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Nektar Therapeutics Announces Phase 2a Clinical Results Regarding the use of NKTR-061 (Inhaled Amikacin) to Treat Gram-Negative Hospital-Acquired Pneumonia Presented at the Annual American Thoracic Society International Conference

SAN FRANCISCO, May 21, 2007 (BUSINESS WIRE) -- Medical professionals seeking to treat the serious and growing problem of hospital-acquired gram-negative pneumonia may have a new weapon: NKTR-061 (inhaled-amikacin), which is a product candidate being developed by Nektar Therapeutics (Nasdaq:NKTR).

Results of a Phase 2a clinical trial evaluating the use of NKTR-061 (Inhaled Amikacin) to treat mechanically ventilated patients with hospital-acquired gram-negative pneumonia were presented today during a poster session from 11:15 a.m. - 2:00 p.m. Eastern Time (8:15 a.m. - 11:00 a.m. Pacific Time) at the annual American Thoracic Society (ATS) International Conference at the San Francisco Marriott Hotel. Electronic copies of the posters presented are available on the Investor Relations section of www.nektar.com.

"The data in this study are very encouraging because they indicate that the adjunctive use of aerosol antibiotics with systemic therapy might be an effective new approach for treating patients infected by hospital-acquired, gram negative pneumonia, many of whom were infected by resistant gram negative pathogens," said Michael S. Niederman, M.D., chairman of the Department of Medicine at the Winthrop-University Hospital and Professor of Medicine at the State University of New York at Stony Brook in Minneola, New York, a lead investigator who presented the data today. "The key to effectively treating this difficult clinical condition is delivering high concentrations of antibiotics to the site of infection, particularly the pneumonic portions of the lung, and thereby eradicating the pathogens. The findings in the study raise the real possibility that the efficacious delivery of aerosolized antibiotics with the system used in this study can lead clinicians to use less systemic antibiotics, while still achieving clinical success. This in turn may make it possible to avoid further development of antibiotic resistance, which is a serious problem in this patient population."

NKTR-061 (inhaled amikacin) is currently being tested to further evaluate the safety, tolerability, and deep lung concentrations of amikacin formulated for inhalation for the adjunctive treatment of gram-negative pneumonia in ventilated patients diagnosed with hospital or ventilator associated pneumonia. This new inhaled antibiotic product candidate is the first of a series of antibiotic products being developed by Nektar that leverage the Company's proprietary micropump technology to rapidly deliver aerosolized antibiotics to the deep lungs, both within and outside of a ventilator system. Nektar's micropump technology enables rapid, reliable and efficient aerosol delivery that can be deployed in a wide range of ventilators without disturbing or complicating existing settings. The result is a potentially more effective treatment modality that provides key advantages over traditional pneumatic or ultra-sonic nebulizer delivery.

Hospital-acquired, gram-negative bacterial pneumonia is a serious problem that afflicts patients even in the world's most advanced clinical settings. Increasing gram-negative antibiotic resistance has been a problem in the setting of hospital-acquired pneumonia. It is commonly acquired by patients in intensive care units who have been put on ventilators for breathing assistance. Current treatment involves the administration of intensive antibiotics, supplemental oxygen, and mechanical ventilator support. Some 25-50% of those who acquire gram-negative bacterial pneumonia will die.

ABSTRACTS

Four poster-board abstracts will illuminate the results of the Phase 2a trial, which allowed the evaluation of NKTR-061's pharmacokinetic, serum and tracheal aspirate concentrations, and its safety and antibiotic reduction properties. The following abstracts are also available on the Investor Relations section of the Nektar Therapeutics website: www.nektar.com:

-- Poster Board #710: Amikacin Aerosol Achieves High Epithelial Lining Fluid Concentrations in Gram-Negative Pneumonia in Intubated Mechanically Ventilated Patients

(Publication Page: A328)

Authors: C.E. Luyt, A. Jacob, A. Combes, A. Nieszowska, C. Fernandez, J.L. Trouillet, K. Corkery, R. Farinotti,

J. Chastre, Paris, France, San Carlos, CA

Introduction: IV aminoglycosides are limited by toxicity and poor lung penetration. Aerosols may improve diffusion to alveoli.

Objective: Evaluate aerosol amikacin (AMK) penetration into the epithelial lung fluid (ELF).

