Aicuris Presents Positive Phase 3 Data for Pritelivir in Immunocompromised Patients with Refractory Herpes Simplex Virus at TANDEM

- Pritelivir met its primary endpoint of superior lesion healing, achieving a 62.7% lesion healing rate compared to 34.0% with standard-of-care therapies (investigator's choice), resulting in an adjusted treatment difference of 28.4% (p = 0.0047)
- Pritelivir demonstrated a favorable safety and tolerability profile, with fewer treatment-emergent adverse events and drug-related discontinuations compared to investigator's choice
- Aicuris is on track to submit a New Drug Application (NDA) to the U.S. FDA in Q1 of 2026
- The 2026 Tandem Meetings cover the latest research and breakthroughs in the evolving field of hematopoietic cell transplantation (HCT), cellular therapy and gene therapy

Wuppertal, Germany, February 5, 2026 - Aicuris Anti-infective Cures AG ("Aicuris") today announced positive results from its pivotal Phase 3 trial (PRIOH-1, NCT03073967), evaluating pritelivir in immunocompromised patients with refractory herpes simplex virus (HSV) infections, with or without resistance (R±R). Pritelivir, a novel small molecule antiviral targeting the helicase-primase complex of HSV, demonstrated superior efficacy and a favorable safety and tolerability profile compared to investigator's choice therapy (ICT). The results will be presented by study investigator Genovefa Papanicolaou, MD, in an Oral Late Breaker presentation at the 2026 Tandem Meetings on February 7, 2026, in Salt Lake City, USA.

As announced in October 2025, the trial met its primary efficacy endpoint and demonstrated favorable safety and tolerability results. Pritelivir achieved a clinically meaningful and statistically significant superiority in lesion healing of 62.7% compared to 34.0% for ICT, with an adjusted treatment difference of 28.4% (p = 0.0047). Pritelivir was associated with fewer drug-related treatment-emergent adverse events (TEAEs), including renal, electrolyte and drug-related TEAEs, leading to discontinuations compared with ICT (2.0% vs. 20% respectively). The most common TEAEs were headache, diarrhea, nausea, decreased appetite, vomiting and dizziness with a ≥5% incidence.

"Current therapeutic options for hematopoietic cell transplant patients with refractory or resistant herpes simplex viral infection are limited by poor response rates, significant toxicities, and the burden of daily intravenous infusions in a healthcare setting," said **Genovefa Papanicolaou, MD, Clinical Director of Infectious Disease Service at Memorial Sloan Kettering Cancer Center and Professor at Weill Cornell College of Medicine**. Pritelivir addresses a critical unmet medical need for an oral agent offering statistically superior and clinically meaningful lesion healing with fewer side effects. It has the potential to significantly improve both clinical outcomes and quality of life for these vulnerable patients."

"For more than two decades, there has been no innovation in antiviral medicines for HSV, leaving clinicians with limited treatment options for patients who do not respond to existing antivirals. By targeting an essential step in the virus's replication process, pritelivir offers a novel approach that can overcome current antiviral resistance," **Cynthia Wat, MD, CMO of Aicuris**, added. "Together, these results mark a pivotal moment for patients with refractory HSV infections, supporting pritelivir's potential to redefine the standard of care for patients at high risk of morbidity and mortality. We look forward to bringing it swiftly to those with few effective and well tolerated alternatives."

The global, controlled, open-label comparative trial (NCT03073967 / Eudra-CT 2023-510088-37-00) randomized and treated a total of 101 immunocompromised patients with R±R HSV infection, including transplant recipients (hematopoietic stem-cell and solid organ), patients with malignancies, autoimmune or inflammatory disorders, and patients with an HIV infection. An additional 56 patients were treated in the non-randomized part of the trial. Participants received either oral pritelivir (100 mg daily, 400 mg loading dose on the first day of therapy) or ICT (IV foscarnet, IV/topical cidofovir or topical imiquimod) for up to 28 days, with the option to extend treatment to 42 days, if lesion improvement was observed.

About Herpes Simplex Virus

Herpes Simplex Virus (HSV) includes two types, HSV-1 and HSV-2, both of which cause lifelong infections. HSV-1 most commonly causes labial herpes, typically presenting as cold sores, while HSV-2 is the primary cause of genital herpes. HSV infections are characterized by recurrent, painful lesions and sores and, in severe cases, can lead to complications such as encephalitis, meningitis, disseminated disease, keratitis and neonatal herpes. HSV infections represent a substantial global public health burden. According to the World Health Organization, an estimated 3.8 billion people under the age of 50, or 64% of the global population, were infected with HSV-1 in 2020. 520 million people aged 15 to 49 were living with HSV-2. The disease burden is particularly high in immunocompromised patients, who are at increased risk of more severe, more frequent and treatment-refractory HSV infections.

About Pritelivir

Pritelivir, a novel helicase-primase inhibitor developed by Aicuris, targets both HSV-1 and HSV-2. These viruses are responsible for genital, oral, or disseminated infections with increasing severity and limited treatment options, particularly in immunocompromised patients where being treatment refractory or resistant to existing antivirals is a significant clinical challenge. Unlike traditional antivirals, pritelivir blocks viral DNA synthesis by inhibiting the helicase-primase complex, a mechanism distinct from marketed nucleoside analogues. Because of this distinct mode of action, pritelivir is active against strains resistant to nucleoside analog-and foscarnet based therapies.[1] Earlier clinical trials in immunocompetent and immunocompromised individuals showed a favorable safety profile and early signals of clinical efficacy compared to standard of care treatments like valacyclovir and foscarnet. Based on these results, pritelivir was granted FDA Breakthrough Therapy designation. In October 2025, Aicuris announced that pritelivir met its primary endpoint in the pivotal Phase 3 trial. The company expects to file for marketing authorization with the U.S. FDA in Q1 of 2026.

[1] Sallée, L. and Boutolleau, D. (2024), Management of Refractory/Resistant Herpes Simplex Virus Infections in Haematopoietic Stem Cell Transplantation Recipients: A Literature Review. Rev Med Virol, 34: e2574. https://doi.org/10.1002/rmv.2574

About Aicuris
Aicuris is meeting the needs of the growing population of immunocompromised people who require precise therapies to effectively treat infection. Our flagship product, PREVYMIS®, marketed by our partner MSD, prevents CMV in a defined group of transplant recipients. Our pivotal Phase 3 candidate, pritelivir, aims to address refractory HSV infections in a broad population of patients with weakened immune systems. For immunocompromised people, an otherwise manageable infection can mean life or death. Aicuris, with its expertise and growing pipeline, is committed to providing therapeutic solutions for them now and in the future.

Contact:
Aicuris Anti-infective Cures AG
info@aicuris.com

Trophic Communications
Dr. Stephanie May and Anja Heuer
Phone: +49 171 1855 682
Email: aicuris@trophic.eu