AiCuris Initiates First-in-Human Phase 1 Trial with Antiviral Agent AIC468 to Address BK Virus Infections in Kidney Transplant Recipients

Wuppertal, Germany, October 31, 2024 - AiCuris Anti-infective Cures AG today announced the initiation of its Phase 1, first-in-human trial of AIC468, a novel antisense oligonucleotide. AIC468 is an antiviral agent which aims to treat BK virus (BKV) infections in kidney transplant (KT) recipients. BKV reactivation in KT recipients is an area of high unmet medical need with no approved drug treatments. This Phase 1 trial (2023-510074-13-00) will evaluate the safety, tolerability and pharmacokinetics of AIC468 in healthy volunteers.

“BK virus infections remain an urgent threat to transplant recipients, leading to graft loss and other serious complications,” said **Cynthia Wat, MD, CMO of AiCuris**. “Advancing AIC468 into clinical trials brings us one step closer to providing a targeted therapeutic option that directly inhibits BK virus replication, that addresses this critical unmet medical need. Our team remains committed to improving outcomes for patients dealing with the challenges of post-transplant viral infections.”

“This trial marks another significant milestone in our mission to develop innovative therapies for patients with weakened immune systems, who are particularly vulnerable to serious viral infections like BK virus infections,” said **Larry Edwards, CEO of AiCuris**. “The initiation of this trial demonstrates the strength and diversity of our pipeline as we continue to advance cutting-edge solutions for high-risk patient populations. With multiple programs now in the clinic, we are confident that our approach can make a meaningful impact on the lives of immunocompromised patients.”

The randomized, double-blind, placebo-controlled first-in-human trial will assess the safety, tolerability, and pharmacokinetics of AIC468 in 72 healthy volunteers. Conducted in Germany, the trial includes both single and multiple ascending doses of AIC468. Topline data readout from the single ascending dose part of the study is expected in 2025.

About BKV

BK virus (BKV) is a common polyomavirus that infects most people in early childhood, typically without symptoms. In immunocompromised individuals, such as organ transplant recipients, BKV can reactivate, leading to serious health issues. In kidney transplant (KT) patients, BKV reactivation can cause BK virus-associated nephropathy (BKVAN), affecting up to 10%[1] of recipients and potentially resulting in graft loss. Current management involves reducing immunosuppressive therapy, which increases the risk of graft rejection. Despite its prevalence, there is no approved antiviral treatment specifically for BKV.

[1] Imlay H. et al., Consensus Definitions of BK Polyomavirus Nephropathy in Renal Transplant Recipients for Clinical Trials, *Clinical Infectious Diseases*, 2022, https://doi.org/10.1093/cid/ciac071

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 recurrent and resistant 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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