

## **AiCuris Announces Strategic Shift to Focus Development and Commercialization of Anti-infectives for Immunocompromised Patients**

- **Company will advance its highly differentiated product portfolio targeting infections that severely affect immunocompromised patients, including a proprietary phase 3 candidate with fast track to market.**
- **AiCuris to continue its transition into a fully integrated biopharmaceutical company leveraging its research, clinical development, and commercialization expertise.**

**Wuppertal, Germany, July 6, 2023** - AiCuris Anti-infective Cures AG, a leading clinical-stage biopharmaceutical company developing novel anti-infective agents, today announced that it has sharpened its strategic focus on the development of novel, therapeutic candidates for the prevention and treatment of moderate to severe and potentially life-threatening infectious diseases in immunocompromised patients. This decision enables the Company to accelerate its development efforts, prepare for market launch and further build its expertise in an area of medical need that will become increasingly important as the population of immune-compromised patients grows worldwide.

With AiCuris' enhanced focus on development and commercialization of anti-infectives for immunocompromised individuals, the Company will discontinue research activities outside of this strategic scope.

**Larry Edwards, CEO of AiCuris Anti-infective Cures AG**, said: “Immunocompromised patients develop severe, partially life-threatening disease from infections that are typically well controlled in immune competent individuals. Unfortunately, anti-infective treatment options for this growing patient population are often limited and few companies are focusing on developing appropriate therapeutic candidates. We at AiCuris decided on focusing our efforts on serving this vulnerable population with high unmet medical need. This strategic change will allow us to be more efficient and effective from an operations perspective and ensure we are able to bring novel treatment options to patients in need. With PREVYMIS<sup>®</sup>, we have already proven our ability to deliver novel treatment options to these underserved patients. By our strengthened focus we will now develop more game-changing, high growth potential products faster.”

“Sharpening our strategic direction is an important step on our way to becoming a fully integrated biopharmaceutical company that covers the entire value chain from research through clinical development and in the future also commercialization,” **Dr. Sabrina Kuttruff-Coqui, CFO of the Company**, continued. “To achieve this goal, we established a U.S. subsidiary as part of the launch preparations for our lead proprietary product Pritelivir. Our development experts and a small, highly experienced and innovative team are driving our research and development engine, which is vital in bringing novel, truly differentiated products to patients in need.”

AiCuris has successfully demonstrated its' ability to deliver anti-infectives to immunocompromised patients through PREVYMIS<sup>®</sup> (Letermovir). The Company's first-in-class antiviral agent for prophylaxis of cytomegalovirus (CMV) infection in allogeneic hematopoietic stem cell (HSCT) and kidney transplant patients, is marketed by MSD (tradename of Merck & Co., Inc.) and has seen growing revenues while protecting and saving the lives of many patients worldwide. AiCuris will continue to build its capabilities in becoming a fully integrated organization moving towards commercialization to deliver the full value of its innovative pipeline of anti-infectives focused on three key programs:

- **Pritelivir** is a proprietary drug candidate in pivotal phase 3 development for the treatment of acyclovir resistant herpes simplex virus (HSV) infections in immunocompromised patients. Pritelivir was granted Breakthrough Therapy Designation by the US FDA for the treatment of mucocutaneous HSV infections in immunocompromised patients. An Early Access Program (EAP) has been launched in various countries globally. Topline data from the ongoing phase 3 trial is expected end of 2024.
- **The anti-sense RNA therapeutic candidate AIC468** aims to prevent active infection of BK virus (BKV) in kidney transplanted patients. It is designed to specifically inhibit the splicing process of a viral mRNA encoding a protein critical for viral replication. AIC468 is expected to enter phase I early next year.
- **Preclinical programs designed to combat human ADV infections**, including systemic infections in pediatric transplant patients as well as ocular infections, specifically epidemic keratoconjunctivitis (EKC). The Company's goal is to develop the first topical treatment specifically designed for ADV infections of the eye.

In immunocompromised people, the ability to fight infections and other diseases is reduced. This can be caused by diseases or conditions such as AIDS, cancer, diabetes and genetic disorders, but also by certain treatments, including chemotherapy and radiotherapy, as well as immunosuppressive treatments like those that are essential for stem cell and organ transplants. As aggressive treatments implemented to enhance life expectancy often result in prolonged immune suppression and given the steadily increasing population of innate or acquired immune deficiencies the need for anti-infective therapeutics is increasing. Currently over 1 billion individuals are at least moderately immunocompromised.

Highly prevalent latent virus infections such as CMV, HSV and BKV can cause severe complications in immunocompromised patients for example, after transplantations.

## **About AiCuris Anti-infective Cures AG**

AiCuris, a clinical-stage biopharmaceutical company, is focused on the discovery, development, and delivery of innovative, anti-infectives drugs for immunocompromised patients aiming to prevent severe conditions and life-threatening diseases.

For more information, please visit [www.aicuris.com](http://www.aicuris.com).

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