AiCuris Announces Final Patient Treated in Clinical Phase 2 Trial (LipP 1) with Topical Pritelivir for the Treatment of recurrent Labial Herpes

Wuppertal, Germany, August 23, 2017- AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that the final patient has been treated in the clinical phase 2 efficacy and safety study LipP 1 evaluating topical pritelivir, a small molecule helicase-primase inhibitor, for the treatment of recurrent labial herpes (cold sores), the most evident sign of a herpes simplex virus type 1 (HSV-1) infection.

LipP 1 (AIC316-02-II-01), a double-blind, placebo and comparator controlled, phase 2 trial has been designed to investigate the efficacy and safety of pritelivir 5% ointment for the treatment of recurrent episodes of labial herpes in adults when applied for four days. Over the course of the study, 362 patients reporting at least four recurrences of labial herpes in the previous year have been randomly assigned to one of the three treatment arms to receive either, pritelivir 5% ointment, placebo or Zovirax® Cream. The patients were enrolled between December 2016 and June 2017 at ten sites in the U.S. After reaching the target number of 71 patients treated with an active cold sore outbreak in each treatment arm, this study has been completed. First results from this study are expected for the fourth quarter of 2017.

"Infections with herpes simplex virus, leading to labial herpes and painful mouth blisters and sores, are widespread and still today, there are only a few specific antiviral treatments available and current topical treatments are often ineffective," said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. "We strongly believe that topical pritelivir, with its novel mode of action, could become a highly effective, easy to use treatment for labial herpes and we are very much looking forward to receiving first results of this study later this year."

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), has clinically completed a 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 also cause psychological distress.

According to the WHO an estimated 3.7 billion people worldwide under the age of 50, or 67% of the population, were infected with HSV-1 in 2012. Prevalence of the infection was estimated highest in Africa (87%) and lowest in the Americas (40-50%).

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, incl. Letermovir, which recently met the primary endpoint in a pivotal phase 3 clinical trial in patients undergoing bone marrow transplantation.

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