Merck Highlights Ongoing Commitment to Fighting Infectious Diseases with More than 30 Data Presentations at ID Week 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 will provide more than 30 scientific data presentations on the company's established and investigational infectious disease medicines and vaccines at ID Week 2016 in New Orleans from Oct. 26-30.

Researchers will present posters showing surveillance, clinical and updated data on the in vitro activity of ZERBAXA® (ceftolozane and tazobactam). 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.

Presentations for ZOSTAVAX® (Zoster Vaccine Live) will include a review of post-marketing safety reports after ten years of use worldwide, as well as an oral presentation from an ongoing real-world observational effectiveness study against post-herpetic neuralgia (PHN). ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older. ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia. ZOSTAVAX should not be used for prevention of primary varicella infection (Chickenpox). ZOSTAVAX was initially approved in May 2006 and subsequently licensed in more than 50 countries.

"For decades, Merck has played a significant role in vaccine and antimicrobial research and development," said Dr. Eliav Barr, senior vice president, global clinical development, infectious diseases and vaccines, Merck Research Laboratories. "Today, Merck is one of only a few large pharmaceutical companies to sustain a focus on developing anti-infective therapies and vaccines to address some of today's pressing health threats."

Select data presentations at ID Week 2016 include:

**ZERBAXA (ceftolozane and tazobactam)**
- Activity of Ceftolozane/Tazobactam and Comparators Tested against Carbapenem Non-susceptible *Pseudomonas aeruginosa* isolates from USA hospitals (Castanheira et al.) Poster Abstract Session #1023: Antibacterial Susceptibility Surveillance, Saturday, Oct. 29, Room: Poster Hall
- Ceftolozane/Tazobactam Activity Tested against Bacterial Bloodstream Isolates from Multiple Infection Sources (Duncan et al.), Poster Abstract Session #1824: Antibacterial Susceptibility Surveillance, Saturday, Oct. 29, Room: Poster Hall
- Pharmacokinetics and Safety of Ceftolozane/Tazobactam in Adolescents and Young Children with Proven or Suspected Gram-negative Infection (Larson et al.) Poster Abstract Session #1965: Antimicrobial Pharmacokinetics and Pharmacodynamics, Saturday, Oct. 29, Room: Poster Hall
- The Importance of Postmarking Surveillance in the Identification of Early Safety Signals of Medication Errors in Patients Receiving a New Combination Antibiotic (Marr et al.) Poster Abstract Session #1801: Antibacterial Susceptibility Surveillance, Saturday, Oct. 29, Room: Poster Hall

**ZOSTAVAX (Zoster Vaccine Live)**
- Effectiveness of Live Zoster Vaccine in Preventing Postherpetic Neuralgia (PHN) (Baxter et al.), Oral Abstract Session #128: Newer and Older Vaccines in Older Adults, Thursday, Oct. 27, 11:00 a.m. CT, Room: 388-390
- Zoster Vaccine Live: A Review of Nearly 10 Years of Post-marketing Experience (Willis et al.), Poster Abstract Session #714: Vaccines, Thursday, Oct. 27, Room: Poster Hall
- VZV Cell-Mediated Immunity 3 Years After The Administration Of Zoster Vaccine To Septuagenarians and Octogenarians Immunized 10 Years Previously (Weinberg et al.), Session: Poster Abstract Session #715: Vaccines, Thursday, Oct. 27, Room: Poster Hall

For more information, including a complete list of presentation titles, please visit the ID Week 2016 website at [http://www.idweek.org/](http://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 10 compounds in Phase 2/Phase 3 clinical trials for the potential treatment or prevention of infectious diseases.

About ZERBAXA (ceftolozane and tazobactam)

ZERBAXA 1.5g (ceftolozane 1g and tazobactam 0.5g) is an antibacterial combination product for intravenous infusion consisting of the cephalosporin-class 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

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 (ceftolozane and tazobactam) 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 ZOSTAVAX (Zoster Vaccine Live)

ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older. ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia. ZOSTAVAX should not be used for prevention of primary varicella infection (Chickenpox).

Select Safety Information about ZOSTAVAX

Vaccination with ZOSTAVAX does not result in protection of all vaccine recipients.

ZOSTAVAX is contraindicated in: persons with a history of anaphylactic or anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; persons with a history of primary or acquired immunodeficiencies; persons on immunosuppressive therapy; pregnant women or women of childbearing age.

A reduced immune response to ZOSTAVAX was observed in individuals who received concurrent administration of PNEUMOVAX® 23 (Pneumococcal Vaccine Polyvalent) and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks.

Serious vaccine-related adverse reactions that have occurred following vaccination with ZOSTAVAX include asthma exacerbation and polymyalgia rheumatica. Other serious adverse events reported following vaccination with ZOSTAVAX include cardiovascular events (congestive heart failure, pulmonary edema). Common adverse reactions occurring in ≥1% of vaccinated individuals during clinical trials include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.

Transmission of vaccine virus may occur between vaccinees and susceptible contacts.
Deferral should be considered in acute illness (for example, in the presence of fever) or in patients with active untreated tuberculosis.

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 and connect with us on Twitter, Facebook, 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. 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).

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


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