

AiCuris Topical Pritelivir, a Highly Active Inhibitor for the Treatment of Herpes Simplex Virus, Achieves Primary Endpoint in Clinical Phase I Study

Wuppertal, August 23rd, 2016 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that pritelivir (one of its lead compounds), a small molecule helicase-primase inhibitor active against herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2), achieved the primary endpoint in a phase I trial for topical treatment of recurrent labial herpes (cold sores). In this trial with healthy volunteers, pritelivir 5% ointment did not show any cumulative irritation potential. This phase I trial is part of a second development program for pritelivir, after it has already shown superiority against standard treatment valacyclovir in a clinical phase II trial in patients with genital HSV-2 infection with oral treatment.

The randomized, single-center, controlled, within-subject comparison phase I trial (AIC316-02-I-01), conducted in the U.S., was designed to determine the local cumulative irritation potential of topical pritelivir on normal human skin in 46 male and female healthy volunteers under occlusive conditions. Each volunteer received daily pritelivir 5% ointment and in parallel three controls for 21 days on the back. The controls were: the vehicle ointment without pritelivir, saline as a negative control and 0.2% sodium lauryl sulfate (SLS) as a positive control. Application sites were assessed daily in a blinded manner by evaluators for dermal reactions using a visual skin irritation scoring system to rate the degree of erythema, edema and other signs of skin irritation. The trial showed that pritelivir 5% ointment had no cumulative irritation potential; as expected, the positive control SLS caused local irritation in all subjects.

“These phase I results, coupled with the preclinical results we have seen with topical pritelivir, are highly promising and strongly support the further development of topical pritelivir for recurrent labial herpes,” said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. “There remains a major unmet medical need to treat HSV-1 infections, such as labial herpes, as there are very few specific antivirals available and available topical treatments are often ineffective. Topical pritelivir, if proven safe and effective in further clinical testing, could be an important new treatment option for this very painful condition. We are looking forward to continued progress with this innovative approach and expect to start a clinical phase II proof of concept study in the U.S. 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, respectively, 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 analogues 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 virus 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 runs two clinical development programs with pritelivir. The most advanced program, **pritelivir (oral)**, showed superiority against standard treatment valacyclovir in a clinical phase II trial in patients with genital HSV-2 infection. **Pritelivir (topical)**, designed for the treatment of recurrent labial herpes (mainly HSV-1), has reported successful phase I clinical results.

About HSV

Herpes simplex viruses (HSV) 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 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, multi-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 of novel drug candidates against HCMV. Letermovir, the most advanced compound under this agreement, is currently in phase III clinical trials in patients undergoing bone marrow transplantation.

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