

AiCuris to Present Clinical Data on AIC649 against Chronic Hepatitis B at the 2019 EASL meeting, the International Liver Congress

- **Single intravenous dose phase 1 trial showed that AIC649 was safe and well tolerated in all dose groups**
- **The trial provided evidence that AIC649 stimulates the immune system of chronic hepatitis B patients**

Wuppertal, Germany, April 4, 2019 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that data from a clinical phase 1 study with its proprietary immunomodulator AIC649 for the treatment of chronic Hepatitis B (CHB) will be presented in the Poster Session “Viral hepatitis B/D: therapy” at the European Association for the Study of the Liver (EASL) – The International Liver Congress™ (ILC). The conference will be held from April 10 to 14, 2019 in Vienna, Austria.

The poster presentation (poster number FRI-199) titled “First in human, single ascending dose clinical trial of AIC649 in patients with chronic hepatitis B” is scheduled for Friday, April 12 from 9:00 am to 5:00 pm in the Poster Area.

AIC649 is an immunomodulator known to induce immune responses and loss of woodchuck hepatitis surface antigen (WHsAg) and induce anti-WHsAg antibodies, suggesting that AIC649 may achieve a functional cure in CHB patients.

This randomized, multi-center, double-blind, placebo-controlled clinical phase 1 trial was designed to assess the safety, tolerability and pharmacodynamics of single ascending intravenous doses of AIC649. Thirty-two CHB patients were randomized in four ascending dose groups. Patients in each group received either single dosages of AIC649 or placebo and were monitored for 84 days. During this time different parameters for hepatitis B virus infection were also assessed in all groups. The high dose groups, 3 and 4, were additionally assessed for HBV parameters at 6 and 12 months post-treatment. In addition, several immunological parameters were measured between baseline and day 14 or up to day 84 post treatment, respectively. A single intravenous dose of AIC649 was safe and well tolerated in all dose groups. Despite the heterogeneity of the patients in the trial, there was evidence that a single dose of AIC649 stimulates immunity.

“We are very pleased to have an opportunity to share new data from this important AIC649 clinical trial with an international audience of experts at this renowned scientific conference,” **said Dr. Holger Zimmermann, CEO of AiCuris.** “The data underlines the potential of AIC649, a promising candidate from our pipeline of innovative compounds, to induce a functional cure in chronic hepatitis B virus (HBV)-infections, a disease with a high unmet medical need. Further clinical trials to study this potential of AIC649 are in preparation.”

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 257 million people worldwide are chronically infected with HBV (July 2017), and more than 880,000 people die each

year due to complications from hepatitis B, including cirrhosis and liver cancer. Market experts have estimated the HBV market will reach \$3.0 billion in 2024 (GlobalData, 2016). There is a major medical need for new and innovative therapies with finite treatment duration 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 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 the potential to be a curative treatment for HBV. AiCuris is currently preparing the next clinical trial, phase 1b/2a study, of AIC649 in chronic HBV patients.

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 targeting infectious diseases. SANTO Holding is the Company's majority investor. PREVYMIS™ (Letermovir), a first-in-class non-nucleoside cytomegalovirus (CMV) inhibitor acting via a novel mechanism of action that was licensed to MSD in 2012, is approved for use in bone marrow transplants in the EU, Switzerland, the USA, Canada and Japan for prevention of CMV infections in adult recipients of an allogeneic hematopoietic stem cell transplant. The Company develops drugs for the treatment of viruses such as human CMV, 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 November 2018, Prof. Dr. Helga Rübsamen-Schaeff, Founding-CEO, and Dr. Holger Zimmermann, CEO of AiCuris, were awarded the German Future Prize 2018 (German President's Award for Innovation in Science and Technology) for the development of Letermovir and their project "Protection in the Absence of the Immune System - a Life-Saving Innovation against Dangerous Viruses" (original title: "Schutz bei fehlendem Immunsystem - die lebensrettende Innovation gegen gefährliche Viren").

For more information, please visit www.aicuris.com.

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