

PRESS RELEASE

AiCuris receives Orphan Drug Designation for its innovative phase II drug AIC246 for the prevention of HCMV disease

Wuppertal, 21th April, 2011 - AiCuris announced today that AIC246, the Company's inhibitor against the human cytomegalovirus HCMV, currently undergoing phase IIb testing, has been granted Orphan Drug designation for the prevention of HCMV disease. This decision was made by the European Commission following the positive opinion released by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

"We are very pleased to have received Orphan Drug status for AIC246. This decision by the authorities confirms our view that this innovative drug will be of significant benefit to those at risk of developing HCMV disease which is a very serious and life-threatening condition. The Orphan Drug status will also support AiCuris in the development of AIC246 as it gives easier access to scientific support by the agencies, e.g. by advice during the product development phase" commented AiCuris CEO, Prof. Rübsamen-Schaeff.

"Clinicians and patients need an effective and safe means to treat HCMV with well tolerated drugs. Current treatment options suffer from dose-limiting toxicities and offer very few solutions to advance patient care, leaving these patients with a deteriorating disease condition, in particular after development of drug resistance. We believe that we are developing a therapy that will prove to be both effective and safe and at the same time remains efficacious, if resistance has developed against the marketed drugs", added AiCuris CSO, Dr. Holger Zimmermann. "This will provide the patient with a much better treatment outcome."

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 the major cause of morbidity and mortality during the first six months after transplantation.

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 a HCMV infection if HIV has already 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 very well 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, as HCMV is immune-suppressive.

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 organ recipients, who develop evidence of CMV infection during routine screening.

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.

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