



April 16, 2013

Bayer Initiates Phase III Trial of Investigational Inhaled Amikacin Solution (BAY41-6551T) in Mechanically Ventilated Patients with Gram-negative Pneumonia

WAYNE, N.J., April 16, 2013 /PRNewswire/ -- Bayer HealthCare Pharmaceuticals Inc. announced today that patient enrollment is underway in its global Phase III trial program to evaluate the efficacy and safety of adjunctive aerosolized BAY41-6551 versus aerosolized placebo in the treatment of intubated and mechanically ventilated patients with Gram-negative pneumonia receiving standard of care intravenous antibiotics. BAY41-6551 consists of amikacin inhalation solution delivered by a Pulmonary Drug Delivery System (PDDS) developed by Nektar Therapeutics (NASDAQ: NKTR).

"Bayer continues to invest in research for potential treatment options for many difficult to treat diseases," said Pamela A. Cyrus, MD, Vice President and Head of U.S. Medical Affairs, Bayer HealthCare Pharmaceuticals. "This study is designed to evaluate the effectiveness of a solution of amikacin formulated for inhalation, delivered through a proprietary drug delivery system, as an adjunctive therapy for Gram-negative pneumonia in intubated and mechanically ventilated patients."

About the Phase III INHALE Study Program

The global INHALE study program is comprised of two prospective, randomized, double-blind, placebo-controlled, multicenter studies to evaluate the safety and efficacy of BAY41-6551 as adjunctive therapy in intubated and mechanically-ventilated patients with Gram-negative pneumonia receiving standard of care intravenous antibiotics. The study will enroll patients age 18 or above that have microbiologically-confirmed pneumonia caused by Gram-negative organisms. INHALE will be a large multi-center global program involving centers in North America, South America, Europe, Japan, Australia and Asia. For more information about the trial, please visit www.clinicaltrials.gov

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare Pharmaceuticals provides products for Diagnostic Imaging, General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

About Nektar Therapeutics

BAY41-6551 is being developed through a collaboration with Nektar Therapeutics (NASDAQ: NKTR). Nektar Therapeutics is a biopharmaceutical company developing therapeutics based on its proprietary technology platforms. Nektar has a robust R&D pipeline of therapeutic candidate in pain, oncology and other therapeutic areas. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at www.nektar.com.

BAYER® and the Bayer Cross® are registered trademarks of Bayer.

Forward-Looking Statement

This news release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

SOURCE Bayer HealthCare Pharmaceuticals Inc.

News Provided by Acquire Media