Patients and Methods: Within a double-blind, placebo-controlled, study of aerosol AMK as adjunct to IV therapy (ATS guidelines) in vent pts with gram-neg pneumonia, 12 pts received 400 mg AMK QD with placebo (ns) 12h later; 400 mg AMK BID; or placebo BID. Day 3, BALs done 30m post aerosol in infected and healthy lobes. ELF was determined by using urea for dilution correction. AMK in tracheal aspirates (TA) was measured .25, 1, 2, 4, 8 and 12 h post aerosol.

Results: AMK level in TA (fig 1) and ELF (fig 2) were high regardless of dose or lobe.

Conclusion: Aerosol AMK achieved very high levels in TA and ELF, including in poorly aerated zones.

-- Poster Board #718

Inhaled Amikacin Reduces IV Antibiotic Use in Intubated Mechanically Ventilated Patients during Treatment of Gram-Negative Pneumonia

(Publication Page: A327)

Authors: M.S. Niederman, J. Chastre, K. Corkery, A. Marcantonio, J.B. Fink, C.E. Luyt, M. Sanchez, the Amikacin Study Group, San Carlos, CA, Mineola, NY, Paris, France, Madrid, Spain

Introduction: Antibiotic resistance is associated with frequency and duration of IV antibiotic administration.

Objective: Evaluate IV antibiotic use with aerosol amikacin (AMK) for gram negative pneumonia.

Patients and Methods: A double-blind, placebo-controlled, study of aerosol AMK delivered via the PDDS, (Nektar Therapeutics) in vent pts with gram-neg pneumonia adjunctive to IV antibiotic therapy (ATS guidelines). Pts randomized to aerosol with 400 mg AMK QD with placebo (ns) 12h later; 400 mg AMK BID or placebo BID. IV antibiotics (agent and duration) determined by attending.

Results: Mean IV antibiotics at end of tx (mean 7d), was 2X greater with placebo than BID AMK (p less than 0.02). Aerosol AMK was well tolerated with no difference in adverse events across treatment groups.

Conclusion: Repeated doses of adjunctive aerosol AMK to ventilated patients with gram neg pneumonia was safe, well tolerated, and associated with less IV antibiotic use than placebo. The impact of inhaled AMK on antibiotic resistance and the clinical impact of adjunctive aerosol therapy remains

to be determined.

-- Poster Board # 719

Amikacin Aerosol Achieves High Tracheal Aspirate Concentrations in Intubated Mechanically Ventilated Patients with Gram Negative Pneumonia: A Pharmacokinetic Study

(Publication Page: A327)

Authors: M.S. Niederman, M. Sanchez, K. Corkery, K. Guntapali, C.E. Luyt, J. Chastre, San Carlos, CA, Mineola, NY, Houston, TX, Paris, France, Madrid, Spain

Introduction: The use of IV aminoglycosides is limited by toxicity and poor lung penetration; aerosol achieves high tracheal aspirate (TA) concentrations.

Objective: Evaluate dose response to aerosol-delivered amikacin (AMK) and the ability to deliver 25 X reference MIC value of 256 ug/mL in TA (6,400 ug/mL).

Patients and Methods: A double-blind, placebo-controlled, study of aerosol AMK delivered via the Pulmonary Drug Delivery System (PDDS, Nektar Therapeutics) in ventilated patients with gram-negative pneumonia as an adjunctive to IV therapy per ATS guidelines. Patients were randomized to receive aerosol containing 400 mg AMK QD with placebo (ns) 12h later; 400 mg AMK BID or placebo BID. AMK concentration was determined in TA collected .25 and 1, 2, 4, 8 and 12 h after morning dose on day 1 and 3.

Results: AMK 400mg BID achieved higher TA concentrations than 400 mg QD. Day 3 TA levels were greater with 400 mg BID (16.2 mg/mL; n=14) than QD (6.9 mg/mL; n= 16). Target levels 25X reference MIC of 256 ug/mL was achieved by 74% BID (4/18) vs 40% QD (8/20). For all patients receiving AMK the TA levels exceeded 1,100 ug/mL or 4 X the reference MIC target. Clinical cure and bacteriologic eradication rates were similar in all groups. Aerosol AMK was well tolerated and there was no difference in adverse events across treatment groups.

