New Data on Letermovir (AIC246) presented at 51st ICAAC

Chicago, 17th September, 2011 - AiCuris today disclosed new data on its HCMV lead compound Letermovir (AIC246) presently completing phase IIb clinical testing at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago.

Positive Study Results from three Phase 1 trials including healthy volunteers and investigations in transplant patients on the drug-drug interaction potential of Letermovir (AIC246) with immunosuppressive drugs were presented by Dr. Holger Zimmermann, CSO of AiCuris, during a poster presentation.

Letermovir (AIC246) is a novel small molecule inhibitor targeting cytomegalovirus infections currently in phase IIb testing in transplanted patients and as such co-administered with immunosuppressive drugs.

AIC246 (Letermovir) was initially tested in healthy volunteers to study drug-drug interactions with Midazolam, Tacrolimus and Cyclosporine showing moderate increases in the co-administered drug concentrations. More importantly, in a phase IIa trial in patients receiving multiple medications no significant effect was seen and dose adjustments were within the normal range. This was confirmed in a patient treated for HCMV disease where no adjustment of the co-administered Tacrolimus in the presence of 240 mg Letermovir (AIC246) was needed.

“The data presented today showed important results indicating that Letermovir (AIC246) has no clinically significant impact on these immunosuppressive drugs in transplanted patients,” said Helga Rübsamen-Schaeff, CEO of AiCuris.

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About HCMV

Human cytomegalovirus (HCMV), a beta herpes virus, represents an important pathogen for immune compromised individuals. It is the most common virus pathogen in solid organ transplant recipients (kidney, heart, liver, lung and pancreas) as well as bone marrow transplant recipients and is furthermore 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: prophylaxis of organ recipients with antiviral agents, or pre-emptive treatment of organ recipients, who develop evidence of CMV infection during routine 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 effect profiles of presently available drugs against HCMV, none has been licensed to treat these children. Neither can pregnant women with an active HCMV infection be treated.

Patients with AIDS may suffer from an HCMV infection, if HIV has caused a massive immune deficiency. In these patients, the virus might lead to blindness as well as to life threatening pneumonia. Thanks to HAART, severe AIDS cases have become rare in the Western world. But in countries, where not everybody has access to anti-viral medication, these consequences are more common.

In addition, recent evidence shows that even when HIV patients are well-suppressed by HAART they may not be able to control HCMV adequately and may, as a consequence, suffer from a chronic and deleterious inflammation caused by HCMV.

Apart from immune compromised patients, another group of individuals may also become affected by HCMV: An American research group found that HCMV also poses 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 associated with longer hospital detention and death. Increasing evidence is accumulating that even a subclinical HCMV replication may be harmful, due to HCMV acting as an immune-suppressive agent.

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About AiCuris

AiCuris GmbH & Co KG is a privately held company located in Wuppertal, Germany. It is devoted to research and clinical development of innovative and 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.

Contact:

AiCuris GmbH & Co. KG Phone: +49 202 317 63 1176
Katja Woestenhemke Fax +49 202 317 63 1177
Friedrich-Ebert-Str. 475/Building 302 E-mail press@aicuris.com
42117 Wuppertal Internet www.aicuris.com