

AiCuris' Licensee MSD Received U.S. FDA Approval of PREVYMIS™ (Letermovir) for Prevention of Cytomegalovirus (CMV) Infection and Disease in Adult Allogeneic Stem Cell Transplant Patients

- **First antiviral drug developed from AiCuris' pipeline to receive market approval**
- **PREVYMIS is the first new medicine for CMV infection approved in the U.S. in 15 years**
- **MSD has worldwide rights for development and commercialization of PREVYMIS**
- **AiCuris to receive milestone payments and royalties on sales**
- **AiCuris now focused on the further development of its pipeline with drugs against antiviral and antibacterial infections**

Wuppertal, Germany, November 09, 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 market approval by the U.S. Food and Drug Administration (FDA) for PREVYMIS (letermovir) once-daily tablets for oral use and injection for intravenous infusion. PREVYMIS is indicated for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

CMV is a common and potentially serious viral infection in allogeneic HSCT recipients. CMV-seropositive patients who undergo an HSCT are at high risk for CMV reactivation. Any level of CMV infection is associated with increased mortality in HSCT patients. CMV prophylaxis with certain existing antivirals has been associated with drug-specific effects, including myelosuppression and renal toxicity, in HSCT recipients.

PREVYMIS (letermovir) is a novel non-nucleoside CMV inhibitor developed by AiCuris through phase II studies prior to licensing the antiviral medicine to MSD in 2012.

"The approval of PREVYMIS by the FDA is a major milestone for our company and is a validation of our scientific approach and ability to successfully discover and develop innovative therapies that have the potential to truly make a difference in the treatment of patients suffering from infectious diseases," said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. "I am proud of the team at AiCuris, which has worked hard and with great commitment and dedication. With a pipeline of candidates in clinical development, including pritelivir, an innovative treatment for HSV infections, and a resistance-breaking antibiotic for Gram-negative bacterial infections, we believe we are well positioned to fight more challenges in treating infectious diseases."

"The approval of PREVYMIS in the U.S. under accelerated review reflects the major medical need for new therapeutic approaches for cytomegalovirus infections," said Prof. Helga Rübsamen-Schaeff, founding CEO and Chair of the Scientific Advisory Board of AiCuris. "When designing this drug, we targeted at a new mode of action with a novel chemical molecule. We are very proud that our work will now help prevent CMV infection and disease in adult seropositive patients undergoing allogeneic hematopoietic stem cell transplantation."

Dr. Thomas Strüngmann, who, together with his brother, Andreas, is the main investor in the Company, said: “The approval of PREVYMIS supports our long-term strategic investment approach, and it is gratifying to see that a project we invested in early on now will be able to positively affect the lives of patients. We congratulate the teams at both AiCuris and MSD on this achievement. We look forward to further successes as AiCuris advances other programs in its pipeline.”

Under the terms of the agreement with MSD, AiCuris is eligible for milestone payments as well as royalties on net sales. The FDA approval of PREVYMIS triggers a milestone payment to AiCuris in the amount of 105 million Euros. MSD has indicated that the company plans to launch PREVYMIS in December.

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

<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 been granted orphan designation for the prevention of CMV disease in at-risk populations in the U.S., EU and Japan, and is under accelerated review in the EU and Japan.

Under 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 in the United States 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 Woestenhemke
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