

## **AiCuris nominated for “Deutscher Innovationspreis 2019”**

- **AiCuris Anti-infective Cures GmbH is one of three companies nominated for the “Deutscher Innovationspreis 2019” in the category Medium-Sized Enterprises**
- **Nomination for the development of Letermovir, the world's first and only drug to prevent infections from a common virus in bone marrow transplant patients, that represents a paradigm shift in the field of transplantation medicine**

**Wuppertal, Germany, March 11, 2019** - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs targeting infectious diseases, announced today that the Company was nominated for the prestigious “[Deutscher Innovationspreis 2019](#)”. Under the auspices of the Federal Ministry of Economics and Energy (“Bundesministerium für Wirtschaft und Energie”, BMWi), the prize is awarded by WirtschaftsWoche together with Accenture and EnBW to German large-, medium-sized enterprises and start-ups to honor outstanding, trend-setting innovations that are transforming their businesses and markets with innovative power. The winners will be announced on March 29, 2019 at an awards ceremony in Munich.

The AiCuris team was the first to identify and to develop an active substance (Letermovir) that prophylactically protects patients with a weakened or ineffective immune system against human cytomegalovirus (CMV) infections.

“We are extremely honored to be nominated for this highly prestigious award,” **said Dr. Holger Zimmermann, CEO of AiCuris.** “AiCuris’ mission is to develop effective drugs against life-threatening infectious diseases with high medical needs. We strongly believe that the most promising way to develop innovative drugs that have the potential to outperform existing therapies, in terms of resistance breaking capabilities and expanded treatment options, is by looking for completely new approaches using novel compound classes and new modes of action. Success received from our first pipeline product being launched onto the market has clearly elevated the Company and pushed AiCuris to the next level of development. We very much look forward to shaping AiCuris’ future as a leading pharmaceutical company in the field of anti-infectives for long-term sustainable growth.”

### **CMV - harmless or life threatening depends on the immune status**

Today, about 50% of the population in the developed world carries a chronic infection from CMV. In developing countries, that figure rises to 90-100% of the population. Individuals with an intact immune system rarely show symptoms after the initial infection, but the virus remains dormant in the body throughout their lifetime. In a weakened immune system, however, CMV can reactivate and lead to serious diseases in various organs, including damage to the gastrointestinal tract, pneumonia or eye infections (retinitis) that can result in blindness.

One group with a high risk to develop a CMV infection is represented by patients suffering from severe diseases including certain cancers of the blood or bone marrow, such as multiple

myeloma or leukemia. For these patients the only effective treatment left is hematopoietic stem cell transplantation (HSCT). During this widely accepted medical procedure the patient's immune system is usually severely damaged by radiation or chemotherapy before being replaced by donor stem cells. This leaves the patient with little to no natural immune protection while normal blood cell production (hematopoiesis) is restored. Therefore, recipients of stem cell grafts carrying latent CMV infections are at high risk of developing CMV infections, which is life-threatening if not controlled. While therapies against CMV are available, strong side effects including bone marrow and liver toxicity, make them unsuitable for protecting bone marrow recipients prophylactically.

### **The paradigm shift in the field of transplantation medicine – prophylaxis instead of treatment**

The innovative drug Letermovir (brand name Prevmis™) offers for the first time the possibility of a prophylactic treatment against CMV infections. Letermovir belongs to a new chemical class working on a completely different principle than nucleoside analogues currently on the market and uniquely differs from all substances previously used against CMV infections.

Letermovir prevents the spread of the virus by attacking a virus-specific structure, that does not naturally occur in the human body. In addition, because the compound only attacks a viral, non-human protein, there are no side effects based on the mechanism of action and the drug is well tolerated by patients.

### **An innovative drug that matured the company**

In 2012, AiCuris granted a worldwide license for Letermovir to Merck & Co (MSD), a partner which added the necessary capabilities and experience to take the compound through Phase 3 clinical development and onto the market. To date, AiCuris has received upfront and milestone payments from this agreement of €260 million. In addition, AiCuris receives royalties on worldwide net sales.

With the payments already received, together with the further milestone payments and share in the turnover, AiCuris will now be cash-positive in the long term. The resulting solid financial base will be used to advance its proprietary research and development pipeline of highly innovative therapies to treat severe and life-threatening viral and bacterial infections. The extensive research and development pipeline of AiCuris in the areas of virology and bacteriology includes almost exclusively active ingredients with new mechanisms of action and/or from new chemical classes.

Based on a solid financial basis AiCuris is able to reasonably invest in infrastructure and people and continue the gradual, further expansion of the company into a new, leading German specialist pharmaceutical company.

## **About Letermovir**

Letermovir is a member of a new class of non-nucleoside CMV inhibitors (3,4 dihydroquinazolines) and inhibits viral replication by specifically targeting the viral terminase complex. Cross-resistance is not likely with drugs outside of this class. Letermovir is fully active against viral populations with substitutions conferring resistance to CMV DNA polymerase inhibitors. Letermovir has no activity against other viruses. Letermovir has been granted orphan designation for the prevention of CMV disease in at-risk populations in the USA, Europe and Japan.

Under an agreement signed in 2012, MSD (through a subsidiary) purchased worldwide rights to develop and commercialize Letermovir (PREVYMIS™) from AiCuris ([www.aicuris.com](http://www.aicuris.com)). The drug is approved for use in bone marrow transplants in the the EU, USA, Japan and other countries.

## **About CMV and Treatment**

CMV is a common virus that infects people of all ages. Many adults are CMV seropositive, meaning they have CMV antibodies in their blood, indicating a previous exposure to, or primary infection from CMV. People with normal immune systems rarely develop CMV symptoms after initial infection, with the virus typically remaining inactive or latent in the body for life. A weakened immune system, however, may give the virus a chance to reactivate, potentially leading to symptomatic disease or a secondary infection due to other pathogens. CMV disease can lead to end-organ damage, including gastrointestinal tract disease, pneumonia or retinitis. Transplant recipients who develop CMV infection post-transplant are at increased risk for transplant failure and death. CMV prophylaxis with certain existing antivirals has been associated with drug-specific effects, including myelosuppression and renal toxicity, in hematopoietic stem cell transplant recipients.

## **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, is approved for use in bone marrow transplants in the EU, Switzerland, the USA, Canada and Japan. for prevention of CMV infections in adult recipients of an allogeneic hematopoietic stem cell transplant. The Company develops 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 November 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".

For more information, please visit [www.aicuris.com](http://www.aicuris.com).

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