Conclusion: Delivery of 400 mg of aerosolized AMK BID achieved higher TA concentrations than QD or placebo. AMK levels exceeded the highest MIC values for pathogens causing gram negative pneumonia. The clinical impact of adjunctive aerosol therapy remains to be determined.

-- Poster Board #720

Amikacin Aerosol Achieves Safe Serum Concentrations after Repeat Dosing in Intubated Mechanically Ventilated Patients with Gram Negative Pneumonia: A Pharmacokinetic Study

(Publication Page: A328)

Authors: J. Chastre, M. Sanchez, K. Corkery, J.B. Fink, C.E. Luyt, M.S. Niederman, San Carlos, CA, Mineola, NY,

Paris, France, Madrid, Spain

Introduction: IV amikacin therapy is monitored to maintain peak serum concentrations below 35 ug/mL and trough levels below 10ug/mL to avoid toxicity. Aerosolized amikacin (AMK) has been reported to achieve high lung concentrations with low serum levels.

Objective: Evaluate the safety of aerosol-delivered (AMK) in order to achieve high lung concentrations and low serum concentration.

Patients and Methods: A double-blind, placebo-controlled, study of aerosol AMK delivered via the Pulmonary Drug Delivery System (PDDS, Nektar Therapeutics) in ventilated patients with gram-negative pneumonia as an adjunctive to IV therapy per ATS guidelines was conducted. Patients were randomized to receive aerosol containing 400 mg AMK QD with placebo (ns) 12h later; 400 mg AMK BID or placebo BID. Peak AMK concentration was determined in serum collected .25, 1, 2, and 4 h after delivery of the AM dose on days 1 and 3 and used to calculate Cmax. Trough concentrations were determined daily 30 minutes prior to the AM dose.

Results: For QD vs BID groups, serum Cmax was 1.3 vs 2.3 ug/mL (respectively) on day 1, and 2.3 vs 3.2 ug/mL on day 3, with mean trough levels of 0.87 vs 1.49 ug/mL. The mean duration of aerosol AMK treatment was 7 days. Aerosol AMK was well tolerated and there was no difference in adverse events across treatment groups.

Conclusion: Delivery of aerosolized AMK achieves safe serum concentrations using the PDDS, vibrating mesh nebulizer. The clinical impact of adjunctive aerosol therapy remains to be determined.

ABOUT NEKTAR

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.

This press release contains forward-looking statements regarding NKTR-061 and the company's pulmonary technology. These forward-looking statements involve risks and uncertainties, including but not limited to: (i) preclinical testing and clinical trials are long, expensive and uncertain processes, (ii) because the NKTR-061 program is in the early phases of clinical development, the risk of failure is high and can occur at any stage of development, (iii) the company's ability to obtain regulatory approval of NKTR-061 and (iv) there can be no assurance that the company's patent applications for NKTR-061 will issue; patents that have issued will be enforceable; or that intellectual property licenses from third parties may not be required in the future. Other important risks and uncertainties are detailed in the company's reports and other filings with the SEC; including its most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q. Actual results could differ materially from the forward-looking statements contained in this press release. The company undertakes no obligation to update forward-looking statements, whether as a result of new information, future events, or otherwise.

Background Information

Pulmonary Antibiotics Platform(1)

Adjunctive Treatment of Pneumonia in Ventilated Patients Diagnosed with Hospital-Acquired or Ventilator-Associated Pneumonia

What is Hospital-Acquired Pneumonia?

Hospital-acquired, gram-negative bacterial pneumonia is a serious problem which afflicts patients even in the world's most advanced clinical settings. Increasing gram-negative antibiotic resistance has been a problem in the setting of hospital-acquired pneumonia. It is commonly acquired by patients in intensive care units who have been put on ventilators for breathing assistance. Current treatment involves the administration of intensive antibiotics, supplemental oxygen, and mechanical ventilatory support. Some 25-50% of those who acquire gram-negative bacterial pneumonia will die.

Included in the category of Hospital-Acquired Pneumonia are:

-- Hospital Acquired Pneumonia (HAP) - pneumonia that occurs 48 hours or more after admission to a hospital, which was not incubating at the time of admission

-- Ventilator Associated Pneumonia (VAP) - pneumonia that arises more than 48-72 hours after endotracheal intubation.

(Definitions from the American Thoracic Society, "Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia," Am J Respir Crit Care Med, Vol 171. pp. 388-416, 2005.)

How often does it occur?

