AiCuris Received 30 Million Euros Milestone Payment from Licensing Partner MSD Following U.S. FDA Approval of PREVYMIS® (letermovir) in Second Indication

- PREVYMIS® now approved for prophylaxis of Cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
- This first-in-class antiviral agent was initially approved by FDA for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT)
- AiCuris received Euro €30 Million milestone payment and additionally is eligible for additional milestone payments and royalties on future net sales

Wuppertal, Germany, August 23, 2023 - AiCuris Anti-infective Cures AG, a leading clinical-stage pharmaceutical company developing novel, therapeutic candidates for the prevention and treatment of severe and potentially life-threatening infectious diseases in immunocompromised patients, announced today that it has received milestone payments in the amount of EUR €30 million from its licensing partner MSD (tradename of Merck & Co., Inc., Rahway, N.J., USA, (NYSE: MRK)) following U.S. Food and Drug Administration (FDA) approval for first-in-class antiviral agent PREVYMIS® in a new indication - the prophylaxis of CMV disease after kidney transplant in Donor CMV-seropositive/Recipient CMV-seronegative patients.

"We are excited that our partner MSD received FDA approval for PREVYMIS® (letermovir) for the prophylaxis of CMV infection in kidney transplanted patients. Since 2017, the drug has already protected thousands of allogeneic stem cell transplanted patients from CMV disease. With this label expansion, CMV-seropositive kidney transplant patients now have a novel, safe and effective treatment option," said **Larry Edwards, CEO of AiCuris Anti-infective Cures AG**. "This important milestone further validates our comprehensive research and development engine and supports the development of our pipeline including our proprietary phase 3 product candidate, Pritelivir, developed for treatment of resistant herpes simplex virus (HSV) infections in immunocompromised patients."

The FDA approval was supported by a Phase 3, randomized, multicenter, double-blind, active comparator-controlled non-inferiority trial (P002, NCT03443869) in 589 adult kidney transplant recipients at high risk (CMV D+/R-). According to the MSD announcement, the study demonstrated that PREVYMIS® was non-inferior to valganciclovir, the current standard of care, for the primary endpoint of incidence of CMV disease (CMV end-organ disease or CMV syndrome, confirmed by an independent adjudication committee) through Week 52 post-kidney transplant.

For more detailed information on the Phase 3 trial, please follow the link to the corresponding press release recently published by U.S. Merck &Co., Inc.

About AiCuris Anti-infective Cures AG

AiCuris aims to discover, develop, and deliver innovative, anti-viral drugs to immunocompromised patients aiming to prevent severe condition and life-threatening diseases.

The company has developed a commercial drug as well as pipeline of clinical-stage and pre-clinical anti-viral candidates. Its lead product PREVYMIS® (letermovir), a first-in-class non-nucleoside cytomegalovirus (CMV) inhibitor, was licensed to MSD and is commercialized for the prevention of human CMV infections in immunocompromised patients who underwent an allogeneic hematopoietic stem cell transplantation or kidney transplantation. AiCuris' wholly owned product candidate, Pritelivir, targeting resistant herpes simplex virus (HSV) infections in immunocompromised patients, is in phase 3 clinical development. Therapeutic candidates for the treatment of other virus infections such as BK virus and adenovirus are in earlier stages of development.

AiCuris is supported by a strong shareholder base, including lead investor SANTO Holding.

For more information, please visit www.aicuris.com.

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