AiCuris' AIC649 Shows Potential to Induce Functional Cure of Chronic Hepatitis B in Preclinical Study

- Twice weekly treatment with AIC649 showed antiviral effect similar to twice daily treatment with Tenofovir in HBV transgenic mice
- Bi-phasic treatment response in woodchuck chronic hepatitis B model
- Data published in peer-reviewed article in PLOS ONE

Wuppertal, January 5th, 2016 – AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced the publication of results from a preclinical study assessing the antiviral efficacy of the Company's proprietary immune modulator AIC649 as well as its potential to induce functional cure in animal models for chronic hepatitis B. The peer-reviewed article titled "AIC649 Induces a Bi-Phasic Treatment Response in the Woodchuck Model of Chronic Hepatitis B" was published on December 14, 2015 online on PLOS ONE (www.plosone.org).

AIC649 is an inactivated parapoxvirus ovis (iPPVO) particle preparation with distinct immunological activities including regulated cytokine release and activation of T-cell responses. Currently, AIC649 is investigated in a clinical phase I study in patients with chronic hepatitis B.

To analyze the antiviral efficacy, hepatitis B transgenic mice were treated either twice-weekly with AIC649 or twice daily with "gold standard" Tenofovir or vehicle over a period of 29 days. Both treatment regimens showed a significant reduction of hepatitis B virus (HBV) titer compared to the control group. Noteworthy, the twice-weekly treatment with AIC649 showed an antiviral effect similar to the twice-daily treatment with Tenofovir.

The potential to induce functional cure of hepatitis B was studied in chronically woodchuck hepatitis virus (WHV) infected woodchucks. Animals were treated twice-weekly with AIC649 or vehicle over an eight-week period followed by an additional 16-week observation period. Hepatitis surface antigen (WHsAg) served as a marker for functional cure.

Treatment of chronic WHV-infected woodchucks with AIC649 revealed a bi-phasic pattern of response. WHV-DNA as well as WHsAg increased and peaked about 2-4 weeks after treatment start to subsequently decline for the rest of the study period. Viremia levels significantly declined between weeks 16 and 20 and stayed at even lower levels compared to the control group until the end of the study. The observed bi-phasic response to AIC649 treatment can be interpreted as the result of a physiologically "concerted", reconstituted immune response against WHV and therefore may indicate a potential for inducing functional cure in HBV-infected patients.

"AiCuris is currently working on the research and development of several candidates with the aim to cure viral hepatitis," said Dr. Holger Zimmermann, CEO of AiCuris. "The data published on PLOS ONE highlight the potential of AIC649 to induce functional cure. In order to follow-up the promising preclinical data from woodchuck experiments, we have initiated the clinical development in chronic hepatitis B patients. We very much look forward to speeding up the clinical development of this promising candidate to provide patients suffering from this life-threatening liver infection with a new treatment option as soon as possible and are open for partnering opportunities."

The publication can be downloaded from the Company's website under www.aicuris.com.

About hepatitis B: Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). Today the infection represents one of the major global health problems and an important occupational hazard especially for health workers. According the World Health Organization (WHO) an estimated 240 million people are chronically infected worldwide (July 2015) with more than 780,000 people dying every year due to complications of hepatitis B, including cirrhosis and liver cancer. Market experts estimated the HBV market to reach $3.9 billion in 2016. The medical need for new and innovative therapies to treat chronic infection with HBV is high as - despite numerous research activities - currently available therapies suppress the virus but provide cure of the disease only in a slight percentage of patients.

About AIC649

AIC649 is a proprietary inactivated parapoxvirus particle preparation. It induces a natural, self-limiting immune response, enhancing appropriate immune responses against unrelated viruses. As a novel biological immunomodulator, AIC649 has been conceived as curative treatment for HBV. AIC649 has the potential to become an ideal combination partner with standard of care for patients chronically infected with the HBV. AiCuris is currently testing AIC649 in a clinical phase I study in chronic HBV patients.

About AiCuris

AiCuris was founded in 2006 as a spin-off from Bayer and focuses on the discovery and development of drugs against infectious diseases. Majority investor is the family office of the Dres. Strüngmann. The company is generating drugs against viruses such as human cytomegalovirus (HCMV), herpes simplex virus and hepatitis B virus (HBV). With respect to bacteria, AiCuris is concentrating on the search for innovative treatment options against life-threatening (multi)resistant nosocomial pathogens. In 2012 AiCuris signed a license agreement with Merck & Co (MSD), which attracted significant attention being one of the largest agreements of this kind in the European biotech industry. The agreement covers the development of novel drug candidates against HCMV. Letermovir, the most advanced compound, is currently in phase III clinical trials in patients undergoing bone marrow transplantation.

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