Merck’s Letermovir, an Investigational Antiviral Medicine for Prevention of Cytomegalovirus (CMV) Infection in Bone Marrow Transplant Recipients, Highly Effective Through Week 24 Post-Transplant in Pivotal Phase 3 Study

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Letermovir Prophylaxis Associated with Lower All-Cause Mortality Through Week 24 Post-Transplant

Company Plans to Submit New Drug Applications for Letermovir in U.S. and EU in 2017

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck & Co., Inc. (NYSE:MRK), known as MSD outside the United States and Canada, today announced results of the pivotal Phase 3 clinical study of letermovir, an investigational antiviral medicine for the prevention of clinically-significant cytomegalovirus (CMV) infection in adult (18 years and older) CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT), also known as bone marrow transplant (BMT). The study met its primary efficacy endpoint, showing that significantly fewer patients with undetectable CMV DNA at the start of study treatment developed clinically significant CMV infection through Week 24 post-HSCT (using a non-complete equals failure approach, in which patients who discontinued from the study prior to Week 24 post-transplant or had a missing outcome at Week 24 post-transplant were counted as failures). In the study, letermovir prophylaxis was associated with lower all-cause mortality. Based on these findings, Merck plans to submit regulatory applications for the approval of letermovir in the United States and European Union (EU) in 2017.

Results from the study were presented for the first time at the BMT Tandem Meetings, the combined annual meetings of the Center for International Blood & Marrow Transplant Research (CIBMTR) and the American Society for Blood and Marrow Transplantation (ASBMT), in Orlando, Fla., Feb. 22-26.

“These results showed that letermovir prophylaxis beginning after HSCT and continuing through Day 100 post-transplant significantly reduced CMV infection requiring preemptive antiviral therapy through Week 24 post-transplant,” said Dr. Francisco M. Marty, associate professor of medicine at Harvard Medical School and attending physician in transplant and oncology infectious diseases at Dana-Farber Cancer Institute and Brigham and Women’s Hospital, who presented the data. “In this study, letermovir was associated with lower all-cause mortality. Based on these findings, letermovir as primary prophylaxis of CMV infection represents a potential new strategy for the prevention of CMV in this high-risk patient population.”

CMV is the most common clinically significant viral infection in allogeneic HSCT recipients. HSCT is a medical procedure in the field of hematologic oncology, most often performed for the treatment of patients with certain cancers of the blood or bone marrow, such as leukemia and lymphoma. While
and commercialize letermovir from a subsidiary. Letermovir also has been granted Fast Track designation by the FDA. Health, Labour and Welfare for the European Medicines Agency, the U.S. Food and Drug Administration.

Letermovir has no activity against other viruses. Letermovir has been granted orphan designation by the European Medicines Agency, the U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare for the prevention of CMV infection and disease in at-risk populations. Letermovir also has been granted Fast Track designation by the FDA.

About letermovir

Letermovir was not associated with myelotoxicity or nephrotoxicity.
About CMV infection

CMV is a common virus that infects people of all ages. Many adults in the United States are CMV seropositive, meaning they have CMV antibodies in their blood, indicating a previous exposure or primary infection to CMV. People with normal immune systems rarely develop CMV symptoms after initial infection, with the virus typically remaining inactive or latent in the body for life. A weakened immune system may give the virus a chance to reactivate, potentially leading to symptomatic disease or a secondary infection due to other pathogens. CMV disease can lead to end-organ damage, including gastrointestinal tract disease, pneumonia or retinitis. Transplant recipients who develop CMV infection post-transplant are at increased risk for injury to a transplanted organ. In severely immunocompromised patients, CMV infection can be life-threatening.

About Merck

For over a century, 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](http://twitter.com), [Facebook](http://facebook.com), [YouTube](http://youtube.com) and [LinkedIn](http://linkedin.com).

Forward-Looking Statement

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)).

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