



| Adding *tomorrows* every day. _____

December 15, 2009

Margaret A Hamburg, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Hamburg:

The Cystic Fibrosis Foundation is pleased that the Anti-Infective Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has recommended that Gilead Sciences' Aztreonam Lysine for Inhalation (AZLI) be approved for treatment to improve respiratory symptoms and pulmonary function in CF patients with *Pseudomonas aeruginosa* (*P. aeruginosa*).

We respectfully urge the FDA to expedite the approval process for this drug so that CF patients in the U.S. will have access to this important new antibiotic as soon as possible.

Cystic fibrosis (CF) is a life-threatening, orphan disease that affects 30,000 people in the U.S and warrants special consideration and a sense of urgency from the FDA. The disease primarily affects children, adolescents and young adults; the median age of the CF population in the U.S. is only 16 years, and the median age of death in 2008 was just 26 years. People with CF struggle with their daily symptoms and they still die an early death as a result of progressive lung disease due to chronic infection. As the Advisory Committee acknowledged in its favorable decision on December 10, 2009, there is an immediate unmet medical need for more than one inhaled antibiotic to improve the pulmonary function of CF patients.

Currently, only one antibiotic for inhalation, Tobramycin Inhalation Solution (TOBI®), is FDA-approved and available to CF patients. One-third of all CF patients do not use TOBI®, including those who do not tolerate the medicine and those for whom it is clinically ineffective. For these patients, there is no FDA-approved inhaled antibiotic to meet their medical needs. Without such a treatment the health of these individuals is severely compromised. Given these limitations, it is clear that FDA approval of additional inhaled antibiotics would fulfill an unmet medical need.

In its review of the AZLI New Drug Application, the FDA's Office of Antimicrobial Products questioned whether a five percent increase in Forced Expiratory Volume in one

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second (FEV₁) was clinically meaningful enough for approval. We know from experts at more than 115 CF care centers nationwide that such an increase in FEV₁ is clinically meaningful and demonstrates efficacy. Data from the CF Foundation patient registry indicate that adolescents and adults experience an annual rate of decline in FEV₁, resulting in a steady decline in lung function and quality of life. A 5% improvement in FEV₁, as provided by AZLI, would provide meaningful clinical benefit to CF patients.

Access to inhaled aztreonam will give children and adults with CF the opportunity to improve health and live a better life. After rigorous review, this drug is already approved in Europe and Canada, and we urge the FDA to approve the drug swiftly so that CF patients in the U.S. can benefit from this important new antibiotic as soon as possible. The CF Foundation stands ready to work with you to address any questions you may have.

Sincerely,



Robert J. Beall, Ph.D.
President and CEO



Preston W. Campbell, III, M.D.
Executive Vice President for Medical Affairs