

AiCuris Announces that its Licensee MSD Received Positive CHMP Opinion for PREVYMIS™ (Letermovir) Recommending Approval in Europe

- **At the end of last week, PREVYMIS received U.S. FDA market approval as first antiviral drug developed by AiCuris**

Wuppertal, Germany, November 13, 2017- AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA), received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending approval of PREVYMIS (letermovir) for prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant (HSCT) in Europe.

The CHMP positive opinion will be considered by the European Commission. If the European Commission affirms the CHMP opinion, it will grant a centralized marketing authorization with unified labeling that is valid in the 28 countries of the European Union (EU), as well as European Economic Area members, Iceland, Liechtenstein and Norway. MSD anticipates that the European Commission decision will be adopted within approximately two months.

PREVYMIS (letermovir) is a member of a new class of non-nucleoside CMV inhibitors developed by AiCuris through phase II studies prior to licensing the antiviral medicine to MSD in 2012.

"We are very pleased that our licensee MSD has received a positive opinion of the EMA's CHMP recommending the approval of PREVYMIS (letermovir) in Europe after we just saw the drug to receive U.S. market authorization by the FDA," said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. "Assuming approval by the European Commission, PREVYMIS (letermovir) will also be available in Europe - a further significant milestone for AiCuris - and a potential new option for appropriate patients undergoing allogeneic HSCT in Europe."

AiCuris is eligible for additional milestone payments following the approval in Europa as well as royalties on net sales.

Please follow the link to the news release issued today by MSD:

[http://www.mercknewsroom.com/news-release/corporate-news/.](http://www.mercknewsroom.com/news-release/corporate-news/)

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 existing drugs and PREVYMIS is fully active against viruses with substitutions conferring resistance to CMV DNA polymerase inhibitors. PREVYMIS has no activity against other viruses. Letermovir has market approval in the United States (U.S.) for the prevention of cytomegalovirus (CMV) infection and disease in adult allogeneic stem cell transplant patients, and has been granted orphan designation for the prevention of CMV disease in at-risk populations in EU and Japan, and is under accelerated review in these countries.

Under the terms of an agreement signed in 2012, MSD (through a subsidiary) purchased worldwide rights to develop and commercialize letermovir from AiCuris (www.aicuris.com).

About CMV infection

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.

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.

Contacts:

AiCuris Anti-infective Cures GmbH

Katja Woestehemke
Friedrich-Ebert-Str. 475/Geb. 302
42117 Wuppertal

Phone +49 202 317 63 0
Fax +49 202 317 63 1601
Email business@aicuris.com
Web www.aicuris.com

Media Relations

MC Services AG

Anne Hennecke
Kaiser-Friedrich-Ring 5
40545 Düsseldorf

Phone +49 211 529 252 22
Fax +49 211 529 252 29
Email anne.hennecke@mc-services.eu
Web www.mc-services.eu