Science. Health. Life.

AiCuris
Anti-infective Cures

AiCuris – The Powerhouse for Anti-Infectives

AiCuris Anti-infective Cures at a Glance

Founded: 2006 as a spin-out from Bayer
Number of employees: > 50
Headquartered: Pharma- and Chemistry Park, Wuppertal, Germany

Management

Dr. Holger Zimmermann
(Chief Executive Officer)

Holger Schmoll
(Chief Financial Officer)

Dr. Alexander Birkmann
(Head of Research)

Dr. Helmut Buschmann
(Head of Chemistry, Pharmaceutical Development and Patent Affairs)

Dr. Manickam Rangaraju
(Head of Development)

Silvia Riffel-Friedrich
(Head of Compliance & Regulatory Affairs)

Scientific Advisory Board

Prof. Dr. Helga Rübsamen-Schaeff,
Chair of the Scientific Advisory Board
former CEO of AiCuris

Dr. Klaus Binder
Binder Associates GmbH

Prof. Dr. Wolff Schmiegel
Ruhr-Universität Bochum

Prof. Per Ljungman
Karolinska University Hospital, Sweden

Investors

SANTO Holding (Deutschland) GmbH
FCP Biotech Holding GmbH
DOM Capital GmbH
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Company/Contact

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Company Profile

AiCuris is a pharmaceutical company focused on the discovery, research and development of novel, resistance-breaking antiviral and antibacterial agents for the treatment of severe and potentially life-threatening infectious diseases.

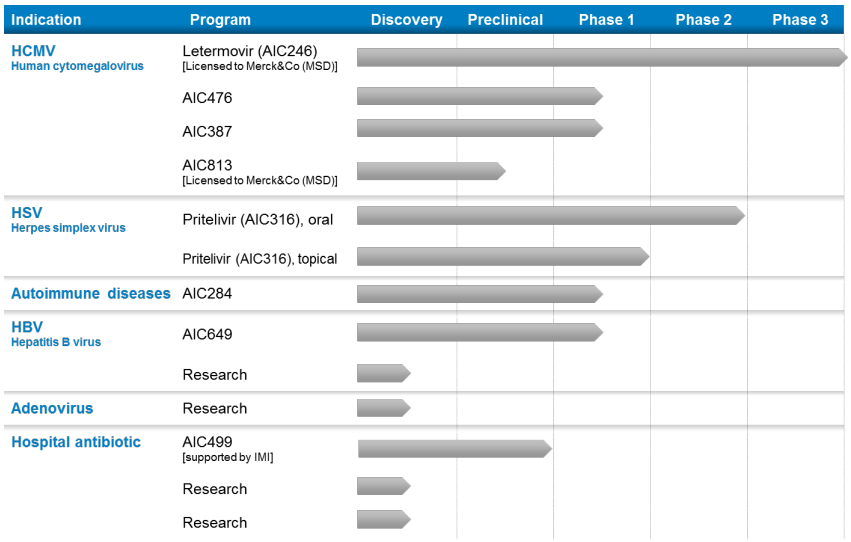
Founded in 2006 as a spin-out from Bayer's virology and bacteriology research department, AiCuris established itself as a "powerhouse for anti-infectives" dedicated to developing a pipeline of innovative anti-infective drugs in areas of high unmet medical needs. AiCuris' compounds represent novel chemical classes and/or act via new modes of action. Thus, AiCuris therapeutics are resistance-breaking by design.

Pipeline / Projects

AiCuris has seven clinical development programs. The most advanced is **letermovir**, a first-in-class molecule derived from a novel chemical class and designed to inhibit the viral terminase of the human cytomegalovirus (HCMV). This compound, licensed to Merck & Co. (MSD), has just completed a pivotal phase 3 trial and met the primary endpoint as an investigational prophylactic therapy against HCMV in bone marrow transplant patients.

Pritelivir, a helicase-primase inhibitor being developed to treat herpes simplex virus Type 1 (HSV-1) and Type 2 (HSV-2) infections, has successfully completed phase 2 clinical trials as an oral formulation against genital herpes. A topical form, targeted against labial herpes, has successfully completed a clinical phase 1 trial. Other clinical and preclinical programs include small molecules against HCMV, hepatitis B virus (HBV) and adenovirus, resistance-breaking hospital antibiotics, as well as two immune modulators. AiCuris has proven its ability to develop its portfolio rapidly and effectively and is actively pursuing the discovery of novel therapies for infectious diseases with high unmet medical need.

With its broad portfolio of anti-infective drugs in specialist indications having profound medical need, AiCuris addresses one of the largest pharmaceutical markets with strong growth potential.



