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FDA Grants Fast Track Designation to Nektar's Amphotericin B Inhalation Powder (ABIP) for Prevention of Pulmonary Fungal Infections in At-Risk Patients; First Inhaled Anti-Fungal Therapy Under Development for Immunosuppressed Patients

SAN CARLOS, Calif., May 22, 2006 (BUSINESS WIRE) -- Nektar Therapeutics (NASDAQ:NKTR) announced today the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Amphotericin B Inhalation Powder (ABIP) for prevention of pulmonary fungal infections in patients at risk for aspergillosis due to immunosuppressive therapy, including those receiving organ or stem cell transplants, or treated with chemotherapy or radiation for hematologic malignancies (leukemias).

The FDA granted Fast Track designation for the following reasons:

-- Invasive aspergillosis is a serious infection that usually affects immunosuppressed patients receiving organ or stem cell transplants, or treated with chemotherapy or radiation for hematologic malignancies. The infection is often lethal in medically immunosuppressed patients.

-- There is no approved agent for prevention of pulmonary fungal infections in patients at risk for aspergillosis due to immunosuppressive therapy, including those receiving organ or stem cell transplants, or treated with chemotherapy or radiation for hematologic malignancies. Therefore, there is an unmet medical need for a new treatment.

Fast Track designation allows the FDA to expedite the review of new drugs that are intended for serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. An important feature of Fast Track designation is that it emphasizes the critical nature of close, early communication between the FDA and the sponsor company to improve the efficiency of product development. Under Fast Track, Nektar is now eligible to submit portions of the marketing application for review on a rolling basis prior to completion of the final registration package for the product.

"We are pleased that the FDA recognizes that Nektar's product for this indication meets the criteria for Fast Track designation and this is an important step toward providing a much-needed medical solution to protect against life-threatening pulmonary infections," said Dr. David Johnston, Nektar senior vice president of research and development. "Our product could represent a major paradigm shift in antifungal therapies as we aim to prevent infections by targeting the lungs directly and therefore avoid the serious systemic and dose-limiting side effects of intravenous and oral therapies. We look forward to working closely with the FDA through the development process."

Nektar announced in February 2006 that the FDA had granted U.S. orphan drug designation to ABIP for the prevention of pulmonary fungal infections in patients at risk for aspergillosis due to immunosuppressive therapy. The Orphan Drug Act provides a seven year period of exclusive marketing to the first sponsor who obtains marketing approval for a designated product for the designated indication.

About Amphotericin B Inhalation Powder (ABIP)

ABIP is under development for the prevention of pulmonary aspergillosis in high-risk immunosuppressed patients. The product is designed to target the site of infection directly with a novel formulation of amphotericin B, a broad spectrum, "gold-standard" antifungal drug. Nektar's innovative formulation and pulmonary delivery method could potentially eliminate systemic, dose-limiting toxicities found with current formulations of amphotericin B that are delivered intravenously.

Immunosuppressed patients -- i.e., those receiving organ or stem cell transplants, or chemotherapy or radiation therapy for hematologic malignancies -- are vulnerable to opportunistic fungal infections, such as aspergillosis, which start in the lungs and spread throughout the body. Aspergillosis has a mortality rate of over 50%, and in some immunosuppressed patient groups the mortality rate may be as high as 100%.(1) Using ABIP for patients at risk of developing the infection may potentially reduce the incidence of these infections, as well as associated high morbidity and mortality and significant treatment costs.

ABIP is currently in a multidose Phase I study. In February and March of 2006, encouraging pre-clinical and Phase I data on ABIP were presented at major scientific congresses, including the 2nd Advances Against Aspergillosis Meeting and Focus on Fungal Infections 16th Annual Meeting. In December of 2005, data on ABIP was also presented at the 45th Annual Interscience

Conference on Antimicrobial Agents and Chemotherapy.

About Nektar

Nektar Therapeutics is a biopharmaceutical company that develops and enables differentiated therapeutics with its industry-leading drug delivery technologies, expertise and manufacturing capabilities. Nektar technology and know-how have enabled nine approved products for partners, which include some of the world's leading pharmaceutical and biotechnology companies. Nektar also develops its own products by applying its drug delivery technologies and expertise to existing medicines to enhance performance, such as improving efficacy, safety and compliance.

This release contains forward-looking statements that reflect management's current views as to Nektar's clinical plans and expectations for a product under development, the potential for new product efficacy, safety, compliance, and economic benefits for patients, and the value and benefits of Nektar technologies such as ABIP. These forward-looking statements involve substantial risks and uncertainties including without limitation the uncertainty and expense of the clinical trial programs and uncertain regulatory approval process for new products (including those granted fast track designation by the FDA) and the commercial feasibility of early stage development products. A further description of other important risks and uncertainties related to these forward-looking statements are detailed in Nektar's reports and other filings with the SEC, including its Annual Report on Form 10-K for the year ended December 2005 and its Quarterly Report on 10-Q for the quarter ended March 31, 2006. Actual results could differ materially from these forward-looking statements.

(1) Lin et al. 2001, Aspergillosis Case-Fatality Rate: Systematic Review of the Literature. Clinical Infectious Disease, 32: 358-366.

NOTE TO EDITORS: Information on ABIP data presented at major congresses by Nektar scientists is available by contacting Nektar Corporate Communications at 650-631-4954.

SOURCE: Nektar Therapeutics

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