AiCuris Initiates U.S. Clinical Phase 2 Trial with Oral Pritelivir for the Treatment of HSV Infections in Immunocompromised Adults

Wuppertal, May 09, 2017 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced the opening of the first site in its clinical phase 2 study, PRIOH-1, to evaluate the efficacy and safety of oral pritelivir, a small molecule helicase-primase inhibitor for the treatment of acyclovir-resistant mucocutaneous herpes simplex virus (HSV) infections in immunocompromised adults.

The PRIOH-1 study announced today is a multi-center, randomized, open label phase 2 trial designed to evaluate the efficacy and safety of oral pritelivir compared to i.v. foscarnet, a virostatic agent which is used mainly for the treatment of herpes viruses resistant to other antiviral drugs. Patients will be randomized (2:1) to receive either pritelivir or foscarnet for up to 28 days. The primary endpoint of the study which is planned to include a total of 30 patients at approx. 20 sites in the U.S. is time to lesion healing.

"There is a major need for safer, more effective treatment options for immunocompromised patients whose HSV infections have become resistant to acyclovir. Current last-resort therapies for these patients can lead to severe side effects, including renal failure" said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. "Pritelivir due to its novel mode of action provides an opportunity to significantly increase efficacy with a convenient oral treatment."

In a phase 2 study published earlier this year in the *Journal of the American Medical Association (JAMA)*, oral pritelivir was shown to improve significantly the suppression of viral shedding compared to the nucleoside analog valacyclovir, the current standard of care, for genital HSV-2 infections.

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 currently in 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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