

## **AiCuris-Team nominated for German Future Prize 2018**

- **Prof. Dr. Helga Rübsamen-Schaeff, Founding-CEO, and Dr. Holger Zimmermann, CEO of AiCuris Anti-Infective Cures GmbH are one of three teams nominated for the German President's Award for Innovation in Science and Technology 2018**
- **AiCuris team nominated for their project, "Protection in the Absence of the Immune System - a Life-Saving Innovation against Dangerous Viruses"**
- **Together, both scientists developed the world's first and only drug to prevent infections with a common virus in bone marrow transplant patients, generating a paradigm shift in this field of transplantation medicine**

**Wuppertal, Germany, September 12, 2018** - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs targeting infectious diseases, announces the publication of the nomination of Prof. Dr. rer. nat. Helga Rübsamen-Schaeff and Dr. rer. nat. Holger Zimmermann for the [German Future Prize](#) (Deutscher Zukunftspreis) 2018 by the Office of the Federal President today. The nominees for one of the most prestigious awards for technology and innovation in Germany were selected by the jury for their project, "Protection in the Absence of the Immune System - a Life-Saving Innovation against Dangerous Viruses". The German Future Prize 2018 will be presented by Germany's President, Dr. Frank-Walter Steinmeier, on November 28<sup>th</sup> in Berlin.

The two nominated researchers together with their team were the first to identify and to develop an active substance (Letermovir) that effectively protects patients with a weakened or ineffective immune system against human cytomegalovirus (CMV) infections. In a newly founded company they developed a drug based on this compound, opening up new perspectives in transplantation medicine. This drug has recently become available to patients undergoing bone marrow transplantation and for whom the virus poses a life-threatening risk.

The basis for the innovation was laid by Prof. Rübsamen-Schaeff at Bayer AG before the drug was further developed in her newly founded company AiCuris. Given the capital-intensive phase 3 clinical trials required, AiCuris licensed the drug to the US company Merck Sharp & Dohme (MSD), which became AiCuris' commercialization partner. The drug is now approved for use in bone marrow transplants in the EU, Switzerland, the USA, Canada and Japan.

Helga Rübsamen-Schaeff founded AiCuris Anti-Infective Cures GmbH in 2006 and served as Chief Executive Officer until 2015, and now serves as Chair of the Scientific Advisory Board. Holger Zimmermann, one of the inventors of Letermovir, took over responsibilities as CEO of the Wuppertal-based company in 2015.

"I am delighted that Prof. Rübsamen-Schaeff and Dr. Zimmermann have been nominated for the German Future Prize 2018. This is a great honor for both of them, in their roles as researchers and as managers as well as an honor for AiCuris. It also represents strong validation of the company's innovative strength in the area of anti-infectives," said **Dr. Thomas Strüngmann, who, together with his brother Andreas, is the main investor in AiCuris Anti-infective Cures GmbH.** "As

primary investors, we have supported AiCuris since it was spun out of Bayer. Throughout this time, we have remained impressed by the passion and commitment of Professor Helga Rübsamen-Schaeff and Dr. Holger Zimmermann for the development of something totally new and groundbreaking - drugs that can truly make a difference in the treatment of patients. Both are pioneers, ready to break new ground in their field but who also have shown they have the conviction, enthusiasm and energy to overcome hurdles and bring a drug successfully through development.”

### **The project: Protection in the Absence of the Immune System - a Life-Saving Innovation against Dangerous Viruses**

For many patients with blood cancer, bone marrow transplantation is the last hope for a cure. In this process, the patient’s bone marrow, including cancer cells, are destroyed and replaced by stem cells from a donor. In order for the patient's body to accept the foreign cells, the immune system must be “switched off” in preparation for the transplant. Due to severe immune deficiency following transplantations, recipients of a stem cell grafts carrying a latent CMV infection have an extremely high risk of developing a CMV infection, which is life-threatening if not controlled.

The innovative drug developed by the nominees offers for the first time the possibility of a prophylactic treatment against CMV infections. Its active substance Letermovir belongs to a new chemical class and thus uniquely differs from all substances previously used against CMV infections. The drug is therefore, not simply another development, but works based on a completely new mechanism: It attacks a virus-specific structure, which does not naturally occur in the human body, and thus prevents the spread of the virus. 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.

Today, about 50% of the population in the developed world carries a chronic infection with CMV. In developing countries, that figure rises to 90-100% of the population. Individuals with an intact immune system rarely show symptoms after their 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 cause blindness. While therapies against CMV are available, strong side effects make them unsuitable for protecting bone marrow recipients.

### **An innovative drug with great potential**

For bone marrow transplant recipients, this drug is the only approved treatment that is effective in preventing CMV infections. It holds great potential to help patients as the number of bone marrow transplants worldwide is steadily increasing. There are currently about 60,000 per year, of which about 40,000 patients are at risk to develop a CMV infection. Additional patient groups could include: AIDS patients, newborns, recipients of other donor organs and patients in other conditions in which the immune system is weakened. Currently, a study is being conducted in kidney transplantation. To date, AiCuris has received upfront and milestones payments of € 260 million. In addition, AiCuris receives royalties on world-wide net sales. Analysts estimate world-wide peak

sales in Euros to be in the high three-digit million range. The company also has the option to co-promote the drug in some European countries.

### **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 GmbH & Co KG ([www.aicuris.com](http://www.aicuris.com)). The drug is approved for use in bone marrow transplants in the EU, Switzerland, the USA, Canada and Japan.

### **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.

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

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