

AiCuris Announces U.S. NIH Support of Preclinical Study with AIC649 against Chronic Hepatitis B

- **Study is designed to explore the potential of AIC649 to cure infections caused by hepatitis B virus and the efficacy when combined with direct-acting antivirals**
- **Study being conducted at Georgetown University**

Wuppertal, November 23, 2016 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced the start of a preclinical study on the proprietary immune modulator AIC649. AiCuris is utilizing the Animal Models of Infectious Disease Program, integral part of a suite of preclinical services supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study is currently underway at Georgetown University, Washington, DC. This preclinical study, which supports the ongoing clinical development of AIC649, should explore the potential of AIC649 to cure infections caused by hepatitis B virus (HBV) and is investigating the efficacy of AIC649 when given in combination with direct-acting antivirals (DAAs), the current standard of care for treating chronic HBV infections.

Woodchucks chronically infected with woodchuck hepatitis virus (WHV) develop progressively severe hepatitis and hepatocellular carcinoma, remarkably similar to the pathology seen in HBV-infected humans. In preclinical results published previously in the peer-reviewed journal PLOS ONE treatment of chronically WHV-infected woodchucks with AIC649 was shown to induce a bi-phasic response pattern, indicating a physiologically “concerted,” reconstituted immune response against WHV, which may indicate the potential for inducing functional cure in HBV-infected patients.

The ongoing preclinical study is expected to provide insight into the effects of using a different dosing route, higher doses and a longer treatment period. In addition to exploring the combination of AIC649 with a DAA, the study will also explore the use of AIC649 as maintenance therapy following DAA treatment. These results should enable AiCuris to optimize the design of its next clinical trial.

“We are very pleased that the NIH is providing preclinical services for this important study. The results should provide us with critical insights into the optimal dose and treatment regimen of AIC649 for human clinical trials, both in combination with the current standard of care, as well as for maintenance therapy,” said Dr. Holger Zimmermann, CEO of AiCuris. “We are making good progress in the development of this potentially curative treatment for chronic HBV infection and look forward to announcing our first clinical results during the first half of 2017.”

About hepatitis B

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). The infection represents a major global health issue and is a significant occupational hazard, especially for healthcare workers. According to the World Health Organization (WHO), an estimated 240 million

people worldwide are chronically infected with HBV (July 2015), and more than 780,000 people die each year due to complications from hepatitis B, including cirrhosis and liver cancer. Market experts have estimated the HBV market will reach \$3.5 billion in 2021 (RnR Market Research, 2015). There is a major medical need for new and innovative therapies to treat chronic infection with HBV as - despite numerous research activities - currently available therapies suppress the virus but cure the disease only in a small percentage of patients.

About AIC649

AIC649 is a proprietary inactivated parapox virus particle preparation. It induces a natural, self-limiting immune response, enhancing appropriate immune responses against unrelated viruses. As a novel biological immunomodulator, AIC649 has the potential to be a curative treatment for HBV. AiCuris is currently testing AIC649 in a clinical phase 1 study in chronic HBV patients. First results from this trial are expected in early 2017.

About AiCuris Anti-infective Cures GmbH

AiCuris was founded in 2006 as a spin-off from Bayer and focuses on the discovery and development of drugs against infectious diseases. The company's majority investor is SANTO Holding. The company is developing drugs for the treatment of viruses such as human cytomegalovirus (HCMV), herpes simplex virus (HSV), hepatitis B virus (HBV), and adenoviruses. In the field of antibacterials, AiCuris seeks to develop innovative treatment options for life-threatening, (multidrug)-resistant hospital-treated pathogens. In 2012, AiCuris signed a license agreement with Merck & Co (MSD), one of the largest agreements of its kind in the European biotech industry. The agreement covers the development and commercialization of novel drug candidates against HCMV. Letermovir, the most advanced compound under this agreement, met the primary endpoint in a pivotal phase 3 clinical trial in patients undergoing bone marrow transplantation.

Contact:

AiCuris Anti-infective Cures GmbH
Katja Woestenhemke
Friedrich-Ebert-Str. 475/Geb. 302
42117 Wuppertal

Phone +49 202 317 63 0
Fax +49 202 317 63 1601
Email business@aicuris.com
Web www.aicuris.com

Media Relations

MC Services AG
Anne Hennecke
Kaiser-Friedrich-Ring 5
40545 Düsseldorf

Phone +49 211 529 252 22
Fax +49 211 529 252 29
Email anne.hennecke@mc-services.eu
Web www.mc-services.eu