

AiCuris Reports Positive Phase 1 Clinical Trial Results with Immunomodulator AIC649 in Patients with Chronic Hepatitis B

- **Single intravenous dose phase 1 trial showed that AIC649 was safe and well tolerated in all dose groups**
- **The trial provides evidence that AIC649 stimulates the immune system of chronic hepatitis B patients**
- **Further trials to study the potential of AIC649 to induce a functional cure in chronic hepatitis B virus (HBV)-infection is warranted**

Wuppertal, Germany, September 3rd, 2018 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs targeting infectious diseases, announced the results from its first-in-human, single-ascending dose clinical phase 1 trial with AIC649 in patients suffering from chronic hepatitis B (CHB).

The randomized, multi-center, double-blind, placebo-controlled phase 1 clinical trial was designed to assess the safety, tolerability and pharmacodynamics of single ascending intravenous doses of AIC649 in CHB patients. Thirty-two 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. The majority of the patients were male, HBeAntigen (HBeAg)-negative, and HBV treatment naive.

A single intravenous dose of AIC649 was safe and well tolerated in all dose groups. There was no dose limiting toxicity and the maximum tolerated dose was not reached with the highest dose administered. Despite the heterogeneity of the patients in the trial, there was evidence that a single dose of AIC649 stimulates the patients' immune system as shown by increases in plasma levels of immune-regulating cytokines including IL-1 β , IL-6, IL-8 and IFN- γ and reductions in IL-10 levels.

“These results from a first-in-human clinical trial are very encouraging. They clearly support our commitment to progressing the clinical development of AIC649, a promising candidate from our broad development pipeline of anti-infective compounds with the potential to induce functional cure in HBV-infected patients,” said **Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH**. “We are now preparing the production for further clinical trials with AIC649.”

In a previous study in a woodchuck animal model of CHB, treatment with AIC649 induced a unique bi-phasic response pattern, and, in combination with Entecavir, led to a sustained loss of woodchuck hepatitis virus (WHV) DNA and surface antigen (WHsAg). The observed sustained loss of WHsAg and the induction of anti-WHsAg antibodies accompanied by cell mediated immune responses support the hypothesis that AIC649 induces a physiologically “concerted”, reconstituted immune response to WHV¹, suggesting that AIC649 treatment may lead to functional cure in CHB patients.

¹ Paulsen D. et al. Hepatology, 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 257 million people worldwide are chronically infected with HBV (July 2018), 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 in the eight major pharmaceutical markets (US, France, Germany, Italy, Spain, UK, Japan, and China) will reach \$3.0 billion in 2024 (RnR Market Research, 2016). 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 can only cure the disease 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 offer a functional cure for HBV. AiCuris has successfully completed a clinical phase 1 trial with AIC649 in chronic HBV patients and is currently stepping up CMC production as well as the next steps of clinical development.

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, received market approval in the U.S., Europa and Japan for prevention of CMV infections in adult recipients of an allogeneic hematopoietic stem cell transplant (HSCT). The Company develops 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.

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