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Cepheid Announces Diagnostic Collaboration With MedImmune And COMBACTE To Facilitate Clinical Trials Of New Monoclonal Antibodies To Prevent Serious Infectious Diseases

GeneXpert Systems and Xpert Tests Expected to Enhance Efficiency of Clinical Trials

SUNNYVALE, Calif., Jan. 13, 2016 /PRNewswire/ --Â Cepheid (Nasdaq: CPHD) today announced a collaboration with MedImmune, the global biologics research and development arm of AstraZeneca, and COMBACTE, a European public/private partnership set up to promote the development of new drugs in the anti-infectives field, to develop a series of rapid diagnostic tests to identify *Staphylococcus aureus* (*S. aureus*) and *Pseudomonas aeruginosa* (*P. aeruginosa*) in respiratory secretions of mechanically ventilated patients.Â These tests will be used to help identify patients for MedImmune's MEDI4893 and MEDI3902 clinical programs, which are being conducted within the COMBACTE consortium to explore the use of biologics in preventing ventilator associated pneumonia (VAP) infections in intensive-care-unit (ICU) patients.

MEDI4893 is a novel monoclonal antibody that targets alpha toxin produced by *S. aureus* and is currently being investigated by MedImmune and COMBACTE for the prevention of nosocomial pneumonia caused by *S. aureus*.Â MEDI3902 is a bispecific antibody under investigation for the prevention of nosocomial pneumonia caused by *P. aeruginosa*, a highly drug-resistant bacterium.Â Â The Xpert® tests are expected to help identify patients colonized with *S. aureus* or *P. aeruginosa* before they have clinical signs of pneumonia, so that these patients can be enrolled in the respective MEDI4893 or MEDI3902 clinical trials.

"Utilizing rapid diagnostics is a key component in effectively targeting serious healthcare-associated pathogens in our MEDI4893 and MEDI3902 clinical trials," said Steve Projan, head of Infectious Diseases and Vaccines, Innovative Medicines unit at MedImmune.Â "We believe that the combination of rapid diagnostics and pathogen-specific antibodies will help physicians identify patients at risk and prevent serious and life-threatening infections in a way that is not possible today.Â By developing diagnostic tests through this collaboration with Cepheid, we can ensure that novel life-saving antibodies are delivered to patients who need them in a rapid and efficient manner."

As part of the collaboration, Cepheid has adapted its existing Xpert MRSA/SA skin and soft tissue infection (SSTI) test cartridge for use in respiratory sample types for detection of patients with respiratory colonization with *S. aureus* and MRSA. Â This test is being used in ongoing clinical trials for MEDI4893.Â In addition, Cepheid has developed a new Xpert test cartridge to support the rapid identification of patients colonized with *P. aeruginosa* for patient enrollment in clinical trials for MEDI3902 starting early in 2016.Â

"Cepheid is pleased to be working with MedImmune and COMBACTE to address the critical challenges posed by serious bacterial infections. We believe this can be achieved through the use of molecular diagnostic tests to precisely target colonized patients, improve clinical trial efficiency, and accelerate these much needed therapeutics to market," said John Bishop, Cepheid's Chairman and Chief Executive Officer.Â "These two initial projects give Cepheid an opportunity to demonstrate its technology leadership, while also building an installed base of GeneXpert systems that could be leveraged for future COMBACTE or broader Innovative Medicines Initiative programs."

Dr. Herman Goossens, the head of COMBACTE's laboratory network who is participating in both the MEDI4893 and MEDI3902 trials and evaluating the new assays added, "We are pleased that COMBACTE is supporting the implementation, training and validation of both the *S. aureus* and *P. aeruginosa* screening tests.Â Our ability to engage the laboratories in the network will ensure timely implementation and standardization of the platform while allowing us to determine the utility of identifying colonized patients before they show clinical signs of pneumonia."

According to the Centers for Disease Control and Prevention, *S. aureus* and *P. aeruginosa* together account for > 40% of VAP infections in the United States (Sievert DM, et al. 2013). Â The length of stay in the ICU is extended on average 17 days after pneumonia onset when either *S. aureus* or *P. aeruginosa* are present, and the attributable mortality can reach 30% despite the use of currently available antibiotics.Â

About Cepheid

Based in Sunnyvale, Calif., Cepheid (Nasdaq: CPHD) is a leading molecular diagnostics company that is dedicated to improving healthcare by developing, manufacturing, and marketing accurate yet easy-to-use molecular systems and tests. By automating highly complex and time-consuming manual procedures, the company's solutions deliver a better way for institutions of any size to perform sophisticated genetic testing for organisms and genetic-based diseases. Through its strong molecular biology capabilities, the company is focusing on those applications where accurate, rapid, and actionable test results are needed most, such as managing infectious diseases and cancer. For more information, visit www.cepheid.com.

