

PRESS RELEASE

AiCuris' novel HSV compound AIC316 shows efficacy in phase II

Wuppertal, July 18, 2011 – Phase II results for AiCuris' novel non-nucleosidic herpes simplex virus (HSV) inhibitor AIC316 reveal safety and efficacy in persons with genital herpes. The data were presented at the 19th ISSTD Meeting (International Society for Sexually Transmitted Diseases Research) in Quebec, Canada, by the coordinating investigator of the trial, Professor Anna Wald from the University of Washington and Fred Hutchinson Cancer Research Center in Seattle, USA,

156 HSV-2 positive participants (105 women and 51 men) were randomized between May 2010 and October 2010 at seven sites in the US. The goal of the trial was to compare the efficacy of four different doses of AIC316 (5, 25, and 75 mg once daily, or 400 mg once weekly) and placebo with respect to the suppression of HSV shedding. All participants received the study drug or placebo daily or weekly for 4 weeks.

AIC316 was safe and well tolerated at all doses administered and led to a significant reduction of viral shedding in a dose dependent manner. The strongest treatment effect was seen in the 400 mg once weekly and the 75 mg once daily dosing groups. Moreover, AIC316 led to a significant reduction of the amount of HSV found. This highly suppressive effect of AIC316 on viral replication also correlated with a significant clinical benefit: the proportion of days with reported genital lesions was reduced from 13,7 % to 1,1 %; the number of recurrences was substantially reduced as well.

"We are very pleased with these data as HSV therapy has not seen much innovation in more than a decade. Our data confirm an excellent antiviral efficacy in humans, a clear dose response and an overall good safety profile. The innovative trial design that used shedding was important to show clearly the benefit of our drug and identify doses for further development", says Prof. Helga Rübsamen-Schaeff, CEO at AiCuris. "The significant clinical benefit of reduced lesions and recurrences combined with a good safety profile are very encouraging for the further development of our drug" adds Dr. Marie-Paule Richard, CMO at AiCuris.

About HSV

Herpes simplex viruses (HSV) are widespread in the human population (seroprevalence up to 100 %, depending on geographic area and population), and are divided into herpes

simplex virus type 1 (HSV-1) and type 2 (HSV-2). While HSV-1 predominantly causes oral lesions (cold sores), HSV-2 manifests in the genital region and is mainly transmitted sexually. However, the past decade has seen an increase in HSV-1 genital infections, which now account for at least half of first episodes of genital herpes in some countries. Both oral and genital herpes are generally self-limiting but can recur frequently. HSV infections have also been associated with a three-fold increase in the risk of sexually acquired HIV. In immunocompromised persons large and painful ulcerations may result, and newborns infected with HSV are at risk of dying from the infection. Currently available herpes drugs share the same mode of action, i.e. inhibition of a viral enzyme, the DNA polymerase. They are similar in efficacy and may exhibit cross-resistance. Unlike these widely used current drugs, AIC316 acts by a separate and unique mechanism of viral inhibition and hence is also active against resistant virus.

About AiCuris

AiCuris GmbH & Co KG, is a privately held company located in Wuppertal, Germany. It is devoted to research and clinical development of novel, resistance-breaking drugs for the treatment of HCMV, Herpes, Hepatitis B, HIV and Hepatitis C as well as resistant Gram positive and Gram negative bacterial infections in hospitals. Furthermore, the portfolio comprises two immune modulators.

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