

## PRESS RELEASE

### **AiCuris successfully completed phase I for novel herpes compound**

**Wuppertal, November 6, 2009** – AiCuris today announced that three phase I studies with its novel compound AIC316 for the treatment of herpes simplex virus infections have been completed successfully. AIC316 is a first-in-class helicase-primase inhibitor.

More than 120 volunteers were exposed in single-dose, multiple-dose and food interaction studies. The drug was generally well-tolerated and showed high and long-lasting exposures in the human subjects.

"We now have all data to enter into phase II, and we are pleased to have obtained evidence for favourable pharmacokinetics of AIC316 which will allow a convenient dosing regimen in patients", said Prof. Helga Rübsamen-Schaeff, CEO of AiCuris. "According to AiCuris' strategy to focus on antibacterial and antiviral substances with resistance-breaking properties only, AIC316 represents a novel chemical class and has a mode of action which is different from the drugs currently available for the treatment of herpes simplex."

"From what we have observed so far, our compound has the potential to become a next-generation therapy for episodic and suppressive treatment of herpes simplex virus infections", explained Dr. Manickam Rangaraju, CMO of AiCuris. "With current herpes therapies, suppression of viral shedding in genital herpes and hence prevention of disease transmission is not sufficiently achieved. Furthermore, resistance may develop upon long-term use in immune compromised individuals. Therefore, there is a need for more efficacious, well-tolerated as well as resistance-breaking treatment options. Such drugs should also offer benefits with respect to ease of administration."

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#### **About herpes**

Herpes simplex viruses (HSV) are widespread in the human population (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). While HSV-1 predominantly causes oral lesions (cold sores), HSV-2 manifests in the genital region and is mainly being 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 labial and genital herpes are generally self-limiting and can recur frequently. HSV infections have also been associated with a three-fold increase in the risk of sexually acquired HIV. In

immune compromised individuals large and painful ulcerations may result, and newborns infected with HSV are at risk of developing herpes encephalitis. Most of the current herpes drugs inhibit a specific viral enzyme, the DNA polymerase. They share the same mode of action and are therefore very similar in their efficacy. Also, cross-resistance can occur.

### **About AiCuris**

AiCuris GmbH & Co KG (the name is derived from: anti infective cures), is a spin-out from Bayer HealthCare. It is a privately held company located in Wuppertal, Germany. AiCuris is devoted to research and clinical development of novel, resistance-breaking drugs for the treatment of Cytomegalovirus (HCMV), Herpes Simplex, 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.

### **Contact:**

AiCuris GmbH & Co. KG  
Sandra Wildhagen  
Friedrich-Ebert-Str. 475/Building 302  
42117 Wuppertal

Phone +49 202 317 63 0  
Fax +49 202 317 63 1601  
E-Mail [press@aicuris.com](mailto:press@aicuris.com)  
Web [www.aicuris.com](http://www.aicuris.com)