

AiCuris' Licensee MSD launches PREVYMIS™ (letermovir) in Germany

- **AiCuris and MSD celebrate successful partnership in an exclusive media roundtable discussion pointing to the importance of pharma / biotech collaborations in drug development**
- **The financial returns from this successful project provide AiCuris with the stability and flexibility to keep discovering and developing innovative therapies**

Wuppertal, Germany, February 23, 2018 - AiCuris Anti-infective Cures GmbH, a leading company in the discovery and development of drugs against infectious diseases, today announced that MSD (in the U.S. and Canada known as Merck & Co., Inc., Kenilworth, N.J., USA), has launched PREVYMIS™ (letermovir) in Germany. PREVYMIS™, that was successfully developed by AiCuris up to clinical phase 2b and licensed to MSD in 2012, has recently been approved by the U.S. and European regulatory authorities for prophylaxis (prevention) of cytomegalovirus (CMV) reactivation and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

In the light of the launch, AiCuris and MSD hosted a roundtable discussion, entitled, “Biotech and Pharma – together successful. AiCuris and MSD show how it works!” The event was held at AiCuris’ headquarters in Wuppertal, Germany. Using the development of PREVYMIS™ as a case study, Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH; Prof. Helga Rübsamen-Schaeff, founding CEO and Chair of the Scientific Advisory Board of AiCuris; Dr. Kristian Löbner, MD, PhD, Medical Director of MSD Germany and Dr. Thomas Strüngmann, main investor of AiCuris discussed with the German press how important a good partnership can be for the success of a project.

The letermovir case study

“At the beginning of our project we analyzed what was available for the patients. There were drugs with bone marrow-toxic side effects which made it impossible to use these drugs in patients undergoing bone marrow transplantation. And the medical experts were deeply convinced that there is no prophylaxis possible for bone marrow transplant patients, but only treatment after the onset of the infection,” said **Prof. Helga Rübsamen-Schaeff, founding CEO and Chair of the Scientific Advisory Board of AiCuris**. “So, avoiding CMV infections in transplant patients was clearly a goal. We wanted to develop something really new and better, a **game changer** that could protect patients and significantly increase their chances of survival. In order to do so, we decided to search for drugs with novel modes of action, which would address viral targets, which are not present in the human body and hence would not have the toxic side-effects of the then available drugs. Now, many years later, we are thrilled to see that our vision has become reality with PREVYMIS™ approved, and on the market.”

“We are convinced that a decade ago, many pharmaceutical companies made a big mistake when they stepped out of anti-infective research. The current development - be it from antibiotic resistance or new epidemics - proves us right,” stated **Dr. Thomas Strüngmann, who, together with his brother, Andreas, is majority investor in AiCuris**. “When I first met the AiCuris team, I was impressed by their enthusiasm and entrepreneurial spirit to develop a drug that could really change the treatment paradigm with anti-infective cures. That is exactly what we look for as investors - pioneers who are ready to pursue

new directions. I am very happy to be part of this success story and would like to express my gratitude to the entire AiCuris team.”

“For AiCuris, it was extremely important to find a global and strong partner who also brings the expertise in the field of anti-infectives - and for whom the AiCuris product really means a valuable extension to the portfolio. In addition, the new partner should fit in terms of research and organizational culture. As it turned out, MSD was a perfect choice,” said **Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures GmbH**. “To see PREVYMIS™, a drug that initially was discovered in our laboratories, approved in the U.S. and Europe and now being launched in Germany, makes us very proud. The financial returns from this successful project provide AiCuris with the stability and flexibility to keep discovering and developing innovative therapies that have the potential to truly make a difference in the treatment of patients suffering from infectious diseases. The current success allows us to further develop AiCuris and build a sustained company.”

Under the terms of the agreement with MSD, AiCuris receives milestone royalties on net sales and is eligible for milestone payments based on achievement of predefined regulatory and commercialization. AiCuris previously received milestone payments of 30 million euros for approval by the European Medicines Agency (EMA) in January 2018 and of 105 million euros for approval by the U.S. Food and Drug Administration (FDA) in November 2017.

The importance of pharma / biotech collaborations in drug development

With a growing gap between newly approved, innovative medicines and ever-increasing medical needs, healthcare stakeholders need to work more closely together to expand basic research, drive innovation and maintain investments in research, development and production. According to the German association of research-based pharmaceutical companies (vfa, Verband forschender Arzneimittelhersteller), an annual investment in research and development of approximately € 5.5 billion resulted in the introduction of 30 new approved medicines in 2016. The developmental path of a new drug is long and rocky. From an average of 5,000-10,000 screened and optimized candidates just one drug reaches the market.

