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Investor News

Amikacin Inhale shows promising results in Phase II Study

Bayer together with Nektar Therapeutics present preliminary Phase II data for the adjunctive treatment of pneumonia in intubated and mechanically-ventilated patients

Leverkusen, May 19, 2008 – Bayer HealthCare together with Nektar Therapeutics (NASDAQ: NKTR), today presented positive preliminary Phase II data on their unique drug-device combination Amikacin Inhale at the American Thoracic Society (ATS) annual meeting. Amikacin Inhale, currently being studied for the adjunctive treatment of Gram-negative pneumonia in intubated and mechanically-ventilated patients, achieved over 1000 times greater lung exposure to the antibiotic amikacin as compared to intravenous route of administration. This shows that targeting antibiotic therapy to the site of infection might offer superior bacterial eradication and increased efficacy, which may result in a higher likelihood of the patient's survival. Currently, Gram-negative pneumonia carries a mortality risk as high as 50 percent in mechanically-ventilated patients.[1]

"Mechanically-ventilated patients in critical care units are at particularly high risk of developing pneumonia. Most of them are already seriously ill because of severe underlying diseases," said Professor Michael Niederman, Chairman, Department of Medicine, Winthrop University Hospital, New York, and one of the lead investigators of the study. "Because of the high morbidity and mortality of Gram-negative pneumonia, fast and efficient treatment is essential. Intravenous therapies cannot always reach effective concentrations in infected lungs at tolerable doses. The new study data shows that the device successfully delivers the antibiotic directly to the site of infection, without reaching high systemic concentrations."

Amikacin Inhale is a unique drug-device combination, being developed by Bayer HealthCare in cooperation with Nektar Therapeutics, combining a special liquid formulation of the aminoglycoside antibiotic amikacin with Nektar Therapeutics' proprietary Liquid Pulmonary Technology (LPT™), designed to deliver amikacin deep into

the infected lungs. The device can be integrated into mechanical ventilation systems and can also be used as a handheld 'off-vent' device for patients no longer requiring breathing assistance. This allows for a unique full course of drug therapy in critically ill patients with Gram-negative pneumonia. 'Gram-negative pneumonia' refers to pneumonia caused by a laboratory-defined group of pathogens, the Gram-negative bacteria. These account for a substantial proportion, if not the majority of pneumonias in intensive care units (ICUs).

"A challenge in treating Gram-negative pneumonia in ICUs is that they have grown increasingly resistant to currently available antibiotics," said Professor Donald Low, Head of the Department of Microbiology at the Toronto Medical Laboratories and Mount Sinai Hospital, Toronto, Canada. "A new treatment option such as Amikacin Inhale, which fights pneumonia directly at the site of infection, may be able to help decrease resistance – especially if concomitant intravenous antibiotic therapy can also be reduced."

Amikacin Inhale will enter Phase III trials later this year to further assess its efficacy and safety in mechanically ventilated patients with Gram-negative pneumonia.
The enrolment for two pivotal Phase III studies will start in the fourth quarter of 2008.

About Phase II Studies

High Amikacin Lung Deposition in MVP[2]

In the multi-center, randomized, double-blind, placebo-controlled Phase II study mechanically ventilated patients (MVP) received 400 mg doses of amikacin with Amikacin Inhale every 24 hours (n=24) or every 12 hours (n=21) for 7-14 days.
Serial serum, tracheal aspirate and urine samples were collected on Day 3. Clinical parameters, such as Clinical Pulmonary Infection Score (CPIS), days on ventilator and intravenous antibiotic use were monitored. In another study healthy volunteers (n=14) inhaled a single dose of 400 mg of amikacin via the proprietary delivery system using the hand held adaptor. This was done to compare the lung doses between on-vent and hand-held adaptors using the same proprietary nebulizer.

Mean peak tracheal aspirate of amikacin after Amikacin Inhale use every 12 hours was 16,212±3,675 µg/mL as compared to 14±4.2 µg/mL after intravenous administration (15mg/kg per day)[3]. After Amikacin Inhale use, peak serum levels of amikacin were 3.2±0.5 µg/mL versus 47±4.2 µg/mL after intravenous administration.
On average, 43 percent of the dose was delivered to the lungs using the hand-held

system with a comparable low systemic exposure. The dose delivered to the lungs with the proprietary nebulizer is comparable between the on-vent and hand-held adaptors.

