AiCuris' Licensing Partner MSD Demonstrates Efficacy in Phase 3 Study with PREVYMIS® for Prevention of Cytomegalovirus Disease in Adults After Kidney Transplantation

- PREVYMIS showed non-inferior efficacy and more favorable safety profile compared to standard of care; MSD presented results in late breaking oral presentation at IDWeek 2022.
- Based on these phase 3 results, MSD plans to submit a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) by the end of this year.
- PREVYMIS is a first-in-class antiviral agent that was approved by the U.S. FDA for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT).
- PREVYMIS was developed by AiCuris through phase 2 studies prior to licensing the antiviral medicine to MSD in 2012. AiCuris is eligible to receive milestone payments and royalties on net sales of PREVYMIS.

Wuppertal, Germany, October 24, 2022 - AiCuris Anti-infective Cures AG, a leading clinical stage pharmaceutical company in the development of novel, resistance-breaking antiviral and antibacterial agents for the treatment of severe and potentially life-threatening infectious diseases, announced today that its licensing partner MSD (tradename of Merck & Co., Inc., Rahway, N.J., USA, (NYSE: MRK)) presented positive findings from a phase 3 clinical trial that assessed safety and efficacy of PREVYMIS (letermovir) compared to valganciclovir for cytomegalovirus (CMV) prophylaxis in 601 adult kidney transplant recipients at high risk for CMV disease. The data were presented during a late-breaking oral session at the IDWeek Annual Meeting (Abstract # LB2307). Based on these findings, MSD plans to submit a sNDA to the FDA by the end of this year.

According to the MSD announcement, the trial results met the primary endpoint demonstrating that PREVYMIS was effective and non-inferior to valganciclovir for preventing CMV disease. At 52 weeks following kidney transplant, 10.4% (n=30) of the PREVYMIS group developed CMV disease versus 11.8% (n=35) of the valganciclovir group (stratum adjusted difference= -1.4, [95% CI, -6.5, 3.8]). PREVYMIS had a more favorable safety profile compared to valganciclovir, with fewer drug-related adverse events and study drug discontinuations due to adverse events reported in the PREVYMIS group (4.1%; n=12) versus 13.5% (n=40) in the valganciclovir group; (95% CI, −14.1, −4.9). Specifically, PREVYMIS-treated patients had significantly less myelotoxicity, as measured by rates of leukopenia or neutropenia, compared to valganciclovir-treated patients; 26.0% (n=76) versus 64.0% (n=190), (95% CI, -45.1, -30.3; p-value <0.0001).

"We are excited that our partner MSD built on the initial success of PREVYMIS in the hematological transplant setting and showed, that PREVYMIS is effectively preventing CMV disease with significantly less toxicities compared to standard of care in adult kidney transplant recipients," said **Dr. Holger Zimmermann, CEO of AiCuris Anti-infective Cures AG**. "This important milestone further validates our ability to successfully develop innovative therapies that have the potential to truly make a difference for patients suffering from serious infectious diseases."

In the phase 3 study, 601 patients were randomized (1:1) to receive once a day either 480 mg of PREVYMIS (n=301) or 900 mg of valganciclovir (n=300), within 7 days post-kidney transplant through 28 weeks (~200 days) post-transplant, with follow-up through 52 weeks. The primary endpoint was the proportion of participants with CMV disease adjudicated by an independent, blinded committee. The median age of participants was 52 years in the PREVYMIS study group and 51 years in the valganciclovir study group. Participants were stratified by use/non-use of lymphocyte-depleting induction immunotherapy.

PREVYMIS is a first-in-class antiviral agent that was approved by the U.S. FDA in 2017 and is indicated for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT).

About CMV and Treatment

CMV is a common virus that infects people of all ages. Many adults in the United States 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. When a transplant recipient who is CMV seronegative receives an organ from a donor who is CMV seropositive, the transplant recipient can get CMV from the donated organ. 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.

About PREVYMIS® (letermovir)

PREVYMIS is the only drug approved in the United States for prophylaxis of CMV infection and disease in adults who are CMV-seropositive and have received an allogeneic HSCT. PREVYMIS is also approved in more than 60 countries outside of the United States, including EU member states, Canada, Japan and China. PREVYMIS is a first-in-class non-nucleoside CMV inhibitor (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.

Under an agreement signed in 2012, MSD purchased worldwide rights to develop and commercialize letermovir from AiCuris Anti-infective Cures AG.

About AiCuris Anti-infective Cures AG

AiCuris, a clinical-stage biopharmaceutical company focuses on the discovery and development of drugs targeting infectious diseases. PREVYMIS® (letermovir), a first-in-class non-nucleoside cytomegalovirus (CMV) inhibitor acting via a novel mechanism of action, was licensed to MSD in 2012 and is approved in the EU, US, Japan, China and other parts of the world for the prevention of human CMV infections in adults who received allogeneic hematopoietic stem cell transplantation. AiCuris has a broad pipeline of clinical-stage and pre-clinical anti-viral and anti-bacterial product candidates. Its wholly owned lead asset, pritelivir, targeting single- or double-resistant herpes simplex virus (HSV) infections, is in phase 3 clinical development. Additional candidates are in development for the treatment of viruses, such as hepatitis B virus (HBV), adenoviruses and BK virus (BKV), as well as SARS-CoV2 and other viruses with pandemic potential. Moreover, AiCuris seeks to develop innovative treatment options for indications with high medical need, including life-threatening, multidrug-resistant, hospital-treated pathogens. Product candidates for antimicrobial resistance (AMR), diabetic foot ulcers and sepsis are in pre-clinical development.

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

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