ENGLISH TRANSLATION

May 29, 2015

Meiji announces that FDA Grants QIDP and Fast Track Designation to ME1100

Meiji Seika Pharma Co., Ltd. (Headquarter: Tokyo, Japan, President: Daikichiro Kobayashi, "Meiji") announces that the U.S. Food and Drug Administration (FDA) has designated the Company's lead antibiotic product, ME1100 (arbekacin inhalation solution), as a Qualified Infectious Disease Product (QIDP) for the adjunctive treatment of mechanically ventilated patients with bacterial pneumonia. FDA additionally granted fast track review of ME1100 under section 505(i) of the Federal Food, Drug and Cosmetic Act.

QIDP designation provides certain incentives under the 2012 U.S. Generating Antibiotic Incentives Now (GAIN) Act as part of the FDA Safety and Innovation Act. These incentives include priority review and an additional five year extension of market exclusivity following product approval.

Meiji completed phase 1 study in health subject last year, with positive safety and tolerability findings at all doses tested in the study, and the phase 1b clinical trial is being planned to evaluate safety, tolerability and pharmacokinetics of ME1100 in patients.

"The GAIN Act is intended to encourage development of products to treat the threat posed by highly resistant 'superbugs'. Meiji is pleased that the FDA has recognized that our product, ME1100 has value as a potential response to this urgent unmet public health need," said Hitoshi Yamaguchi, Managing Executive Officer, Pharmaceutical Development Division of Meiji

About GAIN Act

The GAIN Act, Title VIII (Sections 801 through 806) of the FDA Safety and Innovation Act, seeks to provide pharmaceutical and biotechnology companies with incentives to develop new antibacterial and antifungal drugs for the treatment of life-threatening, infectious diseases caused by drug resistant pathogens. Qualifying pathogens are defined by the GAIN Act to include multi-drug resistant Gram-negative bacteria, including Pseudomonas, Acinetobacter, Klebsiella, and Escherichia coli species. It extends the length of time an approved drug is free from competition and clarifies the regulatory pathway for new antibiotics.

About ME1100

ME1100 is a novel formulation of arbekacin optimized for inhalation. Arbekacin is an aminoglycoside antibiotic launched in 1990 by Meiji as an injectable solution (Habekacin®) for the treatment of pneumonia or sepsis caused by methicillin-resistant Staphylococcus aureus (MRSA). Nonclinical studies demonstrate that ME1100 has strong bactericidal activity against MRSA as well as other common causative microorganisms of severe pneumonia, such as Klebsiella pneumoniae, Pseudomonas aeruginosa and Acinetobacter spp. Direct delivery of ME1100 as an aerosol into the lower respiratory tract, the site of infection of HABP and VABP, by using a customized investigational eFlow® Nebulizer System (eFlow®) is expected to result in higher efficacy and lower systemic side effects.

About eFlow® Technology and PARI Pharma GmbH

ME1100 is delivered by a customized, investigational eFlow® developed by PARI Pharma GmbH. The device uses eFlow® Technology to enable efficient aerosol delivery of medication to patients including those patients on a ventilator. eFlow® Technology uses a vibrating, perforated membrane that includes thousands of laser drilled holes. eFlow® Technology produces aerosols with a small, precisely defined droplet size, reducing aerosol losses and improving delivery of nebulized drugs. PARI Pharma focuses on the development of aerosol delivery devices and inhalation drug development to advance aerosol therapies. More information may be found online at www.paripharma.com.