler compared to placebo included pharyngolaryngeal pain (sore throat), dysphonia (voice alteration) and dysgeusia (taste disturbance) in one study and cough and hypoacusis (decreased hearing) in the other study. In the safety study, the most commonly reported adverse reactions (as defined as >10% in either treatment arm) with TOBI Podhaler were cough, lung disorder (pulmonary or CF exacerbations), productive cough, dyspnea (shortness of breath), pyrexia (fever), oropharyngeal pain (sore throat), dysphonia (voice alteration), hemoptysis (coughing up blood) and headache.

CF is a life-shortening genetic disease that affects about 30,000 children and adults in the US. It primarily impacts the lungs and digestive system, making it hard to breathe and to digest food. Pa is the leading cause of loss of lung function in people with CF. About 80% of people with CF between the ages of 25 and 34 have Pa in their lungs.

The treatment burden for CF is very high. CF therapy requires multiple medications to be used every day with a combined average treatment time of 108 minutes per day.

TOBI Podhaler is anticipated to be available in the US in the second quarter of 2013. Please visit http://www.pharma.us.novartis.com/product/pi/pdf/tobipodhaler.pdf for TOBI Podhaler full Prescribing Information.

ABOUT TOBI

TOBI® (tobramycin inhalation solution, USP) 300 mg/5 mL, is a prescription inhaled medication for cystic fibrosis patients whose lungs contain bacteria called Pseudomonas aeruginosa. TOBI has not been studied in patients under six years of age, in those with lung function (FEV_1) outside of a certain range, or in those whose lungs contain bacteria called Burkholderia cepacia.

IMPORTANT SAFETY INFORMATION

If patients are allergic to antibiotics in the same family as TOBI (i.e., aminoglycosides), they should not take TOBI. They should tell their doctor before starting treatment if they have any history of hearing, kidney, balance, or muscle problems.

Patients taking TOBI may have temporary side effects like coughing or difficulty breathing. Some people taking

TOBI experienced ringing in the ears, hearing loss, or changes in voice (hoarseness). Ringing in the ears may be a warning sign for hearing loss. If patients have ringing in the ears, changes in hearing, or dizziness, they should tell their doctor.

In studies, kidney damage was not seen in patients taking TOBI. However, antibiotics in the same family as TOBI have been linked to kidney damage.

If patients are pregnant, plan to become pregnant, or if they are breast-feeding, they should talk with their doctor before taking TOBI.

Some drugs may interact with TOBI. Patients should discuss all medications they are taking with their doctor.

Patients with cystic fibrosis can have many symptoms. Some of these may be related to their medications. They should tell their doctor if they have new or worsening symptoms.

Patients 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 visit www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf for TOBI full Prescribing Information.

For more information about cystic fibrosis, please visit www.cff.org.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "long-term commitment," "anticipated," or similar expressions, or by express or implied discussions regarding potential future revenues from TOBI Podhaler. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that TOBI Podhaler will achieve any particular levels of revenue. In particular, management's expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures, and unexpected reimbursement decisions; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; unexpected manufacturing issues; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies.

Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 128,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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