

AiCuris launches “PREP – Pandemic and Resistance Emergency Preparedness” program at upcoming 4th AMR Conference

- PREP is a comprehensive four-pillar program to help prevent future pandemics and combat antimicrobial resistance (AMR)
 - Exploring opportunities of AiCuris pipeline products to treat Corona; clinical trial with first drug candidate AIC649 with the potential to become a first-line pandemic therapy under preparation
 - Company commits to driving drug development in resistance breaking antibiotics based on novel scientific approaches
 - AiCuris initiates “AiCubator”, providing long-term support for early but promising research projects in the field of anti-infectives
 - Pursuit of an active licensing strategy for pre-clinical and early clinical projects in the anti-infective space to expand the Company’s portfolio
- AiCuris to participate in several AMR panels and to discuss partnering opportunities at upcoming virtual 4th AMR Conference

Wuppertal, Germany, August 17, 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 launched a four-pillar program, “PREP – Pandemic and Resistance Emergency Preparedness”, to tackle worldwide health threats resulting from upcoming pandemics and antimicrobial resistance (AMR). “As a leading company in anti-infective drug development, AiCuris was always focused on indications with a high medical need such as the prophylactic treatment of human cytomegalovirus (HCMV) in transplant patients, genital herpes caused by herpes simplex virus (HSV), the cure of chronic hepatitis B as well as adenovirus infections. In 2017, together with MSD, we successfully launched our first product, a first-in-class non-nucleoside HCMV inhibitor that initiates a paradigm shift in transplant medicine,” said **Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH**. “With our newly introduced PREP program, we strengthen our efforts and focus our portfolio addressing what we believe will be the biggest threats to global healthcare systems going forward. The need to be prepared for future pandemics and antimicrobial resistance is what the current COVID-19 pandemic has taught us. As a proven expert in anti-infective drug development with deep experience in bringing products through clinical development and to the market, we are highly committed to contribute to and work on Pandemic and Resistance Emergency Preparedness.”

“Pandemic Preparedness” starts inhouse

It takes years to develop new, innovative drugs to combat a viral infection. A faster option in the event of success is evaluating proprietary existing substances to identify a possible active agent against Corona. AiCuris plans to initiate a clinical Phase 1 study with AIC649 for the prevention of COVID-19 and other upcoming infections with pandemic potential. AIC649 is a proprietary inactivated parapoxvirus particle preparation that 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 effective against

a broad range of viruses and therewith to become a first-line therapeutic option in the event of new pandemics.

AIC649 is currently in clinical development and has successfully completed a clinical Phase 1 trial in cHepB patients. The study showed safety of the compound, as well as provided preliminary evidence, that a single dose of AIC649 could stimulate the patient's immune system.

“However, fighting Corona and viral pandemics alone is not enough,” **Dr. Zimmermann** continues. “Evidence has shown that the next healthcare crisis could lie around the corner. With millions of deaths expected by the European Commission between 2015 and 2050 if current infection and resistance trends are not reversed, AMR creates an urgent need for innovative solutions and novel approaches in drug development. Immediate coordinated action across all government sectors and the society is required to push the development of new resistance breaking therapies and minimize the spread and therewith the emergence of AMR.”

Immediate coordination across governmental sectors and novel approaches are needed to fight AMR

AMR is a highly complex problem that affects society on a whole and is driven by many interconnected factors including excessive use of antibiotics (especially in veterinary medicine and livestock feed). Existing reimbursement regulations deflate market pricing, also affecting new antibiotics, making the development of these drugs uneconomical and unattractive to pharma companies. This results in neglected AMR research on novel scientific approaches leading to a lack in development of innovative and resistance breaking antimicrobial therapies.

AiCuris is one of the few European companies that remains highly committed to the development of new antibacterial agents to overcome resistance. The Company has extensive expertise in developing novel, effective therapies and is in a strong position to attack antibiotic resistance in new ways. Most recently, in July 2019, AiCuris signed a long-term cooperation agreement with Lysando AG for the development and optimization of Artilysin®-based drug candidates for various antibacterial indications, including e.g., hospital-acquired pneumonia and sepsis.

In addition, AiCuris is engaged in several early stage antibacterial drug discovery research collaborations, including partners like Jülich Research Center, Cyclenium Pharma, Max Planck Institute (MPI) of Molecular Physiology, several projects funded by the European Commission under the Horizon 2020 framework and the German Federal Ministry of Education and Research.

The “AiCubator” – a new way to collaborate in anti-infectives and support novel approaches

To promote ideas that might lead to the next resistance breaking anti-infective, AiCuris has invested in a program that will support young scientists to further develop their exciting novel approaches by learning from experts about pre-clinical and clinical drug development, as well as the pharmaceutical business characteristics. This newly launched initiative, an innovative corporate accelerator, AiCubator, will provide long-term support for selected anti-infective research and early pre-clinical stage projects.

Academic scientific groups or recently formed biotech start-ups with early stage anti-infectives projects are invited to apply to the AiCuris AiCubator. In this process the main focus lies on Gram-negative resistance-breaking antibiotics, as well as targeted antiviral therapies for the treatment of herpes virus, adenovirus, hepatitis B cure and respiratory viruses. Submitted projects will be evaluated by AiCuris experts on a number of criteria. Every year, up to three projects will be awarded with AiCubator Resident Status. Over a period of up to three years the winning projects will mainly benefit from expert scientific support to grow their underlying ideas and approaches to an advanced level. The program was designed to help scientists and start-ups build their own business by providing financing and business development advice.

“Sometimes, it is not the lack of a groundbreaking idea that prevents the development of a novel, innovative anti-infective drug. The lack of funding but also missing development and business experience as well as limited resources discourages young start-ups and scientific groups, thereby preventing the development of new therapeutic options,” said **Holger Schmoll, CFO of AiCuris Anti-infective Cures GmbH**. “As one of the leading companies in anti-infectives we are committed to help them grow their projects with our expertise, know-how and broad network in the field.”

AiCubator 2020 call - important dates and deadlines:

End of Submission period:	September 31, 2020, mid-night
Announcement of best projects:	December 15, 2020
Start of the AiCubator program:	January 01, 2021

For more information on AiCubator visit: www.aicuris.com/AiCubator.

Expanding pipeline through licensing strategy for late pre-clinical and early clinical projects

AiCuris is constantly evaluating strategic partnerships and collaboration opportunities with biotech or pharmaceutical companies. In addition, with our goal in mind to develop the medicines of tomorrow, we are always interested in any new collaboration with innovative, science-driven organizations and academic institutions.

As an experienced partner with a proven track record, AiCuris is highly committed to jointly accelerate and advance pre-clinical and early clinical programs in the fields of Gram-negative resistance-breaking antibiotics as well as targeted antiviral therapies in indications with high unmet medical needs.

Meet the experts

AiCuris will participate in the digitally delivered [4th AMR Conference 2020](#) from August 24-28, 2020. During the conference AiCuris experts will join the following panels:

Aug 25, 09:15 am - 10:45 am	Expert campus: How to Accelerate Drug development
Aug 25, 01:30 pm – 03:00 pm	SME approach: How to develop strategic decisions in a challenging and global AMR market

Aug 27, 11:00 am – 11:45 am	SME campus (part I): Corporate update
Aug 27, 04:30 pm – 05:30 pm	Behind the scenes: Focusing on early stage investing & financing

If you are interested in meeting with the AiCuris management, please contact us directly under business@aicuris.com or request a meeting using the [conference partnering tool](#).

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.

For more information on PREP, please visit www.aicuris.com/PREP.

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