**PRESSRELEASE**

# HCMV DRUG Letermovir (AIC246) receives Fast Track from FDA. New data at 51st ICAAC

**Wuppertal, 29th August, 2011** - AiCuris announced today that the Food and Drug Administration (FDA) of the United States has granted Fast Track designation for one of the company's lead drugs, AIC246 (INN: Letermovir), an inhibitor of the human cytomegalovirus (HCMV).

Fast Track designation is an FDA status reserved for products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for those conditions. Fast Track designation can also potentially facilitate development and expedite the review and approval process.

"Having obtained Orphan Drug status in the EU, receipt of Fast Track designation for Letermovir in the U.S. is another significant milestone for AiCuris" said Prof. Helga Rübsamen-Schaeff, CEO of AiCuris. "It will hopefully facilitate the regulatory process for this drug and supports our view that Letermovir has the potential to become the treatment of choice for patients at risk to develop severe and life-threatening HCMV disease, such as transplant recipients, newborns, patients in intensive care, certain cancer patients and HIV patients. These patients currently have only limited treatment options, due to the adverse side-effect profiles of existing drugs."

Letermovir is currently being evaluated in an international Phase IIb trial, which - based on the evaluation of an independent safety monitoring committee - has confirmed a positive safety profile. Results on efficacy from this trial are expected by the end of 2011.
Dr. Holger Zimmermann, CSO of AiCuris, will present new data on Letermovir during the upcoming 51st ICAAC in Chicago. This data will demonstrate that Letermovir has no clinically significant drug-drug interactions when co-administered with immunosuppressive drugs (Session 005 on 17th September 2011 at 11:30 Uhr, Presentation A2-045b).

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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.

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