About GeneXpert Systems and Xpert Tests

With more than 9,200 systems in 182 countries, the GeneXpert System is the world's most popular molecular diagnostics' instrument.Â The GeneXpert System's modular configuration means that the system is the most scalable available, offering the ability to perform from one to eighty Xpert tests at the same time.Â As a result, the GeneXpert System meets the throughput requirements of customers of all sizes - from lower volume point-of-care settings to higher volume reference laboratories - enabling accurate, fast and cost effective test results.

GeneXpert Systems run proprietary Xpert test cartridges.Â The Xpert test menu spans healthcare-associated infections, sexual health, critical infectious disease, and oncology, and today offers 23 tests outside the US, and 19 tests in the US.Â More information on the GeneXpert System and the Xpert tests is available on our website at www.cepheid.com.Â

About MEDI4893

MEDI4893 targets alpha toxin produced by *Staphylococcus aureus*, which is one of the leading bacteria often associated with hospital-associated infections and linked to multidrug resistance.Â MedImmune has Fast Track designation from the U.S. Food and Drug Administration for MEDI4893 for the prevention of nosocomial pneumonia caused by the bacterium *Staphylococcus aureus* (*S. aureus*).Â

The molecule is currently in a Phase II trial, named SAATELLITE, through the Innovative Medicines Initiative (IMI) project COMBACTEÂ (*Combatting Bacterial Resistance in Europe*), which is a unique European public/private partnership set up to promote the clinical development of new drugs in the anti-infectives field.Â The MEDI4893 Phase II trial is the first interventional trial ever designed and executed within COMBACTE. It also represents a paradigm shift in the infectious disease field, studying a pre-emptive approach using a monoclonal antibody to help prevent VAP and nosocomial pneumonia due to *S. aureus.* A total of 462 patients are expected to be enrolled in this study across approximately 80 sites in Europe.

About MEDI3902

MEDI3902 is MedImmune's bispecific antibody being investigated for the prevention of nosocomial pneumonia caused by a highly drug resistant bacterium, *Pseudomonas aeruginosa*. In September 2014, the US Food & Drug Administration granted Fast Track designation to MEDI3902.Â Â The molecule is currently in a Phase I trial and a Phase II trial is anticipated to start in 1Q2016.Â

MEDI3902 is part of a new IMI project, COMBACTE-MAGNET (Combatting Bacterial Resistance in Europe - Molecules Against Gram-Negative Infections), which conducts highly innovative studies and activities related to prevention and treatment of infections caused by multi-drug resistant Gram-negative bacteria.

Both COMBACTE and COMBACTE-MAGNET are supported by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI's antimicrobial resistance programme, New Drugs for Bad Bugs (ND4BB), comprises seven projects and has a budget of close to €700 million. More information: www.imi.europa.eu.

Forward Looking Statements

This press release contains forward-looking statements that are not purely historical regarding Cepheid's or its management's intentions, beliefs, expectations and strategies for the future, including those relating to the substance, results and effects of the collaboration among Cepheid, MedImmune and COMBACTE, the results of the MEDI4893 and MEDI3902 clinical programs, the timing, efficiency and accuracy of the tests being developed for the MEDI4893 and MEDI3902 clinical programs and the impact of these tests on the MEDI4893 and MEDI3902 clinical program.Â Because such statements deal with future events, they are subject to various risks and uncertainties, and actual results could differ materially from Cepheid's current expectations. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to: test performance in the field; utilization of Cepheid's tests by clinicians and future changes in medical practice and protocols; Cepheid's ability to successfully and timely develop new products; the completion of clinical trials for new products successfully and in a timely manner; uncertainties related to the United States

FDA, European and other regulatory processes; Cepheid's ability to successfully introduce and sell products in global markets; Cepheid's research and development budget; unforeseen supply, development and manufacturing problems; the potential need for additional intellectual property licenses for tests and other products and the terms of such licenses; the impact of competitive products and pricing; the costs of product components and other factors affecting product pricing; Cepheid's ability to manage geographically-dispersed operations; and underlying regulatory, political and market conditions worldwide. Readers should also refer to the section entitled "Risk Factors" in Cepheid's Annual Report on Form 10-K, its most recent Quarterly Report on Form 10-Q, and its other reports filed with the Securities and Exchange Commission.

All forward-looking statements and reasons why results might differ from those included in this release are made as of the date of this press release, based on information currently available to Cepheid, and Cepheid assumes no obligation to update any such forward-looking statement or reasons why results might differ.

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