

AiCuris Received 15 Million Euros Milestone Payment from Licensing Partner MSD Following EMA Approval of PREVYMIS® for Prevention of CMV Infection in High-Risk Adult Kidney Transplant Recipients

- PREVYMIS® now approved in the U.S. and Europe for prophylaxis of Cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
- EMA approval triggers a €15 Million Milestone payment to AiCuris and AiCuris is eligible for further milestone payments and royalties on future net sales
- Obtained funds will further boost the clinical development of AiCuris' product candidate Pritelivir for treatment of resistant herpes simplex virus (HSV) infections in immunocompromised patients

Wuppertal, Germany, January 9, 2024 - 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 €15 million from its licensing partner MSD (tradename of Merck & Co., Inc., Rahway, N.J., USA, (NYSE: MRK)) following EMA approval for the first-in-class antiviral agent PREVYMIS® (letermovir) for the prophylaxis of CMV disease after kidney transplant in Donor CMV-seropositive/Recipient CMV-seronegative patients at high risk.

“Following the U.S. approval mid-2023, we are excited that our partner MSD now also received European approval for PREVYMIS® (letermovir) in its second indication, the prophylaxis of CMV infection in adult kidney transplanted patients at high risk. This is a further important step to broadly make this drug available to immunocompromised patients being in high need of a novel, safe and effective treatment option against CMV infection and disease,” said **Larry Edwards, CEO of AiCuris Anti-infective Cures AG**. “We are proud to watch the continued success story of letermovir and aim to leverage our comprehensive research and development engine to deliver further novel therapeutic options to immunocompromised patients with high medial need.”

PREVYMIS® (letermovir) is an antiviral agent that was initially approved by the U.S. Food and Drug Administration (FDA) in 2017 and by the EMA in 2018 for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic HSCT. In June 2023, the FDA and in December 2023 the EMA approved PREVYMIS® for prophylaxis of CMV disease in adult kidney transplant recipients at high risk. Moreover, extended 200-day dosing for PREVYMIS® for CMV prophylaxis in adult HSCT recipients at risk for late CMV infection and disease was approved by the FDA in August 2023.

Approvals by national authorities 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.

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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