Merck Highlights Its Commitment to Infectious Disease with 40 Presentations of Data at ICAAC/ICC 2015

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that more than 40 presentations of data on a number of Merck's investigational and established infectious disease products are scheduled for the upcoming Interscience Conference of Antimicrobial Agents and Chemotherapy (ICAAC) and International Congress of Chemotherapy and Infection (ICC) joint meeting in San Diego, Sept. 17-21.

“At Merck we continue to advance a broad portfolio of investigational infectious disease medicines,” said Dr. Eliav Barr, vice president infectious diseases, Merck Research Laboratories. “We look forward to presenting data at ICAAC/ICC with a focus on our antibacterial candidates designed to address serious infections such as C. difficile and the increasing threats presented by resistant Gram-negative bacteria.”

The presentations will include results from two pivotal Phase 3 clinical studies of bezlotoxumab (alone and in combination with actoxumab), an investigational antidote for the prevention of Clostridium difficile (C. difficile) infection recurrence in patients on standard C. difficile antibiotic treatment; data from several studies of ZERBAXA™ (ceftolozane and tazobactam), which is indicated for the treatment of complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI); and Phase 2 clinical data evaluating relebactam, the company’s investigational beta-lactamase inhibitor, for the treatment of cIAI. For more information, including a complete list of abstract titles, please visit the ICAAC website at www.icaac.org.

“Merck is one of a few large pharmaceutical companies that have remained deeply committed to developing novel anti-infective therapies,” said Dr. Julie Gerberding, executive vice president, strategic communications, global public policy and population health, Merck. “Today, with increasing concerns about the rise of antimicrobial resistance, we continue to advocate for appropriate and responsible use of these important medicines.”

Dr. Gerberding, along with other global infectious disease leaders, is scheduled to deliver remarks at the ICAAC Antimicrobial Research Award and Lecture on Saturday, Sept. 19, at 1:30 p.m. PDT.

Merck’s commitment to infectious disease

For more than 80 years, Merck has contributed to the discovery and development of novel medicines and vaccines to combat infectious diseases. In addition to a combined portfolio of antibiotic and antifungal medicines, vaccines, and medicines for HIV and HCV, Merck has multiple programs that span discovery through late-stage development. Merck currently has 25 ongoing Phase 2/Phase 3 clinical trials evaluating several candidates for the prevention or treatment of infectious diseases.

About ZERBAXA

ZERBAXA (ceftolozane and tazobactam) for injection (1.5 g) is an antibacterial combination product for intravenous infusion consisting of the cephalosporin antibacterial drug ceftolozane sulfate and the beta-lactamase inhibitor tazobactam sodium.

ZERBAXA is approved in the United States and is indicated in adult patients for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa. ZERBAXA used in combination with metronidazole is indicated in adult patients for the treatment of complicated intra-abdominal infections (cIAI) 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.

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.
Important Safety Information about ZERBAXA (ceftolozane and tazobactam)

**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 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](http://www.merck.com) and connect with us on Twitter, Facebook and YouTube.

**Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. 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; the company’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 the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company 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 the company’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](http://www.sec.gov)).

Please see Prescribing Information for ZERBAXA (ceftolozane and tazobactam) at [http://zerbaxa.com/pdf/PrescribingInformation.pdf](http://zerbaxa.com/pdf/PrescribingInformation.pdf).

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**Contact:**

Merck

Media:

Doris Li, 908-246-5701
or
Ian McConnell, 973-901-5722
or

Investors:

Teri Loxam, 908-740-1986
or
Justin Holko, 908-740-1879