Aicuris Receives FDA Priority Review for Pritelivir NDA and Presents New Phase 3 Data at ESCMID 2026

- The U.S. Food and Drug Administration has granted Priority Review for Aicuris' New Drug Application for pritelivir, a novel helicase primase inhibitor developed to treat refractory herpes simplex virus infections, with or without resistance (R±R), in immunocompromised patients
- The Prescription Drug User Fee Act (PDUFA) Target Date is in Q4 2026
- The submission is based on positive pivotal Phase 3 data demonstrating superior complete lesion healing and a favorable safety profile compared to investigator's choice therapy
- Higher efficacy rates with extended 42 day treatment of pritelivir were presented at ESCMID 2026, further strengthening the evidence for its clinical benefit

Wuppertal, Germany, April 16, 2026 - Aicuris Anti-infective Cures AG ("Aicuris") today announced that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the New Drug Application (NDA) filed for pritelivir. The submission is based on initial results from the pivotal Phase 3 trial in which pritelivir met its registrational Phase 3 primary endpoint for the treatment of refractory herpes simplex virus (HSV) infection, with or without resistance (R±R), in immunocompromised patients. The FDA has set a Prescription Drug User Fee Act (PDUFA) Target Date in the fourth quarter of 2026.

"Receiving FDA Priority Review is an exciting achievement for pritelivir on its journey to help this vulnerable patient population in an area of high unmet medical need," **said Larry Edwards, CEO of Aicuris**. "If approved, pritelivir would become the first new treatment for HSV in more than two decades. The submission reflects years of dedication from the Aicuris team, and we look forward to collaborating closely with the FDA and Asahi Kasei as we advance toward making pritelivir available to patients."

New Phase 3 data, including extended treatment outcomes, virology results, and subgroup analyses will be presented at the European Society of Clinical Microbiology and Infectious Diseases (ESCMID 2026) congress in Munich, Germany, in a late-breaking oral presentation (ESCMID Abstract: E0203) and ePoster flash session (ESCMID Abstract: 9485):

- Treatment effect and response rates increased with extended treatment up to 42 days; among patients who continued therapy, 82.4% of those treated with pritelivir achieved complete lesion healing compared with 42.0% with investigator's choice therapy (ICT), resulting in an adjusted treatment difference of 40.2% ($p < 0.0001$)
- Pritelivir treatment significantly reduced viral replication and viral burden, shortening the median time to undetectable HSV in lesions to 9 days compared with 21 days with ICT ($p = 0.0581$)
- Pritelivir demonstrated consistent treatment effects across major immunocompromised subgroups, including patients with hematological malignancies, hematopoietic stem cell and solid organ transplant recipients, and people living with HIV

- Pritelivir demonstrated a favorable safety and tolerability profile; treatment emergent adverse events (TEAEs) included renal, electrolyte and drug-related events, with a discontinuation rate substantially lower than reported under ICT (2.0% vs. 20%); the most common TEAEs reported were headache, diarrhea, nausea, decreased appetite, vomiting and dizziness with an incidence above or equal to 5%

"For immunocompromised patients with refractory HSV infections, achieving rapid lesion healing while maintaining tolerability is essential," **said Cynthia Wat, Chief Medical Officer of Aicuris.** "The new 42 day data to be presented at ESCMID demonstrate that continued pritelivir treatment translated early clinical improvement into full lesion healing, while maintaining a strong antiviral response. This efficacy response is independent of the patient's underlying immunosuppressive disease. Combined with a favorable safety profile, these results support our confidence in pritelivir's potential to meaningfully improve outcomes in different vulnerable patient populations."

Part C of the global, controlled, open-label, comparative PRIOH-1 trial (NCT03073967 / EudraCT 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. 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. An additional 56 patients were treated with oral pritelivir (100 mg daily, 400 mg loading dose on the first day of therapy) in non-randomized parts of the trial. Pritelivir met its primary endpoint by demonstrating statistically significant superiority in lesion healing after up to 28 days of treatment and a favorable safety profile compared to investigator's choice therapy (ICT).

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, 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. Pritelivir met its primary endpoint in the pivotal Phase 3 PRIOH-1 trial in immunocompromised patients with refractory HSV infections, and Aicuris submitted a New Drug Application to the FDA in Q1 of 2026.

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. In February 2026, Aicuris entered into an agreement under which Asahi Kasei will acquire Aicuris, with closing expected in the coming months.

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[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