NEWS RELEASE

Jan7Merck Announces Publication of Pivotal Data from Phase 3 Clinical Studies of ZERBAXA™ (Ceftolozane/Tazobactam) in The Lancet and Clinical Infectious Diseases

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Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that The Lancet and Clinical Infectious Diseases have published online the results from the pivotal Phase 3 clinical studies of ZERBAXA™ (ceftolozane/tazobactam) for Injection (1 g/0.5 g) in complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI), respectively. The results will also appear in forthcoming print issues of the journals. Merck acquired ZERBAXA as a part of its purchase of Cubist Pharmaceuticals, Inc.

The publications report the results of two large, global, Phase 3 clinical studies of ZERBAXA – a study in patients with cUTI and a study in patients with cIAI. Both studies met the pre-specified primary endpoints, and results of the secondary analyses for the studies were consistent with and supportive of the primary outcomes.

“Physicians are in need of new treatment options to address complicated infections caused by serious Gram-negative bacteria. Publication of the ZERBAXA Phase 3 clinical study results in The Lancet and Clinical Infectious Diseases provides additional information to the infectious disease community and continues to support ZERBAXA as a new treatment for certain complicated urinary tract and complicated intra-abdominal infections,” said René Russo, Pharm.D, BCPS, vice president, global medical affairs, Cubist Pharmaceuticals.

Approved in the U.S., ZERBAXA is indicated for use in combination with metronidazole in adult patients for the

treatment of complicated intra-abdominal infections caused by the following Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus and Streptococcus salivarius. ZERBAXA also is indicated in adult patients for the treatment of complicated urinary tract infections, including pyelonephritis, caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis and Pseudomonas aeruginosa.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA and other antibacterial drugs, ZERBAXA should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

About the study of ZERBAXA in cUTI

As described in The Lancet, the cUTI study was a multicenter, double-blind trial in which 1,083 hospitalized adult patients with cUTI, including pyelonephritis, were randomized to receive either intravenous (I.V.) ZERBAXA (1.5 g q8h) or high-dose I.V. levofloxacin (750 mg qd) for seven days. In this study, treatment with ZERBAXA was shown to be effective in patients with cUTI and pyelonephritis, including a majority of infections caused by levofloxacin-resistant pathogens. The comparator levofloxacin is a common treatment option for cUTI and pyelonephritis, and is included in international clinical practice guidelines for cUTI.

ZERBAXA met the study's primary endpoint of statistical non-inferiority compared to levofloxacin (10% non-inferiority margin). The primary endpoint was a composite of microbiological eradication and clinical cure rate (composite cure rate) at 5-9 days after the end of therapy (the test of cure visit). The 95% confidence interval around the treatment difference had lower and upper bounds of 2.3% and 14.6%, respectively.

"These clinical trial results are important because ceftolozane/tazobactam is a new treatment option for patients facing complicated urinary tract infections caused by certain susceptible Gram-negative bacteria," said The Lancet publication lead author Florian M. Wagenlehner, M.D., Ph.D., Clinic for Urology, Pediatric Urology and Andrology, Justus-Liebig University, and faculty member of the German Center for Infection Research, Gießen-Marburg-Langen site. "Gram-negative bacteria are prevalent globally and know no geographic boundaries. With the increasing challenge of antibiotic resistance, the treatment of complicated urinary tract infections has become more difficult to manage, and new therapies are needed."

About the study of ZERBAXA in cIAI

As described in Clinical Infectious Diseases, the cIAI study was a multicenter, double-blind trial in which 993 hospitalized adult patients with cIAI were randomized to receive either I.V. ZERBAXA (1.5 g q8h) plus metronidazole (0.5 g q8h) or I.V. meropenem (1 g q8h) for four to 10 days. Treatment could be continued for up to 14 days in patients who had one of the following: multiple abscesses; non-appendix–related diffuse peritonitis, failure of prior antimicrobial therapy, or hospital-acquired infection. Treatment with ZERBAXA plus metronidazole was shown to be effective in patients with cIAI, including those infections caused by certain resistant pathogens, such as extended-spectrum beta-lactamase (ESBL) producing Enterobacteriacae. The comparator meropenem is a common treatment option for cIAI and is included in international clinical practice guidelines for cIAI.

