Pritelivir Demonstrates Superior Efficacy in People Living with HIV with Refractory HSV in Phase 3 PRIOH-1

- In a subgroup analysis of people living with HIV enrolled in PRIOH-1, pritelivir demonstrated superior lesion healing, achieving 61% complete lesion healing compared with 20% receiving investigator's choice therapy (ICT) with an adjusted treatment difference of 37% (p = 0.027) in people living with HIV with refractory HSV infections
- The results were presented as a late-breaking oral presentation at the Conference on Retroviruses and Opportunistic Infections (CROI), which focuses on key clinical and scientific innovations in human retrovirus-associated diseases like HIV

Wuppertal, Germany, February 25, 2026 - Aicuris Anti-infective Cures AG ("Aicuris") today announced superior efficacy results from a subgroup analysis of its pivotal Phase 3 trial (PRIOH-1) evaluating pritelivir vs. investigator's choice in people living with HIV with refractory herpes simplex virus (HSV) infection. The results were presented as a late-breaking oral presentation at the Conference on Retroviruses and Opportunistic Infections (CROI) on February 25, 2026, in Denver, USA.

People living with HIV face a higher risk of severe, refractory HSV infections due to weakened immunity. HSV-2 also increases HIV acquisition risk, and co-infection can cause aggressive, prolonged, painful lesions and may accelerate HIV progression. Repeated antiviral use for treatment of HSV recurrence increases the risk of resistance, underscoring the urgent need for more effective HSV therapies for this vulnerable population.

"Patients living with HIV who develop refractory HSV infections with or without acyclovir resistance often present with prolonged, atypical, and clinically challenging disease courses," **said Professor Jean-Michel Molina, University of Paris Cité, Department of Infectious Diseases, Saint-Louis and Lariboisière Hospitals APHP, Paris France,** a principal investigator in the PRIOH-1 study who made the presentation at CROI. "The subgroup analysis from this Phase 3 trial provides important evidence that pritelivir can achieve meaningful lesion healing in this population, using an oral treatment option. These data add an important piece to our understanding of how refractory HSV can be managed in people living with HIV."

In the subgroup, people living with HIV represented 37.6% (38/101) of all immunocompromised patients enrolled in the PRIOH-1 Phase 3 trial and had a mean CD4 cell count of 334.8 cells/mm³. Among these patients, 81.6% (31/38) had refractory HSV (no clinical improvement in HSV lesions after ≥ 7 days of treatment), and 18.4% (7/38) had laboratory-confirmed acyclovir resistance. 40% of the study cohort had another underlying immunosuppressive condition.

Similar to other subgroups, pritelivir achieved superior lesion healing of 61% (14/23) within up to 28 days of treatment, compared with 20% (3/15) for ICT, with an adjusted treatment

difference of 37%, p = 0.027 [95%CI 7.6, 66.8] (post-hoc analysis). The majority (96%) of people living with HIV completed pritelivir treatment compared with 60% in the investigator's choice treatment group.

"People living with HIV often experience more complex clinical manifestations of HSV, which can make infections particularly difficult to treat," said **Cynthia Wat, CMO of Aicuris**. "As an antiviral with a novel mechanism of action, pritelivir has shown efficacy in the treatment of refractory HSV infections with or without resistance (R±R) and may offer an important option for people living with HIV facing severe, refractory HSV disease."

Aicuris announced positive efficacy and favorable safety results for pritelivir at the 2026 Tandem Meetings earlier this month. The global, controlled, open-label comparative trial (PRIOH-1, NCT03073967 / Eudra-CT 2023-510088-37-00) included 101 randomized patients and 56 non-randomized patients with R±R HSV infection, including patients living with HIV, hematopoietic stem-cell and solid organ transplant patients, and patients with malignancies, autoimmune or inflammatory disorders. Patients were treated with either oral pritelivir or ICT (IV foscarnet, IV/topical cidofovir, or topical imiquimod). Pritelivir demonstrated a favorable safety and tolerability profile. It was associated with fewer renal, electrolyte events and drug-related TEAE discontinuations (2.0%) compared with ICT (20.0%). The most common TEAEs that occurred while receiving pritelivir were headache (13.7%), diarrhea (11.8%), nausea (7.8%), decreased appetite (7.8%), vomiting (5.9%) and dizziness (5.9%).

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

[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

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.

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.

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