

## **Approval of MSD's PREVYMIS™ (letermovir) in Japan triggers EUR 15 million milestone payment for AiCuris**

- **Approval allows MSD to market this innovative product in Japan**
- **AiCuris to receive next milestone payment of 15 million Euros, bringing the total amount of upfront and milestone payments received from MSD to 260 million Euros**

**Wuppertal, Germany, April 25, 2018** - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs targeting infectious diseases, announced today that in March the Japanese Ministry of Health, Labor and Welfare (MLHW) granted marketing authorization to MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA), for PREVYMIS™ (letermovir) for the prevention of cytomegalovirus (CMV) infections in allogeneic hematopoietic stem cell transplant (HSCT) patients.

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 the development and the commercialization of PREVYMIS™.

Under the terms of the agreement with MSD, AiCuris receives milestone payments as well as royalties on net sales. Marketing approval in Japan triggered a milestone payment in the amount of 15 million Euros, bringing the total amount of upfront and milestone payments AiCuris has received from MSD to 260 million Euros.

“We are delighted that PREVYMIS™ has additionally been approved in Japan after receiving a positive decision from the FDA and EMA”, said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. “This approval enables our partner MSD to commercialize this important new approach for the prevention of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients undergoing allogeneic hematopoietic stem cell transplantation in three major markets and we are looking forward to the next steps in the development of PREVYMIS™.

### **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 targeting infectious diseases. SANTO Holding is the Company's majority investor. PREVYMIS™ (letermovir), a first-in-class non-nucleoside cytomegalovirus (CMV) inhibitor acting via a novel mechanism of action that was licensed to MSD in 2012, received market approval in the U.S., Europa and Japan for prevention of CMV infections in adult recipients of an allogeneic hematopoietic stem cell transplant (HSCT). The Company develops 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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