Partnering & Licensing

AiCuris follows a proof-of-concept strategy before out-licensing its development projects. Furthermore, AiCuris is actively in-licensing preclinical projects that help making a real difference in the anti-infectives field. AiCuris' key areas of interest are viral indications, in particular HBV, adenovirus, influenza virus, norovirus, and life-threatening nosocomial bacterial infections especially caused by Gram-negative pathogens.

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Project Pipeline

HCMV - Letermovir (licensed to Merck & Co. (MSD))

- **HCMV infections in cases of immune incompetency, deficiency or immunosuppressed patients**
- **Inhibition of HCMV viral terminase**
- **Met primary endpoint in pivotal phase 3 trial**

Herpes-simplex - Pritelivir

- **HSV infections Type 1 (HSV-1) and Type 2 (HSV-2)**
- **Inhibition of HSV helicase-primase**
- **Pritelivir, oral (genital herpes) successfully completed phase 2**
- **Pritelivir, topical (labial herpes) successfully completed phase 1**

Hepatitis B - AIC649

- **Functional cure of chronic HBV infections**
- **Inactivated parapox virus particles that activate the immune system inducing a natural, self-limiting antiviral state**
- **Phase 1 ongoing**

Hospital Antibiotics - AIC499

- **Nosocomial infections caused by multidrug resistant (MDR) gram-negative bacteria**
- **Resistance-breaking ß-lactam for broad empiric use in combination with ß-lactamase inhibitor (BLI)**
- **Phase 1 scheduled**

Research

- **Research activities in viral indications (HBV, adenovirus) & hospital antibiotics (Gram-negative and Gram-positive)**
- **Focus on innovative and resistance-breaking antiviral & antibacterial agents from novel compound classes and/or with novel modes of action**

HCMV - Letermovir (AIC246/MK-8228)

Letermovir (AIC246, also known as MK-8228) is an oral, once-daily antiviral drug for prevention and treatment of human cytomegalovirus (HCMV) infections. It is a first-in-class molecule derived from a novel chemical class and is designed to selectively inhibit the HCMV viral terminase. In 2012, AiCuris and MSD entered into an exclusive worldwide license agreement for AiCuris' HCMV program, including letermovir. Under the agreement, MSD gained worldwide rights to develop and commercialize AiCuris' HCMV drug. Just recently letermovir met the primary endpoint in a pivotal clinical phase 3 trial for the prevention of HCMV infections in allogeneic hematopoietic stem cell transplant recipients.

Herpes simplex virus (HSV) - Pritelivir (AIC316)

Pritelivir (AIC316) is a potent inhibitor of HSV replication. It originates from a novel chemical class, acts via a new mode of action (inhibition of the viral helicase-primase enzyme complex) and has a favorably long plasma half-life. Based on this new mode of action – and in contrast to nucleoside analogues – pritelivir does not require activation by viral enzymes and therefore can also protect uninfected cells. Pritelivir is active against both labial and genital herpes virus strains and retains activity against viruses which have become resistant to marketed drugs. In phase 2 trials, pritelivir met all endpoints and has shown superiority against the market standard valaciclovir in suppression therapy. Pritelivir is currently being developed for systemic and topical use.

Hepatitis B - AIC649

AIC649 is a proprietary inactivated parapox virus (iPPVO) particle leading to maturation of antigen presenting cells (APCs), proliferation of T cells and cytokine release. The compound induces a natural, self-limiting immune response, leading to induction of immune responses against unrelated viruses. As a novel biological immune modulator, AIC649 is aiming at a curative treatment for hepatitis B virus (HBV). AiCuris is currently testing AIC649 in a phase 1 study in chronic HBV patients. The compound is also being tested in a NIH-supported preclinical woodchuck model of chronic hepatitis B. In this model the efficacy of AIC649 when given in combination with direct-acting antivirals (DAAs), the current standard of care for treating chronic HBV infections, is investigated. AIC649 is being developed as first-line therapy in combination with standard of care for patients chronically infected with HBV.

Novel resistance-breaking Gram-negative antibiotic - AIC499

AIC499 is an innovative beta-lactam antibiotic which addresses the urgent unmet medical need arising from hospital-acquired infections with Gram-negative bacteria. In combination with a beta-lactamase inhibitor (BLI), AIC499 shows very potent antibacterial activity against Gram-negative pathogens including multi-drug resistant strains of Pseudomonas and Acinetobacter. Due to its unique profile and extensive coverage, AIC499 has the potential to become the best treatment option for present and future resistant Gram-negative infections. AIC499 is currently in preclinical development. AiCuris plans to start phase 1 clinical trials in late 2016 within the European Innovative Medicines Initiative program (IMI) and to continue development up to the end of clinical phase 2. AiCuris is also active in early research programs focusing on new Gram-negative and Gram-positive resistance breaking agents.