# AiCuris Granted Fast Track Designation by U.S. FDA for Oral Pritelivir for Treatment of HSV Infections in Immunocompromised Adults

**Wuppertal, August 01, 2017** - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that the Company has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for oral pritelivir, AiCuris' lead candidate for the treatment of acyclovir-resistant mucocutaneous herpes simplex virus (HSV) infections in immunocompromised adults. Fast track is a process designed to facilitate the development, expedite the review and accelerate the approval process of drugs to treat serious conditions and fill an unmet medical need, with the purpose of getting important new drugs to patients sooner.

Oral pritelivir, a small molecule helicase-primase inhibitor with a novel mode of action, is currently in a clinical phase 2 study, called PRIOH-1, in the U.S. to evaluate the product candidate's efficacy and safety compared to i.v. foscarnet, a virostatic agent which is used mainly for the treatment of herpes viruses resistant to other antiviral drugs. In a prior phase 2 study, oral pritelivir showed to significantly improve the suppression of viral shedding compared to the current standard of care for genital HSV-2 infections, the nucleoside analog valacyclovir. The results of this study were published in the *Journal of the American Medical Association* *(JAMA)* earlier this year.

"The decision by the FDA to grant fast track designation to oral pritelivir underscores that our product might fill the major need for innovative, more efficacious therapies for immunocompromised patients with HSV infections that have become resistant to standard treatments," said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. "Fast Track designation should enable us to further accelerate the development of pritelivir, which already has shown that it may have the potential to become an important alternative to current treatments as a highly effective and convenient oral therapy."

## About Fast Track Designation

The FDA's Fast Track program was designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need to make important new drugs available to patients sooner. The designation enables early and frequent communication between the FDA and a product sponsor throughout the drug development and review process. Through the Fast Track program, a product may be eligible for Accelerated Approval and priority review if the requisite criteria are met and may also be eligible to submit completed sections of the New Drug Application (NDA) on a rolling basis before the complete application is submitted. For more information about Fast Track, please visit: https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm.

## About Pritelivir

Pritelivir is an innovative, highly active and specific inhibitor of herpes simplex virus (HSV). Derived from a novel chemical class (thiazolylamides), pritelivir is active against both types of herpes simplex virus (HSV-1 and HSV-2), causing labial and genital herpes, and retains activity against viruses which have become resistant to marketed drugs. Pritelivir has a mode of action that is distinct from other antiviral agents currently in use for treating HSV infections (i.e., the nucleoside analogs acyclovir and its

prodrug valacyclovir as well as famciclovir, the prodrug of penciclovir). While nucleoside analogs terminate ongoing DNA chain elongation through inhibition of viral DNA polymerase, pritelivir prevents de novo synthesis of viral DNA through inhibition of the helicase-primase complex. In addition, it does not require activation within an HSV infected cell by viral thymidine kinase and is therefore also protective to uninfected cells.

Currently the Company is running two clinical development programs with pritelivir. The most advanced program, pritelivir (oral), showed superiority against standard treatment valacyclovir in a clinical phase 2 trial in patients with genital HSV-2 infection and is now in a phase 2 trial in immunocompromised patients whose HSV infections have become resistant to acyclovir. Pritelivir (topical), designed for the treatment of recurrent labial herpes (mainly HSV-1), is about to complete a clinical phase 2 trial, following successful phase 1 results.

**About HSV**

Herpes simplex viruses are widespread (seroprevalence up to 100%, depending on geographic area and subpopulation) and are divided into herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2). Infections lead to lifelong persistence of the virus, with frequent and sometimes painful recurrences. While HSV-1 predominantly causes oral lesions (cold sores), HSV-2 manifests in the genital region and is mainly sexually transmitted. In immunocompromised patients, HSV can lead to serious complications. The negative stigma associated with genital herpes and visible facial lesions may cause psychological distress.

According to the World Health Organization (WHO), an estimated 417 million people aged 15-49 (11%) worldwide were living with genital herpes caused by HSV-2 in 2012. Prevalence of HSV-2 infection was estimated to be highest in Africa (31.5%), followed by the Americas (14.4%). It was also shown to increase with age, although the highest numbers of newly infected people were adolescents.

**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. In 2012, AiCuris signed a license agreement with Merck & Co (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 3 clinical trial in patients undergoing bone marrow transplantation.

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