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Nektar Announces That U.S. FDA Has Granted Orphan Drug Designation to the First Amphotericin B Inhalation Powder to Prevent Pulmonary Fungal Infections in Immunosuppressed Patients

SAN CARLOS, Calif., Feb 14, 2006 (BUSINESS WIRE) -- Nektar Therapeutics (Nasdaq:NKTR) announced today the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the first amphotericin B inhalation powder for prevention of pulmonary fungal infections in patients at risk for aspergillosis due to immunosuppressive therapy. Using a small proprietary pocket size inhaler, the company has conducted two Phase I trials and has long-term toxicity studies underway to support the planned pivotal trials early next year.

Immunosuppressed patients -- i.e., those receiving organ or stem cell transplants, or chemotherapy or radiation therapy for hematologic malignancies -- commonly develop fungal infections in their lungs which spread throughout the body (aspergillosis). Inhaling amphotericin B inhalation powder into the lungs prior to developing an aspergillosis infection may potentially reduce the incidence of these infections as well as the subsequent high morbidity and mortality and significant treatment costs associated with them. Nektar developed the amphotericin B inhalation powder to target the lungs directly with this potent, broad spectrum, fungicidal "gold-standard" antifungal drug, while potentially eliminating systemic toxicities associated with current formulations of amphotericin B which must be delivered intravenously.

Orphan products are developed to treat diseases or conditions that affect fewer than 200,000 people in the U.S. The Orphan Drug Act provides a seven-year period of exclusive marketing to the first sponsor who obtains marketing approval for a designated orphan drug.

"Given the high incidence of invasive aspergillosis in immunocompromised patients, and high mortality rates despite available therapies, this potential new therapy could represent a significant breakthrough in antifungal medicine," said Kieren Marr, M.D., Assistant Professor Medicine, Allergy and Infectious Diseases, Fred Hutchinson Cancer Research Center, Seattle, Washington.

"In the U.S., more than 75,000 immunocompromised patients annually are at risk of developing often fatal and costly fungal infections in the lungs. There are no approved pharmaceutical therapies to prevent fungal infections like aspergillosis, caused when *Aspergillus*, a widely prevalent genus of molds, infects the lungs and invades the body, causing systemic infections that are very difficult to cure and are associated with an extremely high mortality rate," said Dr. David Johnston, Nektar Senior Vice President, Research and Development.

"Fungal spores are routinely inhaled. An immunosuppressed patient is susceptible to fungal infections, like aspergillosis, normally not seen in those with healthy immune systems. Nektar's approach delivers amphotericin B directly to the potentially vulnerable organ through inhalation in the same manner that the fungal spores are inhaled, and could represent a breakthrough in prevention of these infections with such high mortality rates," said Johnston.

The FDA granted orphan drug designation to Nektar's amphotericin B inhalation powder upon review of the application which included pre-clinical data presented at the 45th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in December 2005. These data indicated that the inhaleable amphotericin B provided a statistically significant improvement in survival of immunosuppressed rabbits challenged with a pulmonary dose of *Aspergillus fumigatus* spores. In separate toxicology studies, there was little or no pulmonary toxicity when animals were administered ten times or more than the expected amphotericin B powder dose for humans. Further, data indicated that there was no systemic toxicity and low amounts of the drug in the bloodstream -- less than the concentration generally regarded as toxic in blood in humans -- even when delivered at doses more than ten times the level expected for humans.

Data from the two clinical studies completed to date reinforce the pre-clinical results. Nektar scientists will present data from the first of these clinical studies at upcoming conferences, including: 2nd Advances Against Aspergillosis, Athens, Greece, February 22-25, 2006; and Focus on Fungal Infections 16, Las Vegas, Nevada, March 8-10, 2006. Pivotal trials are on target to begin in early 2007.

Nektar Amphotericin B Inhalation Powder

Amphotericin B is a potent, broad spectrum, fungicidal drug which has been used intravenously for decades for treatment and

remains the "gold-standard" therapy for fighting fungal infections, limited only by its systemic toxicities. The Nektar amphotericin B inhalation powder product enables the inhalation of a therapeutic concentration of amphotericin B directly to the lungs, at levels similar to or greater than the lung concentrations achieved by intravenous dosing of amphotericin B or lipid-associated amphotericin B products. By delivering amphotericin B directly to the site of potential infection, Nektar's inhaleable amphotericin B will potentially eliminate life-threatening pulmonary fungal infections, while minimizing common dose-limiting toxicities associated with intravenous amphotericin B therapy. Nektar's unique delivery mode has been designed to encourage long-term compliance and may have significant cost benefits for this high-risk patient population.

About Nektar

Nektar Therapeutics develops and enables high-value, differentiated therapeutics with its industry-leading drug delivery technologies, expertise and manufacturing capabilities. The world's top biotechnology and pharmaceutical companies are developing new and better therapeutics using Nektar's advanced technologies and know-how. Nektar also develops its own products by applying its drug delivery technologies and its 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. These forward-looking statements involve substantial risks and uncertainties including without limitation the uncertainty and expense of the clinical trial and regulatory process for new products 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, as amended, for the year ended December 2004 and its Quarterly Report on 10-Q for the quarter ended September 30, 2005. Actual results could differ materially from these forward-looking statements.

SOURCE: Nektar Therapeutics

Nektar Therapeutics
Joyce Strand, 650-631-3138
Jennifer Ruddock, 650-631-4954

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