ICU MANAGEMENT & PRACTICE



# Phase III study program with Amikacin Inhale in addition to standard of care in intubated and mechanically ventilated patients with Gram-negative pneumonia does not meet primary endpoint of superiority

Bayer announced on 24 November 2017 that INHALE, a global Phase III clinical study program investigating Amikacin Inhale in addition to standard of care in intubated and mechanically ventilated patients with Gram-negative pneumonia, did not demonstrate superiority versus standard of care and aerosolized placebo. The primary endpoint, as well as secondary endpoints were similar in both treatment arms, and were therefore not met. Amikacin Inhale is the development name of an integrated drug-device combination, consisting of a specially formulated Amikacin Inhalation Solution and a proprietary Synchronized Inhalation System with a vibrating mesh nebulizer.

The primary outcome measure was survival at day 28-32. Secondary outcome measures included pneumonia-related mortality through to day 28-32, early clinical response up to day 10, number of days on mechanical ventilation up to day 28-32, and number of intensive care unit (ICU) days up to day 28-32. Overall, there was a comparable safety profile across both treatment arms. Efficacy and safety analyses from this study will be published in due course.

“The results of the INHALE study are disappointing, considering that morbidity and mortality remain significant in these patients. However, the study provides important clinical data for this difficult-to-treat disease,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Development.

The program included 725 patients. Patients were randomized into two arms. Patients in the first arm received 400 mg of aerosolized amikacin every 12 hours for 10 days administered using the Synchronized Inhalation System. In the comparator arm patients received aerosolized placebo every 12 hours for 10 days, also administered using the Synchronized Inhalation System. Both groups received standard of care IV antibiotics in parallel in line with American Thoracic Society (ATS) guidelines or local guidelines. The Amikacin Inhale program is being developed through a collaboration with Nektar Therapeutics (NASDAQ:NKTR).

## About Gram-negative pneumonia

Gram-negative organisms are frequently found to be causative pathogens for pneumonia in intubated and mechanically ventilated patients. Many Gram-negative bacteria have become resistant to commonly used antibiotics. Hospital-acquired pneumonia accounts for up to a quarter of all infections in intensive care units patients. Up to 90% of these hospital-acquired pneumonia cases occur in patients who are on mechanical ventilators for breathing assistance. The incidence of pneumonia in ventilated patients has been shown to be 3.8- to 20-fold greater than in non-ventilated patients.

## About Amikacin Inhale

Amikacin Inhale (BAY 41-6551) is the development name for a drug-device combination product studied as a treatment in combination with standard of care for intubated and mechanically ventilated patients with Gram-negative pneumonia. Amikacin Inhale combines a specially formulated Amikacin Inhalation Solution with Nektar Therapeutics’ proprietary Synchronized Inhalation System with a vibrating mesh nebulizer. Amikacin Inhale has been shown to achieve aerosol delivery of approximately 50% of the nominal dose into the lungs. This result as shown in in-vitro studies compares favourably to other commercially available nebulizers, which deliver 10-20% of the nominal dose to the lungs.

## About the Phase III program INHALE

The global INHALE program is a multinational, randomized, placebo-controlled, double-blind, multi-centre study program which investigated the clinical efficacy and safety of Amikacin Inhale in combination with standard of care over IV standard of care and aerosolized placebo for the treatment of Gram-negative pneumonia in adult patients who are intubated and mechanically ventilated.

Source: Bayer

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