Merck Highlights Ongoing Commitment to Fighting Infectious Diseases with More than 30 Data Presentations at ASM Microbe 2016

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that researchers are scheduled to provide more than 30 scientific data presentations on the company's established and investigational infectious disease medicines and vaccines at the American Society for Microbiology's ASM Microbe 2016 meeting in Boston, June 16-20.

Researchers will present results of a Phase 2 clinical trial of relebactam, the company’s investigational beta-lactamase inhibitor, in combination with imipenem/cilastatin (an approved carbapenem antibiotic), in patients with complicated urinary tract infections, including those caused by antibiotic-resistant pathogens.

Among other presentations, researchers also will present studies showing updated data from the Phase 3 trials and updated data on the in vitro activity of ZERBAXA® (ceftolozane and tazobactam) 1.5 g. ZERBAXA is indicated for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis, and in combination with metronidazole, complicated intra-abdominal infections (cIAI) caused by designated susceptible Gram-negative and Gram-positive bacteria.

Select data presentations at ASM Microbe include:

**Relebactam + Imipenem/Cilastatin**
- Phase 2 Study of Relebactam (REL) + Imipenem/Cilastatin (IMI) vs. IMI Alone in Subjects with Complicated Urinary Tract Infection (cUTI), M. Sims (Poster No. 472, 12:30 - 2:30 p.m., Monday, June 20, Exhibit Halls A and B)
- *In Vitro* Activity of Imipenem-Relebactam (MK-7655) against Enterobacteriaceae and *Pseudomonas aeruginosa* from the United States - SMART 2015, M. Hackel (Poster No. 340, 12:45 p.m. - 2:45 p.m., Saturday, June 18, Exhibit Halls A and B)
- Activity of Imipenem-Relebactam (MK-7655) against Enterobacteriaceae and *Pseudomonas aeruginosa* from Europe - SMART 2015, M. Hackel (Poster No. 337, 12:45 - 2:45 p.m., Saturday, June 18, Exhibit Halls A and B)

**ZERBAXA (ceftolozane and tazobactam)**
- Activity of Ceftolozane-Tazobactam (TOL/TAZ) against Drug-Resistant Gram-Negative Pathogens Collected from USA Medical Centers in 2015, M. Huband (Poster No. 430, 12:30 - 2:30 p.m., Monday, June 20, Exhibit Halls A and B)
- *In Vitro* Activity of Ceftolozane-Tazobactam against *Pseudomonas aeruginosa* and Enterobacteriaceae Isolates Collected from Medical Centers in the USA in 2015, M. Huband (Poster No. 431, 12:30 - 2:30 p.m., Monday, June 20, Exhibit Halls A and B)
- Analysis of Diabetes Patients with Complicated Intra-Abdominal Infection or Complicated Urinary Tract Infection in Phase 3 Trials of Ceftolozane/Tazobactam, M. Popejoy (Poster No. 430, 12:30 - 2:30 p.m., Friday, June 17, Exhibit Halls A and B)

For more information, including a complete list of presentation titles, please visit the ASM Microbe website at www.asmmicrobe.org.

**Merck's commitment to infectious diseases**

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 10 compounds in Phase 2/Phase 3 clinical trials for the potential treatment or prevention of infectious diseases.

**About ZERBAXA**

ZERBAXA 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 (ceftolozane and tazobactam) 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**

**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**

For 125 years, Merck has been a global health care leader working to help the world be well. Merck is known as MSD outside 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 health care through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](https://twitter.com), [Facebook](https://www.facebook.com), [YouTube](https://www.youtube.com) and [LinkedIn](https://www.linkedin.com).

**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 2015 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).

**Language:**