



## News Release

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### FOR IMMEDIATE RELEASE

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### **Merck Initiates Phase 3 Study of Letemovir, an Investigational Antiviral for Prevention of Cytomegalovirus (CMV) Infection in High-Risk Bone Marrow Transplant Patients**

WHITEHOUSE STATION, N.J., July 24, 2014 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the first patient has been enrolled in a global Phase 3 clinical study of letemovir (MK-8228), an investigational antiviral agent. The multicenter, randomized, placebo-controlled study will evaluate the efficacy and safety of letemovir for the prevention of clinically-significant cytomegalovirus (CMV) infection in adult (18 years and older) CMV-seropositive recipients of allogeneic hematopoietic stem cell transplants.

“There remains a need for additional therapeutic options in the prevention of CMV infection in high-risk patients,” said Dr. Michele Trucksis, executive director, Infectious Diseases, Merck Research Laboratories. “Merck is pleased to initiate this global Phase 3 study with letemovir.”

“This study marks a very important step in the development of letemovir and for AiCuris as licensor of this compound,” said Prof. Helga Rübsamen-Schaeff, CEO of AiCuris. “We are very excited to have reached this stage and look forward to the results.”

In the study, letemovir will be administered once daily, either as an oral tablet or IV formulation, for 14 weeks after transplant. The dose will be 240 mg once daily for participants receiving concomitant cyclosporin A and 480 mg once daily for participants not receiving cyclosporin A. The primary outcome measure of the study will be the percentage of participants with clinically-significant CMV infection through 24 weeks after transplant who were administered letemovir compared to placebo.

Merck expects approximately 540 patients will be enrolled in the study at more than 70 centers in 20 countries, including the United States. The estimated study completion date is July 2017.

To learn more about the study, please contact Merck at 1-888-577-8839 or visit [www.merck.com/clinical-trials](http://www.merck.com/clinical-trials). Additional details can also be found online at [www.clinicaltrials.gov/ct2/show/NCT02137772](http://www.clinicaltrials.gov/ct2/show/NCT02137772).

### **About letermovir**

Letermovir is an investigational once-daily antiviral agent under development for the prevention of human CMV infection. It is derived from a novel chemical class (quinazolines) and is designed to inhibit the human CMV viral terminase. Letermovir has been granted Orphan Product Designation by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for the prevention of CMV viremia and disease in at-risk populations and also has been granted Fast Track Status by the FDA.

Under an agreement signed in 2012, Merck (through a subsidiary) purchased worldwide rights to develop and commercialize letermovir from AiCuris GmbH & Co KG ([www.aicuris.com](http://www.aicuris.com)).

### **About CMV**

CMV is widely spread in the human population and can cause severe, life-threatening infections in cases of immune incompetency or immune deficiency, such as, for example, in transplant recipients. CMV infection is characterized by fever, leukopenia (very low white blood cell count) and thrombocytopenia (very low platelet numbers) with or without specific organ dysfunction. Two main strategies to prevent CMV infection in transplant recipients at risk have been adopted: anti-CMV drug prophylaxis or surveillance and pre-emptive treatment of transplant recipients with evidence of CMV viremia.

### **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside of the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care 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 healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#).

### **Forward-Looking Statement**

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These

statements are based upon the current beliefs and expectations of Merck'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; Merck'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 Merck patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck 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 Merck's 2013 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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