Penetration of Amikacin Inhale in Lower Respiratory Tract[4]

This study evaluated Amikacin Inhale penetration into the fluid lining of the epithelial surface (ELF) of the lower respiratory tract of the pneumonia-infected lung. Treatment was adjunctive to IV treatment. Mechanically ventilated patients (n=28) with Gram-negative pneumonia received 400 mg doses of aerosolized amikacin every 12 hours for 7-14 days. The delivery of aerosolized Amikacin Inhale achieved high aminoglycoside amikacin concentrations in the ELF of the lower respiratory tract, including in the pneumonic area of the lung while maintaining safe serum concentrations. Median ELF levels were 976.1 µg/mL [135.7-16,127.6], always exceeding the amikacin MIC (minimum inhibitory concentration) for microorganisms usually responsible for Gram-negative pneumonia.

High in vivo Amikacin Lung Deposition Correlates with in vitro Findings[5]

This study describes the in-vitro and in-vivo characterization of a hand held version of Amikacin Inhale, intended for use in extubated patients. In-vitro, amikacin 400 mg was aerosolized continuously, and emitted mass captured on absolute filters distal to the mouthpiece during simulated adult tidal breathing. Emitted mass was 87 percent of the 400 mg amikacin nominal dose, with a predicted lung dose of 45-50 percent. In-vivo, Amikacin Inhale (400 mg amikacin) labeled with 99mTc was administered to healthy subjects using the hand-held version. In these, mean amikacin lung dose determined via scintigraphy was 172.2 mg, 43 percent of the nominal dose. These results show that the hand-held drug-device combination delivered a large fraction of the starting dose, confirming the high delivery efficiency predicted by in vitro aerosol characterization. The study also confirmed that the in vitro model is predictive of the in-vivo experience. Lung doses in the range of those observed are expected to achieve bacteriological eradiation.

Copies of abstracts are available and can be viewed online at the ATS website: www.abstracts2view.com/ats08/

About Bayer

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is

one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

About Bayer Schering Pharma

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About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company that develops and enables differentiated therapeutics with its industry-leading PEGylation and pulmonary drug development platforms. Nektar PEGylation and pulmonary technology, expertise, manufacturing capabilities have enabled nine approved products for partners, which include the world's leading pharmaceutical and biotechnology companies. Nektar also develops its own products by applying its pulmonary and PEGylation technology platforms to existing medicines with the objective to enhance performance, such as improving efficacy, safety and compliance. Find more information at www.nektar.com.

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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.

Forward-Looking Statements
This press release contains forward-looking statements by Nektar regarding the potential and clinical development plans for Amikacin Inhale. These forward-looking statements involve risks and uncertainties, including but not limited to: (i) Nektar's or its partners' clinical trials may fail to meet minimum clinical end points; (ii) Nektar or its partners may ultimately fail to obtain regulatory approval of one or more product candidates; and (iii) the timing or success of commencing or concluding clinical trials is subject to a number of risks uncertainties including but not limited to clinical trial design, patient enrollment, regulatory requirements, manufacturing scale-up and clinical outcomes. These forward-looking statements involve substantial risks and uncertainties, including those risks and uncertainties that are detailed in Nektar's reports and other filings with the SEC including its most recent Quarterly Report on Form 10-Q filed on May 9, 2008. Actual results could differ materially from the forward-looking statements contained in this press release. Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events, or otherwise. No information regarding or presented at the medical and scientific meetings referred to above (or contained at the Internet links provided) is intended to be incorporated by reference in this press release.

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[1] Chastre J & Fagon J-Y. *Am J Respir Crit Care Med* 2002;165:867-903
[2] Corkery K, *et al*. Evidence of High Amikacin Lung Deposition in Mechanically Ventilated Patients (MVP) with Pneumonia and Healthy Subjects (HS) dosed using NKTR-061. Poster 517 American Thoracic Society International Conference, May 19, 2008
[3] Santre C. Georges H, Jacquier JM, Leroy O , Beuscart C, Buguin D, Beaucarie G *et al*, Amikacin levels in bronchial secreations of 10 pneumonia patients with respiratory support treated once daily versus twice daily. *Antimicrob Agents Chemother* 1995; 39:264-7
[4] Luyt CE, *et al*. NKTR-061 (inhaled amikacin) BID achieves high epithelial lining fluid concentrations in pneumonic portions of lung. Poster 516 American Thoracic Society International Conference, May 19, 2008
[5] J. Fink, MS, *et al*. High in vivo Amikacin Lung Deposition after NKTR-061 dosing correlates with in vitro aerosol characterization. Poster 518 American Thoracic Society International Conference, May 19, 2008