AiCuris was Granted Breakthrough Therapy Designation by U.S. FDA for Pritelivir for the Treatment of HSV Infections in Immunocompromised Patients

- Receiving Breakthrough Therapy Designation will facilitate AiCuris goal of bringing pritelivir to patients as quickly as possible
- AiCuris is currently preparing to add a pivotal Phase 3 trial part to the ongoing Phase 2 study in immunocompromised patients whose HSV infections have become resistant to acyclovir as a basis for NDA submission
- The company to discuss partnering opportunities at upcoming BIO Digital

Wuppertal, June 05, 2020 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that the Company has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA) for oral pritelivir, AiCuris' lead candidate for the treatment of acyclovir-resistant mucocutaneous herpes simplex virus (HSV) infections in immunocompromised adults. Breakthrough Therapy designation is intended to accelerate the development and review of a potential therapy for a serious or life-threatening disease, with clinical evidence of substantial improvement over existing options. The program includes more intensive FDA guidance throughout therapy development — such as ensuring efficient design of clinical trials — and eligibility for priority review.

Pritelivir is a new small molecule, a helicase-primase inhibitor with a novel mode of action. In a phase 2 study conducted earlier for suppressive treatment, oral pritelivir showed to significantly improve the suppression of viral shedding compared to the current standard of care for genital HSV-2 infections, the nucleoside analog valacyclovir.

Oral pritelivir is currently in a phase 2 clinical trial in the U.S., to assess efficacy and safety comparing pritelivir to i.v. foscarnet, a virostatic agent which is used mainly for the treatment of HSV resistant to other antiviral drugs. Based on early results AiCuris is in close communication with the FDA and preparing to add a pivotal Phase 3 part to this trial as a basis for NDA submission.

"The decision by the FDA to grant Breakthrough Therapy designation for oral pritelivir underscores the potential of our product to fill the major need for innovative, more efficacious therapies for immunocompromised patients with HSV infections that have become resistant to standard treatments," said Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH. "Pritelivir already has shown clinically that it has the potential to become an important alternative to current treatments as a highly effective and convenient oral therapy. The Breakthrough Therapy designation should enable us to further accelerate the development of this compound."

With the Breakthrough Therapy designation, AiCuris reached an important milestone and is now looking for a partner for the further development of pritelivir. AiCuris will also be participating in the digital format of BIO International Convention, BIO Digital, taking place from June 8th – 12th 2020. If you are interested in meeting with the company, please request a meeting using the conference partnering system or contact AiCuris directly.

About Breakthrough Therapy Designation

Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s) to make important new drugs available to patients sooner. The designation enables early and frequent communication between FDA involving senior managers and a product sponsor throughout the drug development and review process. Through the Breakthrough Therapy program, a product may be eligible for Accelerated Approval and priority review if the requisite criteria are met and may also be eligible to submit completed sections of the New Drug Application (NDA) on a rolling basis before the complete application is submitted. For more information about Breakthrough Therapy, please visit:

https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy

About Pritelivir

Pritelivir is an innovative, highly active and specific inhibitor of herpes simplex virus (HSV). Derived from a novel chemical class (thiazolylamides), pritelivir is active against both types of herpes simplex virus (HSV-1 and HSV-2), causing labial and genital herpes, and retains activity against viruses which have become resistant to marketed drugs. Pritelivir has a mode of action that is distinct from other antiviral agents currently in use for treating HSV infections (i.e., the nucleoside analogs acyclovir and its prodrug valacyclovir as well as famciclovir, the prodrug of penciclovir). While nucleoside analogs terminate ongoing DNA chain elongation through inhibition of viral DNA polymerase, pritelivir prevents de novo synthesis of viral DNA through inhibition of the helicase-primase complex. In addition, it does not require activation within an HSV infected cell by viral thymidine kinase and is therefore also protective to uninfected cells. Pritelivir, showed superiority against standard treatment valacyclovir in a clinical phase 2 trial in patients with genital HSV-2 infection and is now in a phase 2 trial in immunocompromised patients whose HSV infections have become resistant to acyclovir.

About HSV

Herpes simplex viruses are widespread (seroprevalence up to 100%, depending on geographic area and subpopulation) and are divided into herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2). Infections lead to lifelong persistence of the virus, with frequent and sometimes painful recurrences. While HSV-1 predominantly causes oral lesions (cold sores), HSV-2 manifests in the genital region and is mainly sexually transmitted. In immunocompromised patients, HSV can lead to serious complications. The negative stigma associated with genital herpes and visible facial lesions may cause psychological distress.

According to the World Health Organization (WHO), an estimated 491 million people aged 15-49 (13%) worldwide were living with genital herpes caused by HSV-2 in 2016. Prevalence of HSV-2 infection was estimated to be highest in Africa (44% in women and 25% in men), followed by the Americas

(24% in women and 12% in men). It was also shown to increase with age, although the highest numbers of newly infected people were adolescents.

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, 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. In the field of antibacterials, AiCuris seeks to develop innovative treatment options for life-threatening, multidrug-resistant, hospital-treated pathogens.

In 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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Contacts:

Company:

AiCuris Anti-infective Cures GmbH

Katja Woestenhemke
Phone: +49 202 317 63 0

Email: press@aicuris.com

Media relations:

MC Services AG

Dr. Solveigh Mähler
Phone: +49 211 529 252 19

E-Mail: aicuris@mc-services.eu