

PRESS RELEASE

AiCuris' novel HCMV compound shows good tolerability and efficacy in phase II study

Wuppertal, September 15, 2009 – AiCuris presented first phase II data for its novel non-nucleosidic HCMV inhibitor at the 49th ICAAC (“Interscience Conference on Antimicrobial Agents and Chemotherapy”) meeting in San Francisco demonstrating a good tolerability of AIC246 in transplant recipients and an efficacy comparable to standard of care.

In this phase II study, a total of 27 patients (26 kidney transplant recipients, 1 bone marrow transplant recipient) were randomized to receive two different doses of AIC246 per day or standard of care (Valganciclovir) after having developed HCMV viraemia post transplantation (pre-emptive treatment). Objectives were to study the decline in HCMV DNA load after a 14-day treatment, the tolerability and the pharmacokinetics of the drug in transplant recipients.

The drug was generally very well tolerated. There was no serious adverse event attributed to the drug. Within the limits of the small sample size, comparable efficacy was observed in the standard of care group and the two regimens of AIC246. The new HCMV inhibitor has also shown efficacy in the treatment of one patient who had developed viraemia due to multi-resistant (Ganciclovir, Foscarnet and Cidofovir) HCMV.

"We are pleased to have confirmed the good tolerability of AIC246, which we have already seen in more than 200 healthy volunteers, in patients and to have confirmed that AIC246, which was designed to overcome resistance, has shown activity even against multi-resistant HCMV in the clinic", says Prof Helga Rübsamen-Schaeff, CEO of AiCuris.

The trial has further shown that co-administration of AIC246 and immuno-suppressants could be handled in an easy and safe manner.

About HCMV

Human cytomegalovirus (HCMV), a beta herpes virus, represents an important pathogen for immune compromised individuals, as well as the major infectious cause of birth defects. It is the most common virus pathogen in solid organ transplant recipients (kidney, heart, liver, lung and pancreas) as well as for bone marrow transplant recipients and is the major cause of morbidity and mortality during the first six months after transplantation. CMV 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 CMV disease have been adopted: prophylaxis of organ recipients with antiviral agents, or pre-emptive treatment of solid organ recipients, who develop evidence of CMV infection during routine screening.

About AiCuris

AiCuris GmbH & Co KG, a spin-out from Bayer HealthCare, 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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