PRESS RELEASE

AiCuris promising drugs against Herpes simplex (AIC316) and Human Cytomegalovirus (Letermovir, AIC246) in preparation for phase III:

Key note at International Herpesvirus Workshop Calgary, Canada

Wuppertal, August 6, 2012 –
AiCuris will present at the International Herpesvirus Workshop in Calgary, Canada, on its two front-running compounds targeting herpes viruses, on August 8th 2012 at 2 pm, in the plenary session on interventions.
AIC 316 and Letermovir (AIC246) have successfully completed double-blinded, placebo-controlled phase II dose-ranging trials, meeting the primary and secondary study endpoints with excellent and dose-proportional efficacy and a good safety profile. Both compounds can be administered orally once daily for prophylaxis and suppression of the virus. The long halflife of AIC316, in addition, likely allows dosing only one pill per herpes episode.

AIC316 and Letermovir are non-nucleosidic drugs and act via a novel mode of action targeting viral enzymes different from polymerases: AIC316 is an inhibitor of the viral helicase-primase of Herpes simplex 1 and -2 virus, while Letermovir inhibits the viral terminase of HCMV. Based on these novel modes of action the compounds offer significant benefits over existing polymerase-inhibitors:
- AIC316 does not need to be activated inside the cell by a viral enzyme and thus protects uninfected cells from infection. In addition, the very long halflife of the compound allows to protect uninfected cells over extended periods of time, in contrast to the nucleoside analogues in the market. These features result in fast onset of action and powerful suppression of viral shedding.

- Letermovir, by addressing a target at a critical step of the virus life cycle, exhibits a very steep dose-response curve and is able to suppress high viral loads. This has led to highly significant suppression of HCMV in the phase II trial, when the drug was given prophylactically. In addition, as the target of Letermovir does not exist in the human body there is no target-related toxicity as is seen with the marketed nucleoside analogues and the drug has a very good safety profile.

“Given the fact that there has been no innovation in the treatment of Herpes or Human Cytomegalovirus for years, we are extremely proud of having created two very innovative drugs, which are in preparation for phase III and which hopefully will make a major
difference for patients suffering from these viral infections and disease conditions. Based on their novel modes of action they will also be active against viruses which have acquired resistance against the marketed drugs”, says Prof. Helga Rübsamen-Schaeff, CEO at AiCuris.

Regarding AIC316 AiCuris' project leader Dr. Alexander Birkmann adds: “The benefit of strongly suppressed viral shedding combined with protection of uninfected cells, may even reduce the viral burden in Herpes patients treated long term or repeatedly over time and may reduce the frequency and severity of outbreaks, which is not achievable by present drugs.”

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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 or suffering permanent disabilities from the infection. Currently available therapies share the same mode of action and are similar in their efficacy, whilst also exhibiting possible cross-resistance. Unlike most of the current herpes drugs, which inhibit a specific viral enzyme, the DNA polymerase, AIC316 acts by a separate and unique mechanism of viral inhibition and hence is also active against resistant viruses.

About Human Cytomegalovirus (HCMV)
Human cytomegalovirus (HCMV), a beta herpes virus, represents an important pathogen for immune compromised individuals. It is the most common virus pathogen in bone marrow and solid organ (kidney, heart, liver, lung and pancreas) transplant recipients. HCMV is the major cause of morbidity and mortality during the first six months after transplantation.

HCMV disease is characterised by fever, leucopenia (very low white blood cells) and thrombocytopenia (very low platelet numbers) with or without specific organ dysfunction. Two main strategies to prevent HCMV disease have been adopted: anti-HCMV drug prophylaxis or pre-emptive treatment of transplant recipients who are at risk or have evidence of HCMV infection upon screening.

Besides transplant recipients, newborn children are highly threatened by HCMV infections. The infection can be acquired before, during or after birth and can lead to severe
neurological damage or death. Because of the side effects of presently available drugs against HCMV, it is nearly impossible to treat these children. Neither can pregnant women with an active HCMV infection be treated.

Patients with AIDS might suffer from HCMV infection or disease, once HIV has caused severe immune deficiency. In these patients, the virus might affect various organs and may e.g. lead to blindness or life threatening pneumonia. Thanks to HAART, AIDS cases with HCMV disease have become rare in the Western world. But in countries where access to anti-HIV therapy is not freely available such HCMV infections are more common.

Increasing evidence is accumulating that even subclinical HCMV replication may be harmful, as HCMV is a virus, which is immune-suppressive on its own. For HIV-infected individuals several recent investigations showed that even when HIV is well-suppressed by HAART, the patients may not be able to control HCMV very well and may, as a consequence, suffer from a chronic and deleterious inflammation.

Similarly, HCMV also appears to pose a risk to patients under intensive care (e.g. after heart attack, suspected sepsis or burn). In this patient group, an active HCMV infection was found to be associated with increased time of hospitalisation and increased risk of death. Furthermore, in patients being treated for an auto-immune disease by the administration of immuno-suppressive agents, it has been observed that an opportunistic HCMV infection may occur.

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About AiCuris
AiCuris GmbH & Co KG, a spin-out from Bayer HealthCare, 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 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, one for auto-immune diseases, the other for hepatitis B/C and fibrosis.

Contact:
AiCuris GmbH & Co. KG
Katja Woestenhemke
Friedrich-Ebert-Str. 475/Building 302
42117 Wuppertal

Phone   +49 202 317 63 0
Fax      +49 202 317 63 1601
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