# Aicuris Presents Positive Phase 2 Results for Pritelivir and Favorable Phase 1 Safety Data for AIC468 at ID Week 2025

- Results from pritelivir Phase 2 study demonstrate a favorable safety profile and a numerically higher lesion healing rate vs. foscarnet
- Pritelivir Phase 2 results supported FDA Breakthrough Therapy Designation and informed the pivotal study design, which recently culminated in positive Phase 3 topline results
- Phase 1 results for AIC468 showed favorable safety and pharmacokinetics, supporting further development for BK virus infections in kidney transplant recipients
- Aicuris remains on track to deliver key pipeline milestones in 2026, including regulatory submissions and trial initiations

**Wuppertal, Germany, October 20, 2025** - Aicuris Anti-infective Cures AG, today announced the presentation of new clinical data at the 2025 ID Week Annual Meeting, taking place October 19–22 in Atlanta, Georgia. The company presented results from two key pipeline programs: Aicuris' lead candidate pritelivir and AIC468. Pritelivir has recently met the primary endpoint showing statistical superiority in a Phase 3 pivotal trial for the treatment of refractory herpes simplex virus (HSV) infections. Phase 2 data were presented in an oral presentation at ID week. In addition, a poster presentation featured new safety data from the Phase 1 trial of AIC468, a novel antisense oligonucleotide (ASO) being developed for the treatment of BK virus (BKV) infection.

"The data presented at ID Week underscore the strong and consistent performance of both our clinical candidates. Findings from the pritelivir Phase 2 program were recently confirmed in a positive registrational trial, while the AIC468 Phase 1 results support further development in kidney transplant recipients at risk of BK virus-associated nephropathy," said **Cynthia Wat, MD, Chief Medical Officer of Aicuris.** "These data further validate our pipeline and reflect our commitment to developing antiviral therapies for patients with limited or no treatment options."

Aicuris presented a comprehensive update on pritelivir, including Phase 2 results (2023-510088-37-00) comparing the candidate to foscarnet (Fos) in immunocompromised patients infected with refractory mucocutaneous HSV with or without resistance (R±R). In the multi-center study a total of 22 patients were randomized 2:1 and treated with pritelivir or Fos. 8 additional patients, that were also Fos R±R or Fos intolerant, were treated with pritelivir in a non-randomized arm. All pritelivir-treated patients received a daily dose of 100mg oral pritelivir for 28 days following an initial 400mg loading dose. Pritelivir showed numerically improved efficacy compared to Fos, with 93% vs. 57% of patients achieving lesion healing within 28 days of treatment. Pritelivir was associated with fewer adverse event-related discontinuations (0% vs. 42.9%).

Following the recently announced positive Phase 3 topline results, Aicuris remains on track for a New Drug Application (NDA) submission in 2026 and is actively preparing for commercial launch in the US.

Aicuris also presented new safety data from its ongoing first-in-human Phase 1 trial (2023-510074-13-00) of AIC468, a novel antisense oligonucleotide (ASO), in healthy volunteers. The randomized, double-blind, placebo-controlled study includes single and multiple ascending dose cohorts, with subcutaneous doses ranging from 25 mg to 600 mg and an

intravenous dose of 200 mg. Weekly subcutaneous dosing over one month (120 mg to 330 mg) was also evaluated. Across all cohorts, AIC468 was safe and well tolerated, with no evidence of ASO-related class toxicities, no severe adverse events, no dose-related safety trends, and no treatment discontinuations. Favorable PK characteristics are consistent with expected profile for a 2nd generation ASO.

These findings support the further clinical development of AIC468 for the treatment of BKV infections in kidney transplant recipients, a patient population at high risk of BK viremia and BK virus-associated nephropathy, which can result in renal dysfunction or graft loss. Despite the seriousness of BKV-related complications, there are currently no approved antiviral therapies targeting the virus. Based on favorable safety and pharmacokinetic data, Aicuris plans to submit an investigational new drug dossier (IND) later in 2025 to initiate a Phase 2 trial in the first half of 2026.

“Aicuris has made significant strides across both early- and late-stage clinical programs,” commented **Larry Edwards, Chief Executive Officer of Aicuris**. “Pritelivir stands out as a cornerstone asset with clear potential to change the treatment landscape for HSV in immunocompromised patients. At the same time, we are advancing AIC468 into a patient population with clear unmet need. With regulatory submissions planned, clinical milestones ahead, and commercialization activities underway, we are executing on our mission to rapidly bring life-saving treatments to patients with severe infectious diseases.”

**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 that are often difficult to treat with a higher risk of resistance development in immunocompromised people. Unlike traditional antivirals, pritelivir blocks viral DNA synthesis by inhibiting the helicase-primase complex, a mechanism distinct from marketed nucleoside analoges. Because of this distinct mode of action, pritelivir is active against viral strains that are resistant to nucleoside analogs[1]. Based on previous clinical trial results, pritelivir received FDA Breakthrough Therapy Designation. Enrollment of the Phase 3 pivotal trial has been completed, and the Phase 3 primary superiority endpoint has been met. Pritelivir demonstrated statistically significant treatment benefit over standard-of-care. Pivotal trial results are expected to serve as a basis for filing for marketing authorization in 2026.

**About AIC468**

AIC468 is an antisense oligonucleotide therapy designed to treat BK virus reactivation in kidney transplant patients, a condition that can pose a significant health risk. The candidate blocks viral replication within infected cells by inhibiting splicing of the pre-mRNA that encodes for the virus’ large T-antigen. This innovative approach has already demonstrated potent antiviral activity along with a favorable pharmacokinetic and safety profile in preclinical studies and is currently being evaluated in a Phase 1 clinical trial.

**About Aicuris**

[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

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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