The primary endpoint of this study was the clinical cure rate 24-32 days after the initiation of therapy (the test of cure visit). For the U.S. Food and Drug Administration, the primary analysis was conducted in the microbiological intent-to-treat population; the non-inferiority margin was 10%; and the lower and upper bounds of the 95% confidence interval were -8.9% and 0.5%, respectively. For the European Medicines Agency (EMA), the primary analysis population was clinically evaluable patients; the non-inferiority margin was 12.5%; and the lower and upper bounds of the 99% confidence interval were -4.2% and 4.3%, respectively.

“Complicated intra-abdominal infections are tissue-invasive infections that can lead to abscess formation or generalized peritonitis. Having new antibiotics to address these types of serious infections, particularly those caused by Gram-negative pathogens, has been a major medical need,” said the Clinical Infectious Diseases publication lead author Joseph Solomkin, M.D., professor of surgery emeritus, Department of Surgery, University of Cincinnati College of Medicine. “These clinical trial results reinforce that ZERBAXA is an effective new treatment for adult patients with complicated intra-abdominal infections.”

About ZERBAXA (ceftolozane/tazobactam)

ZERBAXA, approved in the U.S., is an antibacterial combination product consisting of the cephalosporin antibacterial drug ceftolozane sulfate and the beta-lactamase inhibitor tazobactam sodium for intravenous administration. The recommended dosage regimen of ZERBAXA is 1.5 g (1 g/0.5 g) administered every eight hours by intravenous infusion over one hour in patients 18 years or older and with normal renal function or mild renal impairment. Dosage adjustment is required for patients whose creatinine clearance is 50 mL/min or less.

In the European Union, the EMA has accepted for review the Marketing Authorization Application for ZERBAXA for the treatment of cUTI and cIAI. A decision from the European Commission is expected during the second half of 2015.

Important Safety Information about ZERBAXA

Patients with renal impairment: Decreased efficacy of ZERBAXA has been observed in patients with baseline CrCl of 30 to <=50 mL/min. In a clinical trial, patients with cIAIs with CrCl ≥50 mL/min had a clinical cure rate of 85.2% when treated with ZERBAXA plus metronidazole vs 87.9% when treated with meropenem. In the same trial, patients with CrCl 30 to ≤50 mL/min had a clinical cure rate of 47.8% when treated with ZERBAXA plus metronidazole vs 69.2% when treated with meropenem. A similar trend was also seen in the cUTI trial. Monitor CrCl at least daily in patients with changing renal function and adjust the dose of ZERBAXA accordingly.

Hypersensitivity: ZERBAXA is contraindicated in patients with known serious hypersensitivity to ceftolozane/tazobactam, piperacillin/tazobactam, or other members of the beta-lactam class. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam antibacterials. Before initiating therapy with ZERBAXA, make careful inquiry about previous hypersensitivity reactions to cephalosporins, penicillins, or other beta-lactams. If an anaphylactic reaction to ZERBAXA occurs, discontinue use and institute appropriate therapy.

Clostridium difficile–associated diarrhea (CDAD), ranging from mild diarrhea to fatal colitis, has been reported with nearly all systemic antibacterial agents, including ZERBAXA. Careful medical history is necessary because CDAD has been reported to occur more than two months after the administration of antibacterial agents. If CDAD is confirmed, antibacterial use not directed against C. difficile should be discontinued, if possible.

Development of drug-resistant bacteria: Prescribing ZERBAXA in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.

Adverse reactions: The most common adverse reactions occurring in >= 5% of patients were headache (5.8%) in the cUTI trial, and nausea (7.9%), diarrhea (6.2%) and pyrexia (5.6%) in the cIAI trial.

About Gram-negative bacteria and certain complicated infections

Gram-negative bacteria are a serious global public health concern. The U.S. Centers for Disease Control and Prevention has categorized certain Gram-negative bacteria among the most serious threats to public health. Gram-negative bacteria are common causes of cIAI and cUTI. E. coli is the most common cause of cUTIs, and cases of cUTI caused by Pseudomonas aeruginosa are increasing. Additionally, Pseudomonas aeruginosa is the second most common cause of catheter-associated UTIs. Major pathogens in cUTIs are Enterobacteriaceae, including Escherichia coli (E. coli) and Klebsiella pneumoniae.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside of the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit **www.merck.com** and connect with us on **Twitter**, **Facebook** and **YouTube**.

Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2014 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (**www.sec.gov**).

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Please see Prescribing Information for ZERBAXA™ (ceftolozane/tazobactam) at **http://zerbaxa.com/pdf/PrescribingInformation.pdf**.

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