Merck Highlights Ongoing Commitment to Fighting Infectious Diseases With 40 Data Presentations at ID Week 2017

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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 will provide 40 scientific data presentations on the company’s established and investigational infectious disease medicines and vaccines at ID Week 2017 in San Diego from Oct. 4-8. Antimicrobial research remains an important area of focus at Merck, with ongoing clinical studies in antibiotic, antiviral and antifungal medicines; adult and pediatric vaccines; and medicines for HIV and HCV.

“At Merck, we remain deeply committed to developing medicines and vaccines that help to prevent and treat serious infectious diseases to help address some of the most pressing public health threats in the world today,” said Dr. Joan Butterton, executive director and section head for antibacterials/CMV, infectious disease clinical research, Merck Research Laboratories. “We also continue to collaborate with researchers, clinicians and other stakeholders worldwide to provide important surveillance data and to advocate for antimicrobial stewardship.”

Presentations at ID Week 2017 will include new data analyses from the pivotal Phase 3 clinical study of letermovir, Merck’s investigational antiviral medicine for prophylaxis of cytomegalovirus (CMV) infection or disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT).

Results from a Phase 3 study of V212, Merck’s investigational vaccine for herpes zoster, in autologous HSCT recipients will be discussed during an oral presentation at the meeting.

Researchers also will present real-world susceptibility and clinical use data, as well as data on the in vitro activity of ZERBAXA. ZERBAXA® 1.5 g (ceftolozane 1 g and tazobactam 0.5 g) 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.

Other studies to be presented include in vitro data collected as part of the SMART (Study for Monitoring Antimicrobial Resistance Trends) surveillance program. SMART was initiated by Merck in 2002 to monitor the in vitro susceptibility of clinical isolates to several commonly used antibiotics in different regions of the world to monitor changing trends in antibiotic susceptibility. Bacterial samples have been collected and characterized from patients with intra-abdominal, urinary tract and lower-respiratory tract infections.

Select data presentations at ID Week 2017 include:

**Letermovir**
- A Mortality Analysis of the Cytomegalovirus (CMV) Infection Letermovir Prophylaxis Trial in CMV-
Seropositive Recipients of Allogeneic Hematopoietic Cell Transplantation (HCT), P. Ljungman (Poster 1029, 12:30 - 2:00 p.m. PT, Friday, Oct. 6, Hall CD)

- Cost of Hematopoietic Stem Cell Transplant and Cytomegalovirus Related Complications in a Large Inpatient Claims Database, J. Schelfhout (Poster 2436, 12:30 - 2:00 p.m. PT, Saturday, Oct. 7, Hall CD)

Merck Vaccines

- Immunogenicity of Inactivated Varicella Zoster Vaccine (ZVIN) in Autologous Hematopoietic Stem Cell Transplant (auto-HSCT) Recipients, M. Boeckh (Oral Abstract 1818, 10:45 a.m. PT, Saturday, Oct. 7, Room: 07AB)

ZERBAXA (ceftolozane and tazobactam)

- Real World Analysis of Prescribing Patterns and Susceptibility of Ceftolozane/tazobactam (C/T) Treatment using an Electronic Medical Record (EMR) Database in the United States, J. Pogue (Poster 797, 12:30 - 2:00 p.m. PT, Thursday, Oct. 5, Hall CD)

- Real World Evaluation of Ceftolozane/tazobactam Use and Clinical Outcomes at an Academic Medical Center in Las Vegas, K. Leuthner (Poster 828, 12:30 - 2:00 p.m. PT, Thursday, Oct. 5, Hall CD)

- Antimicrobial Activity of Ceftolozane-Tazobactam Tested against Contemporary (2012-2016) Enterobacteriaceae and Pseudomonas aeruginosa Isolates by US Census Division, D. Shortridge (Poster 1216, 12:30 - 2:00 p.m. PT, Friday, Oct. 6, Hall CD)

- Activity of Ceftolozane-Tazobactam Against Global Pseudomonas Aeruginosa Isolates: SMART 2016, S. Lob (Poster 1244, 12:30 - 2:00 p.m. PT, Friday, Oct. 6, Hall CD)

For more information, including a complete list of presentation titles, please visit the ID week 2017 website at www.IDWeek.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 eight compounds in Phase 2/Phase 3 clinical trials for the potential treatment or prevention of infectious diseases.

About ZERBAXA (ceftolozane and tazobactam)

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 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 creatinine clearance (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 (ceftolozane and tazobactam) 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 more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. 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. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer’s disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

**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 2016 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).

Please see Prescribing Information for ZERBAXA (ceftolozane and tazobactam) at http://www.merck.com/product/usa/pi_circulars/z/zerbaxa/zerbaxa_pi.pdf