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European Commission Grants Orphan Medicinal Product Designation to Nektar's Amphotericin B Inhalation Powder (ABIP) for the Prevention of Pulmonary Fungal Infections in Patients Deemed At Risk

SAN CARLOS, Calif., Sep 18, 2006 (BUSINESS WIRE) -- Nektar Therapeutics (Nasdaq:NKTR) announced today that its Amphotericin B Inhalation Powder (ABIP) product has been granted orphan medicinal product designation by the European Commission for the prevention of pulmonary fungal infections in patients deemed at risk. This designation is based on a recommendation from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMEA).

"Prevention of these serious fungal infections in the lung is a major priority, given the increasing incidence of invasive pulmonary aspergillosis in immunosuppressed patients," said Dr. David Denning, professor of medicine and medical mycology at the University of Manchester. "Any therapy that reduces the incidence of invasive pulmonary aspergillosis in particular is welcome, as these infections are frequently fatal, and can be expensive to treat."

According to the EMEA, orphan medicinal products are for diagnosing, preventing or treating life-threatening or very serious conditions that are rare and affect less than five of every 10,000 persons in the European Union (EU). An orphan drug designation provides 10 years of potential market exclusivity if the product candidate is approved for marketing in the EU. It also allows for regulatory assistance in preparing the marketing application, free protocol assistance to optimize clinical development, reduced regulatory fees associated with applying for marketing approval and direct access to the centralized procedure for Marketing Authorization Application through the EMEA.

"We are pleased to make continued progress in our ABIP program and look forward to using the scientific guidance and assistance available through the EMEA's Orphan Medicinal Drug Program," said David Johnston, Nektar senior vice president of research and development. "ABIP holds the promise of preventing fatal fungal infections that start in the lungs, can be very difficult to treat, and are associated with extremely high mortality rates in spite of currently available treatments."

In the U.S., the Food and Drug Administration (FDA) granted both Fast Track designation and Orphan Drug designation to ABIP for prevention of pulmonary fungal infections in patients at risk for aspergillosis due to immunosuppressive therapy.

About Amphotericin B Inhalation Powder (ABIP)

ABIP is under development for the prevention of pulmonary fungal infections such as 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, fungicidal 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, for example, 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 near 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 recently completed a multi-dose, dose escalation clinical study in preparation for pivotal trials to begin in 2007.

(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.

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 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 Orphan Medicinal Product Designation designation by EMEA) and the commercial feasibility of early stage development products such as ABIP. 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. Nektar assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments that may occur after the date of this release.

SOURCE: Nektar Therapeutics

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