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FDA Approves Merck's ZINPLAVA™ (bezlotoxumab) to Reduce Recurrence of Clostridium difficile Infection (CDI) in Adult Patients Receiving Antibacterial Drug Treatment for CDI Who Are at High Risk of CDI Recurrence

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved ZINPLAVA™ (bezlotoxumab) Injection 25 mg/mL. Merck anticipates making ZINPLAVA available in first quarter 2017.

ZINPLAVA is indicated to reduce recurrence of *Clostridium difficile* infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. ZINPLAVA is not indicated for the treatment of CDI. ZINPLAVA is not an antibacterial drug. ZINPLAVA should only be used in conjunction with antibacterial drug treatment of CDI.

CDI is caused by bacteria that produce toxins, including toxin B. Symptoms of CDI include mild-to-severe diarrhea, abdominal pain and fever. The incidence of recurrent CDI is higher in certain patient populations, including people 65 years of age or older and those with compromised immune systems.

"For generations, Merck has been steadfast in its commitment to fighting infectious diseases - and that commitment continues today. ZINPLAVA is a human monoclonal antibody that binds to *C. difficile* toxin B and neutralizes its effects," said Dr. Nicholas Kartsonis, vice president of clinical development, infectious diseases, Merck Research Laboratories.

Selected safety information about ZINPLAVA

Heart failure was reported more commonly in the two Phase 3 clinical trials in ZINPLAVA-treated patients compared to placebo-treated patients. These adverse reactions occurred primarily in patients with underlying congestive heart failure (CHF). In patients with a history of CHF, 12.7% (15/118) of ZINPLAVA-treated patients and 4.8% (5/104) of placebo-treated patients had the serious adverse reaction of heart failure during the 12-week study period. Additionally, in patients with a history of CHF, there were more deaths in ZINPLAVA-treated patients [19.5% (23/118)] than in placebo-treated patients [12.5% (13/104)] during the 12-week study period. The causes of death varied, and included cardiac failure, infections, and respiratory failure. In patients with a history of CHF, ZINPLAVA (bezlotoxumab) should be reserved for use when the benefit outweighs the risk.

The most common adverse reactions occurring within 4 weeks of infusion with a frequency greater than placebo and reported in ≥4% of patients treated with ZINPLAVA and Standard of Care (SoC) antibacterial drug therapy vs placebo and SoC antibacterial drug therapy included nausea (7% vs 5%), pyrexia (5% vs 3%) and headache (4% vs 3%).

Serious adverse reactions occurring within 12 weeks following infusion were reported in 29% of ZINPLAVA-treated patients and 33% of placebo-treated patients. Heart failure was reported as a serious adverse reaction in 2.3% of ZINPLAVA-treated patients and 1.0% of placebo-treated patients.

In ZINPLAVA-treated patients, 10% experienced one or more infusion specific adverse reactions compared to 8% of placebo-treated patients, on the day of or the day after, the infusion. Infusion specific adverse reactions reported in ≥0.5% of patients receiving ZINPLAVA and at a frequency greater than placebo were nausea (3%), fatigue (1%), pyrexia (1%), dizziness (1%), headache (2%), dyspnea (1%) and hypertension (1%). Of these patients, 78% experienced mild adverse reactions, and 20% of patients experienced moderate adverse reactions. These reactions resolved within 24 hours following onset.

As with all therapeutic proteins, there is a potential for immunogenicity following administration of ZINPLAVA. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to bezlotoxumab in two Phase 3 studies with the incidence of antibodies in other studies or to other products may be misleading. Following treatment with ZINPLAVA in these two studies, none of the 710 evaluable patients tested positive for treatment-emergent anti-bezlotoxumab antibodies.

About bezlotoxumab

Bezlotoxumab was developed by researchers at the University of Massachusetts Medical School's MassBiologics Laboratory in conjunction with Medarex (now part of Bristol-Myers Squibb), and was licensed to Merck in 2009.

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. 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).

Please see Prescribing Information for ZINPLAVA (bezlotoxumab) at http://www.merck.com/product/usa/pi_circulars/z/zinplava/zinplava_pi.pdf and

Patient Information for ZINPLAVA at http://www.merck.com/product/usa/pi_circulars/z/zinplava/zinplava_ppi.pdf

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