AiCuris starts pilot trial with proprietary immunomodulator AIC649, a unique therapy to prevent severe symptoms in SARS-CoV-2 infections

- **First evaluation of widely applicable novel therapy AIC649 in SARS-CoV-2 infected patients**
- **The pilot program focuses on accessing safety, tolerability, and antiviral efficacy of multiple dosing of AIC649 in asymptomatic or mildly symptomatic COVID-19-patients**
- **AIC649 significantly improved survival, clinical disease scores and viral load in a preclinical SARS-CoV-2 infection model**
- **In a phase 1 trial in Hepatitis B -positive patients, AIC649 already showed that it is safe and well tolerated**

Wuppertal, Germany, September 20, 2021 - AiCuris Anti-infective Cures AG, a leading company in the discovery and development of drugs against infectious diseases, today announced the start of a pilot study with immunomodulator AIC649 for treatment of asymptomatic or mildly symptomatic COVID-19-patients to prevent more severe symptoms including respiratory failure that may develop with progression of the disease.

AIC649 is an inactivated parapoxvirus (iPPVO), which was previously in development for the treatment of chronic HBV infections at AiCuris. In a preclinical SARS-CoV-2 infection model it was shown that administration of iPPVO significantly improves survival, clinical disease scores and viral load. Based on the immunostimulatory properties and the broad antiviral spectrum of the compound (including SARS-CoV-2) and its resulting potential to enhance control of viral infections, AIC649 could be used against SARS-CoV-2 and other viruses with pandemic potential.

In pre-clinical models AIC649 demonstrated anti-viral activity in prophylactic and treatment settings against several viruses including SARS-CoV-2

"We are excited about the start of this pilot study with AIC649, a drug candidate that already showed its antiviral efficacy in a preclinical SARS-CoV-2 infection model," **said Holger Zimmermann, CEO of AiCuris Anti-infective Cures AG.** "Despite the increase in the number of people being fully vaccinated against SARS-CoV-2, with emerging variants and disparities in vaccination rates, there remains a major need for effective therapeutic options. With this novel therapy we aim to protect patients with SARS-CoV-2 infections to develop a more severe form of COVID-19 including respiratory failure. In addition, based on promising pre-clinical findings, AIC649 could have potential as therapy against other respiratory viral infections with pandemic potential."

The trial "A randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of AIC649 in the treatment of otherwise healthy subjects with asymptomatic or mildly symptomatic SARS-CoV-2 infection" is designed to provide valuable information on safety and

tolerability of multiple dosing of AIC649, as well as providing insights into potential antiviral efficacy through exploratory virological, clinical, and immunological endpoints. In addition, the study aims to investigate the effect of AIC649 on the serum immunological pattern of subjects with SARS-CoV-2 infections.

The trial will be conducted in two clinical sites in Germany and South Africa. Up to 60 otherwise healthy male and female subjects with a confirmed SARS-CoV-2 infection and at most mild COVID-19 symptoms at screening will be hospitalized for screening and randomized 1:1 to receive intravenously either AIC649 or placebo on days 1, 3 and 5. Subjects will be discharged from the clinical site on day 7 at the earliest, provided they have no, or only mild COVID-19 symptoms and no fever. Regular and frequent SARS-CoV-2 sampling as well as monitoring of COVID-19 related symptoms will be performed up to the end of trial examinations.

About AIC649

AIC649 is a proprietary inactivated parapoxvirus particle (iPPVO) 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. In addition, in pre-clinical infection models, iPPVOs demonstrated broad-spectrum activity against various unrelated human viral pathogens. AIC649 is currently being investigated in a pilot study as a pre-emptive treatment for SARS-CoV-2 infections.

About AiCuris Anti-infective Cures AG

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, was licensed to MSD in 2012 and is approved in the EU, the USA, Japan and other parts of the world for use in bone marrow transplants for the prevention of HCMV infections in adults who receive an allogeneic hematopoietic stem cell transplant. The Company is developing drugs for the treatment of viruses such as human CMV, herpes simplex virus (HSV), hepatitis B virus (HBV), and adenoviruses as well as for SARS-CoV-2 and other viruses with pandemic potential. In the field of antibacterials, AiCuris seeks to develop innovative treatment options for indications with high medical need, including life-threatening, multidrug-resistant, hospital-treated pathogens.

In 2018 Dr. Holger Zimmermann, CEO of AiCuris, and Prof. Dr. Helga Rübsamen-Schaeff, Founding CEO, 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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