"Innovations come from research and we urgently need to find new ways to promote and fund research to ensure medical progress for patients," said **Dr. Kristian Löbner, MD, PhD, Medical Director of MSD, Germany**. "MSD is preparing for the future and is setting up several new research sites in the US and Europe for nearly 500 scientists to further strengthen its positioning, especially in biotechnology. In addition, we are open for external partnerships and are constantly screening the market for new innovative approaches. The successful cooperation with AiCuris and the resulting introduction of PREVYMIS™, which now has been launched in Germany, confirm our strategy.”

About PREVYMIS™ (letermovir)

PREVYMIS™ is a member of a new class of non-nucleoside CMV inhibitors (3,4 dihydro-quinazolines) and inhibits viral replication by specifically targeting the viral terminase complex. Cross resistance is not likely with drugs outside of this class. PREVYMIS™ is fully active against viral populations with substitutions conferring resistance to CMV DNA polymerase inhibitors. These DNA polymerase inhibitors are fully active against viral populations with substitutions conferring resistance to

PREVYMIS™. PREVYMIS™ has no activity against other viruses. PREVYMIS™ has been granted orphan designation for the prevention of CMV disease in at-risk populations in the U.S., EU and Japan.

Under an agreement signed in 2012, MSD (through a subsidiary) purchased worldwide rights to develop and commercialize PREVYMIS™ from AiCuris GmbH & Co KG (www.aicuris.com).

About CMV and Treatment

CMV is a common Herpes virus that infects people of all ages. Today, approximately 50% of the people in the developed world are CMV seropositive, meaning they have CMV antibodies in their blood, indicating a previous exposure to or primary infection with 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 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 and bone marrow toxicity, in HSCT recipients.

Up to now standard treatment of CMV infections in transplant patients was mainly done with nucleosidic drugs. Despite their effectiveness, they have limitations that are based on the mode of action. Nucleosidic drugs require activation by a viral enzyme in order to be effective, which means that the drug can only be effective in infected cells.

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 against infectious diseases. The Company's majority investor is SANTO Holding. The Company is developing drugs for the treatment of viruses such as human cytomegalovirus (HCMV), 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.

About MSD

MSD – Merck & Co., Inc., in the USA and Canada, with headquarters in Kenilworth, NJ, USA – is a leading global healthcare company with a more than 125-year history of discovering and developing new solutions for health challenges worldwide. The company has approximately 69,000 employees and operates in more than 140 countries. MSD generated sales of approximately 40.1 billion US dollars in 2017 and is the world's fifth-largest pharmaceutical company by revenue (Forbes Global 2000 List 2017). The corporation has its German headquarters in Haar near Munich.

MSD's core business is the discovery, development, production and distribution of prescription medicines, vaccines, biologic therapies, and animal health products. To continue to be successful with innovative health solutions, MSD invests one out of every four US dollars in research and development (about 10 billion US dollars in 2017). Areas of focus are both the prevention and the treatment of cancer,

cardiovascular diseases, Alzheimer's and infectious diseases like HIV and ebola. MSD also offers solutions to health challenges all over the world with a wide variety of corporate responsibility programs.

Tel: 0800 673 673 673; Fax: 0800 673 673 329; E-Mail: infocenter@msd.de; Internet: www.msd.de;
Twitter: @MSD_Deutschland

Contacts

AiCuris Anti-infective Cures GmbH

Katja Woestehemke
Friedrich-Ebert-Str. 475/Geb. 302
42117 Wuppertal

Phone +49 202 317 63 0
Fax +49 202 317 63 1601
Email business@aicuris.com
Web www.aicuris.com

Media Relations

MC Services AG

Anne Hennecke
Kaiser-Friedrich-Ring 5
40545 Düsseldorf

Phone +49 211 529 252 22
Fax +49 211 529 252 29
Email anne.hennecke@mc-services.eu
Web www.mc-services.eu

MSD SHARP & DOHME GMBH

Stephanie Ralle-Zentgraf
Lindenplatz 1
85540 Haar

Phone +49 89 4561-1540
Fax +49 89 4561-1329
Email stephanie.ralle-zentgraf@msd.de
Web www.msd.de