

**PRESS RELEASE**

## **AiCuris receives Orphan Drug Designation for Letermovir (AIC246) from FDA**

**Wuppertal, 5<sup>th</sup> January, 2012** - AiCuris announced today that AIC246 (Letermovir), the Company's novel inhibitor against the human cytomegalovirus HCMV, has been granted Orphan Drug Designation in the US for the prevention of HCMV viremia and disease in at risk populations. This decision was made on 12 December 2011 by the FDA Office of Orphan Products Development.

Letermovir has recently successfully completed a phase IIb trial for the prophylaxis of HCMV infection and disease in bone marrow transplanted patients. Results will be announced shortly.

"After orphan drug designation was granted earlier last year in Europe, we are very pleased to have now also received this designation in the USA. For the further development of this innovative drug, the Orphan Drug Designation will provide easier access to scientific support by the agencies, which will help to develop new treatment paradigms against this dangerous virus" commented AiCuris CEO, Prof. Rübsamen-Schaeff.

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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 in bone marrow transplant recipients. HCMV 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 organ recipients, who have evidence of CMV 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 a massive 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, severe 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, in immune-compromised patients, 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 for death. Furthermore in patients being treated for an auto-immune disease by the administration of immuno-suppressive agents, it has been observed that opportunistic HCMV infection may take place while the patients are transiently immuno-compromised..

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### **About AiCuris**

AiCuris GmbH & Co KG is a privately held company located in Wuppertal, Germany and specializes in infectious diseases. Its activities comprise research and clinical development of innovative and resistance-breaking drugs against HCMV, Herpes, Hepatitis B, HIV and Hepatitis C as well as resistant Gram positive and Gram negative bacterial infections in hospitals. Furthermore, AiCuris' portfolio comprises two immune modulators.

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