Isis Pharmaceuticals' Ibis T5000 Universal Biosensor System Highlighted at ICAAC

CARLSBAD, Calif., Sept. 29 /PRNewswire-FirstCall/ -- Isis Pharmaceuticals, Inc. (Nasdaq: ISIS) announced today that scientists from its Ibis Biosciences™ (Ibis) division and collaborators presented the results of five diverse studies emphasizing the importance and breadth of applications of the Ibis biosensor technology and the Ibis T5000™ Biosensor System in identifying and characterizing infectious organisms. The studies were presented at the 46th Annual International Conference on Antimicrobial Agents and Chemotherapy (ICAAC) held this week in San Francisco, CA, which hosted more than 10,000 attendees comprising physicians, clinicians and researchers working in the fields of clinical diagnostics, drug discovery and microbiology.

The Ibis T5000 is a breakthrough universal biosensor system that supports the rapid and efficient identification, characterization and quantification of a broad range of bacteria, viruses and fungi in virtually any sample without prior knowledge of what organisms may be present. The system does not require time- and labor-intensive steps such as sequencing or culture, and it can be used to obtain high-resolution genotypes of organisms in a rapid, high-throughput manner. The Ibis T5000 Biosensor System has been extensively validated for a number of assays and is being commercialized by Ibis and its partner, Bruker Daltonics, a subsidiary of Bruker BioSciences Corporation.

Commenting on the ICAAC presentations, Dr. David Ecker, Chief Scientific Officer of Ibis Biosciences and Vice President of Isis, said, "We are very pleased with the breadth of data presentations included at this meeting. The studies highlighted exemplify the substantial contribution the Ibis T5000 Biosensor System can make in the identification and characterization of infectious organisms in broad applications, from epidemiologic surveillance to identifying and preventing hospital-acquired infections, and eventually to disease diagnostics. As we begin to commercialize our Ibis biosensor technology, the opportunity to display its capabilities, with the strong support of our collaborators, to the broader infectious disease community is invaluable."

A summary of the presentations follows:

An MLST Schema and Rapid MLST Analysis Strategy for Molecular Genotyping of Acinetobacter baumannii for Infection Control


Acinetobacter infections are frequent complications of wound infections and have been particularly problematic in military personnel injured in Iraq. The Ibis T5000 Biosensor System rapidly identified and characterized with regard to virulence and drug resistance factors, Acinetobacter organisms in more than 267 samples from infected soldiers. The method required less than 4 hours to provide genotypic identification of the Acinetobacter strain types that caused the infections.

Such information was used to determine that the source of the infection was hospital-based, disproving the initial hypothesis that the infections were soil-based, and allowed appropriate steps to be taken to reduce the incidence of future infections.

Rapid Determination of Ciprofloxacin Resistance in Clinical Isolates of Acinetobacter spp. Using Polymerase Chain Reaction Electrospray Ionization Mass Spectrometry (PCR/ESI-MS)

Authors: K. M. Hujer(1), A. M. Hujer(1), T. D. Pennella(2), C. Massire(2), M. W. Eshoo(2), D. J. Ecker(2), R. A. Bonomo(1); (1) VA Medical Center, Cleveland, OH; (2)Ibis Biosciences

In the treatment of serious bacterial infections, the rapid initiation of appropriate antimicrobial therapy is life saving. We showed that the Ibis T5000 Biosensor System can be used to determine the sequence variability of the housekeeping genes, gyrA and parC, in Acinetobacter spp. and rapidly characterize a quinolone-resistant phenotype. Seventy-five Acinetobacter spp. isolates from the Walter Reed Army Medical Center in Washington, DC were analyzed. More than 90% of the isolates in this polyclonal collection are resistant to ciprofloxacin. Single point mutations encoding amino acid in gyrA topoisomerases highly correlated with phenotypic ciprofloxacin resistance in Acinetobacter spp. The Ibis T5000 analysis showed that base compositions of these regions unambiguously distinguished ciprofloxacin-susceptible from ciprofloxacin-resistant isolates. There was agreement between data provided by the Ibis T5000, restriction enzyme digestion and MICs, confirming the reliability of the Ibis T5000 analysis. This novel and rapid approach to the characterization of infectious organisms can provide essential information for resistance determinant identification and therapeutic decision making.
According to Robert A. Bonomo, M.D., Section Chief, Infectious Diseases, Louis Stokes Cleveland Veterans Affairs Medical Center, "Conventional methods would have required months of work, but in this project, we were able to get the results from the Ibis T5000 system within a few days. Our vision is that this technology will be used to simultaneously identify pathogens and determine resistance phenotypes so that appropriate therapy can be rapidly instituted."

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**TIGER PCR Mass-Spectrometry and Rep-PCR Characterization of Community-Acquired Oxacillin Resistant Staphylococcus aureus Isolates**

Authors: D. M. Wolk(1), D. Shepley(2), D. Sloane(2), R. Sampath(3), V. Harpin(3), L. Blyn(3), D. Ecker(3), V. Wysocki(4), S. Hofstadler(3); (1)SAVAHCS/Univ. of Arizona, Tucson, AZ; (2)SAVAHCS, Tucson, AZ; (3)Ibis Biosciences; (4)Univ. of Arizona, Tucson, AZ

Drug resistant Staphylococcus aureus is an important cause of hospital-acquired infections (HAI), a significant and growing public health issue. These infections are often life threatening and poorly treated because the infective organisms are so virulent and drug resistant. Oxacillin-resistant Staphylococcus aureus is a strain that is prevalent in both hospitals and in the community at large.

