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Meiji Initiates Phase 1 Clinical Trial of Arbekacin Inhalation Solution (ME1100) in the U.S. and Enters into a Licensing Agreement with PARI Pharma for a Customized eFlow® Technology Inhalation Device

Meiji Seika Pharma Co., Ltd. (Headquarter: Tokyo, Japan, President: Masahiko Matsuo, “Meiji”) announces that it has initiated a Phase 1 clinical trial of ME1100 in the United States for the treatment of hospital acquired bacterial pneumonia (HABP) and ventilator associated bacterial pneumonia (VABP).

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.

The Phase 1 clinical trial evaluates safety, tolerability and pharmacokinetics of ME1100 in healthy subjects after a single dose of the investigational drug.

Meiji also announces that it has entered into a worldwide licensing agreement with PARI Pharma GmbH (Starnberg, Germany, “PARI”) for the development and commercialization of PARI’s eFlow® to administer ME1100. Under the agreement, Meiji has acquired an exclusive right and license to develop and commercialize ME1100 with the eFlow®. PARI, in return, receives an upfront payment, milestone payments upon successful completion of certain development milestones, and royalties on sales of ME1100.

About HABP and VABP

HABP (Hospital Acquired Bacterial Pneumonia or HAP) is defined as bacterial pneumonia contracted by a patient in a hospital at least 48 hours after admission. The mortality rate associated with HABP is the second highest among nosocomial infections after sepsis. VABP (Ventilator Associated Bacterial Pneumonia or VAP) is a sub-type of HABP occurs in a patient at least 48 hours after endotracheal intubation. The disease significantly worsens the outcome in intensive care unit (ICU) patients. Main pathogens of HABP and VABP

are methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* and *Acinetobacter* spp.

About eFlow® Technology and PARI Pharma

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.