

AiCuris' licensee MSD says Letemovir, an investigational prophylactic therapy against HCMV in bone marrow transplant patients, met Primary Endpoint in Pivotal Phase III Study

Wuppertal, Germany, October 19, 2016 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced, in reference to a news release issued by licensee MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA), that letemovir, an investigational antiviral medicine, met the primary endpoint in the pivotal phase III study. The global, multicenter, randomized, placebo-controlled trial was designed to 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 an allogeneic hematopoietic stem cell transplant (HSCT). MSD will present top line results from this study at an upcoming scientific conference.

Since foundation in 2006, AiCuris has been developing letemovir through phase II studies prior to licensing the antiviral medicine to MSD in 2012. Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH comments: "The positive outcome of this study is an important milestone for our company. It's a long journey with many challenges to develop new drugs. Today's news validates our scientific expertise and our capabilities to discover and develop new therapies. These results make me proud of our team, which has worked hard for many years with great commitment and dedication and I am very thankful for the confidence our investors place in us."

Dr. Thomas Strüngmann, who, together with his brother has been the main investor in the Company, is very pleased with the AiCuris team about these positive results. "Taking such long term investment strategies is often considered risky. We look forward to further good news from the other projects of our Company's pipeline." Thomas wants also to take the opportunity to thank Bayer for the good long-term relationship and trust when he took over the anti-infective spin-out which became AiCuris.

Prof. Dr. Helga Rübsamen-Schaeff, the founding CEO of AiCuris Anti-infective Cures GmbH and current Chair of the Scientific Advisory Board, noted: "The letemovir program is a good example of our dedicated research and development strategy, which over many years was committed to finding novel mechanisms of action against CMV. This resulted in the innovative chemical molecule under investigation, letemovir, which targets the viral terminase protein. I am very happy that the pivotal phase III study with letemovir met its primary endpoint."

AiCuris received a €110 million upfront payment in 2012 under the licensing agreement with MSD, and under the terms of the agreement, will receive future payments if specific milestones are achieved as well as post approval and market launch royalty payments.

Please follow the link to the news release issued today by MSD: <http://www.mercknewsroom.com/news-release/corporate-news/merck-announces-pivotal-phase-3-study-letemovir-investigational-antivir>

About Letermovir

Letermovir is an investigational once-daily antiviral medicine under development for the prevention of CMV infection and disease. It is a member of a new class of non-nucleoside CMV inhibitors (3,4 dihydro-quinazolines) and inhibits viral replication by targeting the viral terminase complex. Letermovir has been granted orphan designation by the European Medicines Agency, the U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare for the prevention of CMV infection and disease in at-risk populations. Letermovir also has been granted Fast Track designation by the FDA.

In 2012, AiCuris granted worldwide rights to further develop and commercialize letermovir (AIC246) to MSD after successful completion of a clinical phase IIb trial.

About HCMV

The Human Cytomegalovirus (HCMV) is widely spread in the human population and represents an important pathogen for immunocompromised individuals. HCMV infection is characterized by fever, leucopenia (very low white blood cell count) and thrombocytopenia (very low platelet numbers) with or without specific organ dysfunction. Two main strategies to prevent HCMV infection have been adopted: anti-HCMV drug prophylaxis or pre-emptive treatment of transplant recipients who are at risk and have evidence of HCMV infection upon screening.

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 adenovirus. In the field of antibacterials, AiCuris seeks to develop innovative treatment options for life-threatening, (multidrug-)resistant hospital-treated pathogens. In 2012, AiCuris signed a license agreement with MSD, one of the largest agreements of its kind in the European biotech industry. The agreement covers the development and commercialization of novel drug candidates against HCMV. Letermovir, the most advanced compound under this agreement, met the primary endpoint in a pivotal phase III clinical trial in patients undergoing bone marrow transplantation.

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