The Ibis T5000 Biosensor System was used to characterize 87 isolates of Oxacillin-resistant Staphylococcus aureus and the results were compared to results from traditional culture methods and the Cepheid IDI-MRSA assay. The Ibis T5000 rapidly produced extremely accurate and sensitive results, and supported high-throughput analysis, making it an ideal approach to the identification and genotyping of both community- and hospital-acquired drug-resistant Staphylococcus aureus.

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**Rapid Detection and Molecular Characterization of Influenza Virus Using RT-PCR/ESI-MS Technology**


Because influenza viruses mutate constantly, there are many flu strains. The virulence of and immunological responses to each strain of virus vary substantially. Epidemics occur annually and these epidemics are frequently caused by different strains. Furthermore, influenza viruses that infect species other than humans occasionally acquire the ability to infect humans. Thus a rapid, efficient system such as the Ibis T5000 that can identify, quantify and genotype influenza viruses is urgently needed.

In this study presented by Ibis scientists and collaborators, the Ibis T5000 Biosensor System was able to very rapidly and reliably identify and genotype all influenza viruses including avian strains. It was able to 'map' epidemics and to determine the strains involved in several annual influenza epidemics.

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**Broad-Range Detection and Identification of Alphaviruses in Biological Backgrounds Using RT-PCR and High Resolution Mass Spectrometry**

Authors: M. W. Eshoo(1), C. Whitehouse(2), L. B. Blyn(1), T. A. Hall(1), J. Ecker(1), T. D. Pennella(1), C. Massire(1), A. Desai (3), R. Sampath(1), D. J. Ecker(1), S. A. Hofstadler(1); (1)Ibis Biosciences; (2)U.S. Army Med. Res. Inst. of Infectious Diseases, Fort Detrick, MD; (3)SAIC, San Diego, CA

Alphaviruses are a diverse group of RNA viruses that are principally mosquito-borne. They cause a number of diseases such as encephalitis and are of concern as potential biological weapons.

The Ibis T5000 Biosensor System was used to genotypically characterize 31 diverse strains of alpha viruses. This study demonstrates the utility of the Ibis T5000 in rapidly and efficiently determining the causes of diverse viral diseases and defining the causes of viral epidemics as well as potentially bioengineered organisms.

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**About Ibis T5000 Biosensor System and Isis’ Ibis Biosciences Division**

Ibis Biosciences, a division of Isis Pharmaceuticals, has developed the Ibis T5000 Biosensor System for rapid identification and
characterization of infectious agents. The Ibis T5000 is capable of identifying virtually all bacteria, virus and fungi, and can provide high-resolution information about drug resistance, virulence and strain type of these pathogens. Commercial applications for the Ibis T5000 Biosensor System include epidemiologic surveillance, monitoring of pandemic diseases, identification of emerging or previously unknown pathogens, forensic characterization of human samples, identification of sources of hospital-associated infections, and, in the future, human infectious disease diagnostics. Bruker Daltonics, a subsidiary of Bruker BioSciences Corporation, is globally responsible for manufacture, order processing, installation and service of Ibis T5000 instruments. Ibis Biosciences develops, manufactures and markets Ibis T5000 assay kits. Additional information about Isis' Ibis division can be found by selecting the Ibis Biosciences link from Isis' homepage at www.isispharm.com.

The Ibis Biosciences division has received development funding from U.S. government agencies including the Defense Advanced Research Projects Agency (DARPA), the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation (FBI), the Department of Homeland Security (DHS), and others.

About Isis Pharmaceuticals

Isis is exploiting its expertise in RNA to discover and develop novel drugs for its product pipeline and for its partners. The Company has successfully commercialized the world's first antisense drug and has 15 drugs in development. Isis' drug development programs are aimed at treating cardiovascular, metabolic and inflammatory diseases. Isis' partners are focused in disease areas such as inflammatory, ocular, viral and neurodegenerative diseases, and cancer. As an innovator in RNA-based drug discovery and development, Isis is the owner or exclusive licensee of approximately 1,500 issued patents worldwide. Additional information about Isis is available at www.isispharm.com.

This press release includes forward-looking statements regarding the development and commercialization of the Ibis T5000 Biosensor System. Any statement describing Isis' goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement, including those statements that are described as Isis' goals. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, in developing and commercializing systems to identify infectious organisms that are effective and commercially attractive, and in the endeavor of building a business around such products. Isis' forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause its results to differ materially from those expressed or implied by such forward-looking statements. Although Isis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Isis. As a result, you are cautioned not to rely on these forward-looking statements. These and other risks concerning Isis' programs are described in additional detail in Isis' annual report on Form 10-K for the year ended December 31, 2005, and its quarterly report on Form 10-Q for the quarter ended June 30, 2006, which are on file with the SEC. Copies of these and other documents are available from the Company.

Ibis Biosciences™ is a trademark of Isis Pharmaceuticals, Inc.

Ibis T5000™ is a trademark of Isis Pharmaceuticals, Inc.

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