

## **Approval of MSD's PREVYMIS™ (letermovir) by the European Commission triggers the next EUR 30 million milestone payment for AiCuris**

- **EC approval allows for MSD to market this innovative product across Europe**
- **AiCuris to receive next milestone payment of 30 million EUR**
- **AiCuris focused on advancing its pipeline of innovative candidates within the anti-infective field**

**Wuppertal, Germany, January 31, 2018** - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that the European Commission (EC) on Jan. 8, 2018 granted marketing authorization to MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA), for PREVYMIS™ (letermovir) for prophylaxis (prevention) of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). EC approval allows for marketing in all 28 European Union (EU) member states, as well as European Economic Area members, Iceland, Liechtenstein and Norway. The launch in Germany is planned in February.

PREVYMIS™ is a first-in-class non-nucleoside CMV inhibitor acting via a novel mechanism of action that was successfully developed by AiCuris up to clinical phase 2b and afterwards subsequently licensed to MSD in 2012. MSD has worldwide rights for development and commercialization of PREVYMIS.

Under the terms of the agreement with MSD, AiCuris receives milestone payments as well as royalties on net sales. The EU approval triggers a milestone payment to AiCuris in the amount of 30 million Euros on top of the 105 million Euro milestone payment received already following the approval by the U.S. Food and Drug Administration (FDA) in November 2017.

“We are delighted that PREVYMIS™ has also been approved in the EU soon after the positive decision by the FDA at the end of last year. This approval enables our partner MSD to launch this important new approach to prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients undergoing allogeneic hematopoietic stem cell transplantation across Europe. For AiCuris, the EU approval triggers a major milestone payment, and we will use these funds to support our research and development to find more solutions to fight other challenges in treating infectious diseases,” said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. “It is very gratifying to see that a novel drug acting via a new mode of action initially developed at AiCuris now helps to prevent CMV reactivation and disease in this highly vulnerable patient population,” added Prof. Helga Rübsamen-Schaeff, founding CEO and Chair of the Scientific Advisory Board of AiCuris.

### **About PREVYMIS™ (letermovir)**

PREVYMIS is a member of a new class of non-nucleoside CMV inhibitors (3,4 dihydro-quinazolines) and inhibits viral replication by specifically targeting the viral terminase complex. Cross resistance is not likely with drugs outside of this class. PREVYMIS is fully active against viral populations with substitutions conferring resistance to CMV DNA polymerase inhibitors. These DNA polymerase inhibitors are fully active against viral populations with substitutions conferring resistance to

PREVYMIS. PREVYMIS has no activity against other viruses. PREVYMIS has been granted orphan designation for the prevention of CMV disease in at-risk populations in the U.S., EU and Japan.

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

### **About CMV and Treatment**

CMV is a common virus that infects people of all ages. Many adults are CMV seropositive, meaning they have CMV antibodies in their blood, indicating a previous exposure to or primary infection with 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 transplant failure and death. CMV prophylaxis with certain existing antivirals has been associated with drug-specific effects, including myelosuppression and renal toxicity, in HSCT recipients.

### **About AiCuris Anti-infective Cures GmbH**

AiCuris was founded in 2006 as a spin-off from Bayer and focuses on the discovery and development of drugs against infectious diseases. The Company's majority investor is SANTO Holding. The Company is developing drugs for the treatment of viruses such as human cytomegalovirus (HCMV), herpes simplex virus (HSV), hepatitis B virus (HBV), and adenoviruses. In the field of antibacterials, AiCuris seeks to develop innovative treatment options for life-threatening, (multidrug)-resistant hospital-treated pathogens.

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