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FDA Advisory Committee supports use of tobramycin inhalation powder from Novartis for patients with cystic fibrosis

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- -Tobramycin inhalation powder (TIP) recommended for management of cystic fibrosis (CF) patients six years and older with P. aeruginosa bacteria in their lungs
- -P. aeruginosa (Pa) is the leading cause of loss of lung function in people with CF; about 80% of CF patients aged 25-34 years have Pa in their lungs
- -In clinical studies, TIP improved lung function vs. placebo and gave similar efficacy to nebulized tobramycin with 70% shorter administration time
- -CF is a life-threatening genetic disease that primarily impacts the lungs and digestive system, affecting about 30,000 children and adults in the US

EAST HANOVER, N.J., Sept. 5, 2012 /PRNewswire/ -- The Anti-Infective Drugs Advisory Committee (AIDAC) to the US Food and Drug Administration (FDA) today voted 13 to 1 that there was adequate evidence of efficacy and safety to support the use of tobramycin inhalation powder (TIP) for the management of cystic fibrosis (CF) patients whose lungs contain bacteria called Pseudomonas aeruginosa (Pa). Pa is the leading cause of loss of lung function in people with CF. TIP is intended for use in CF patients aged six years and older whose lung function is within a certain range (i.e., FEV_1 between 25% and 80% predicted).

The AIDAC based its recommendation on three Phase III clinical studies involving more than 650 CF patients aged six years and older, of whom 425 patients received at least one dose of TIP. The studies found that treatment with TIP resulted in improved lung function.

"While advances in research and medical treatments have substantially enhanced and extended the lives of patients with CF, the treatment burden remains very high," said TIP clinical investigator Michael Konstan, MD, Chairman of the Department of Pediatrics and Director of the Cystic Fibrosis Center at Rainbow Babies and Children's Hospital and Case Western Reserve University School of Medicine in Cleveland, Ohio. "Today's vote is exciting for the CF community as TIP could reduce this treatment burden because of its shorter administration time and greater portability compared to nebulized tobramycin."

Tobramycin is currently marketed in the US by Novartis Pharmaceuticals Corporation as TOBI® (tobramycin inhalation solution, USP), and is administered as a nebulized solution with an indication similar to that proposed for TIP. In contrast, investigational TIP is a new inhaled formulation of tobramycin consisting of dry powder in capsules delivered via a dry powder inhaler. The new formulation was developed using proprietary Novartis PulmoSphere™ technology. This enabled the creation of hollow porous particles of tobramycin that can be delivered as a dry powder rather than as a nebulized solution.

"Novartis is committed to addressing the needs of patients with CF, and we are very encouraged by the Advisory Committee's vote to support the use of TIP in the US," said Tim Wright, Global Head of Development, Novartis Pharma. "The company is dedicated to introducing innovative, safe and effective treatment options for patients and physicians, and we look forward to working closely with the FDA as it finalizes its review of TIP."

CF is a life-threatening 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. The treatment burden for CF is extremely high, with as many as 20 medications having to be used every day with a combined average treatment time of 108 minutes. The overall time to administer all the necessary treatments and perform physiotherapy and exercise can be as much as two to three hours each day.

Pa is a 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. Once a CF patient is infected with Pa in their lungs, it never completely goes away.

The Phase III clinical trial program consisted of two trials comparing TIP to placebo and one trial comparing TIP to TOBI, at the proposed TIP dosage of 112 mg twice-daily (inhaling the contents of four 28 mg capsules per dose) in a cycle of 28 days on, 28 days off treatment. Compared to patients on placebo, patients treated with TIP showed improved lung function. TIP also demonstrated comparable efficacy to TOBI 300 mg administered via a nebulizer with a reduction in administration time of approximately 70%, saving about 13 hours per treatment cycle. This does not include the time saved on setting up and maintaining the nebulizer and compressor.

The safety profile of TIP is similar to the profile of TOBI, other than local effects due to powder inhalation. In the Phase III clinical trial program, the most commonly reported adverse events with TIP were cough, lung disorder (i.e., CF/pulmonary exacerbations), increased sputum, dyspnea and pyrexia.

Tobramycin inhalation powder is approved in 38 countries, including the European Union, Canada, Switzerland and Australia. TIP is currently available in Canada and a number of countries in the European Union under the brand-name TOBI® Podhaler®. The proposed brand-name in the US, pending FDA approval, would be TOBI® Podhaler™.

TOBI® (tobramycin inhalation solution, USP) 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 a lung function 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.

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The foregoing release contains forward-looking statements that can be identified by terminology such as "supports," "support," "intended," "could," "committed," "encouraged," "look forward to," "proposed," "would," or similar expressions, or by express or implied discussions regarding potential marketing approvals for TIP or regarding potential future revenues from TIP. 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 with TIP to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that TIP will be approved for sale in the US or any additional markets. Nor can there be any guarantee that TIP will achieve any particular levels of revenue in the future. In particular, management's expectations regarding TIP could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; 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 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 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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