According to the American Thoracic Society, the incidence of hospital acquired pneumonia is usually between 5 and 10 cases per 1,000 hospital admissions depending on the case definition and study population. The incidence of ventilator-associated pneumonia is 6- to 20-fold greater than in non-ventilated patients. Arlington Medical Research (AMR) estimated 1 million patients with hospital acquired pneumonia (including ventilator-associated pneumonia) in hospitals in 2005. Of these, 144,000 were mechanically ventilated with the number of deaths at 46,000.

(Sources: American Thoracic Society, "Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia," Am J Respir Crit Care Med, Vol 171. pp. 388-416, 2005.; and, Arlington Medical Resources (AMR), Hospital Antibiotic Market Guide, 2006-7.)

ICU Units

Pneumonia has accounted for approximately 15% of all hospital-associated infections and 27% and 24% of all infections acquired in the medical intensive-care unit (ICU) and coronary care units, respectively, making it the second most common hospital-associated infection after that of the urinary tract. Being intubated and attached to a mechanical ventilator is the most common risk factor for the infection.

(Source: Guidelines For Preventing Health-Care-Associated Pneumonia, 2003, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee)

Long-term Care Facilities

In long-term care facilities such as nursing homes, pneumonia is the first or second most common infection and accounts for 13-48% of all nursing home-associated infections, according to data culled by the CDC.

(Source: Guidelines For Preventing Health-Care-Associated Pneumonia, 2003, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee)

How serious is the problem?

The fatality rates for hospital-associated pneumonia in general, and ventilator-associated pneumonia in particular, are high. For hospital-associated pneumonia, attributable mortality rates of 20%-33% have been reported; in one study, ventilator-associated pneumonia accounted for 60% of all deaths due to hospital-associated infections.

The case-fatality rate of pneumonia in nursing home residents is reported to be from 6% to 23%.

(Source: Guidelines For Preventing Health-Care-Associated Pneumonia, 2003, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee)

What causes the pneumonia?

Sources of pathogens for hospital acquired pneumonia include the surroundings of the patient (air, water, equipment), and commonly the transfer of microorganisms between the patient and staff or other patients.

(Source: American Thoracic Society, "Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia," Am J Respir Crit Care Med, Vol 171. pp. 388-416, 2005.)

What is the current treatment?

Current therapy of patients with severe hospital acquired pneumonia or ventilator associated pneumonia requires the use of antibiotics at optimal doses, to ensure maximum efficacy. This can be associated with severe side effects such as kidney and hearing damage.

(Source: American Thoracic Society, "Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia," Am J Respir Crit Care Med, Vol 171. pp. 388-416, 2005.)

What is the financial impact?

Analyses of pneumonia-associated morbidity have shown that hospital-associated pneumonia can prolong ICU stay by an average of 4.3-6.1 days and hospitalization by 4-9 days, adding an average of \$40,000 in direct costs per patient.

(Source: Guidelines For Preventing Health-Care-Associated Pneumonia, 2003, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee)

Nektar's Solution

Current therapy for these types of pulmonary infections relies almost exclusively upon high doses of intravenous antibiotics, which can be associated with severe side effects such as kidney and hearing damage.

NKTR-061 (inhaled amikacin) is currently being tested to further evaluate the safety, tolerability, and deep lung concentrations of amikacin formulated for inhalation for the adjunctive treatment of gram-negative pneumonia in ventilated patients diagnosed with hospital or ventilator associated pneumonia. This new inhaled antibiotic product candidate leverages Nektar's proprietary Aerosol Generator that is designed to effectively deliver aerosolized antibiotics to the deep lungs, both within and outside of a ventilator system. The result is a potentially more effective treatment modality which provides key advantages over traditional pneumatic or ultra-sonic nebulizer delivery.

Sources:

http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/CDCpneumo_guidelines.pdf (Due to its length, this URL may need to be copied/pasted into your Internet browser's address field. Remove the extra space if one exists.)

Arlington Medical Resources (AMR), Hospital Antibiotic Market Guide, 2006-7.

American Thoracic Society, "Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia," Am J Respir Crit Care Med, Vol 171. pp. 388-416, 2005

(1) This pulmonary antibiotics system is a prototype being tested for NKTR-061 (inhaled amikacin). It is not an approved product.

SOURCE: Nektar Therapeutics

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