



## AiCuris: Focusing on life-saving anti-infectives

There was a time when large pharma companies didn't consider it worthwhile to invest in the development of drugs for infectious diseases. In 2004, for instance, Bayer announced it was abandoning its research into anti-infectives. But the head of this research division, the renowned virologist Helga Rübsamen-Schaeff, fought to continue her work and found financially strong investors in the Strüngmann brothers. Under her leadership, they launched AiCuris (Anti-Infective Cures) on 1 March 2006 in Wuppertal as an independent company.

Through expertise, through strategic intelligence and by placing trust in a proven team, Rübsamen laid the foundation for AiCuris's current success. Her first major decision was to stake almost everything on a promising niche indication: the prevention of cytomegalovirus infection after bone-marrow transplants. A team at Bayer led by Holger Zimmermann, who would later become AiCuris's CEO, had already developed the compound letermovir to an advanced stage ready for clinical testing. A large majority of the human population is infected with cytomegalovirus (CMV). A CMV infection usually proceeds without symptoms because the immune system prevents the virus from replicating and causing disease. But for immunocompromised patients, especially people who have had a transplant, CMV can often be fatal. In its first clinical trial, AiCuris tested whether this can be prevented by administering letermovir postoperatively.

All previous CMV drugs were unsuitable for prophylaxis because they attacked not only the virus, but also the human organism. Letermovir, on the other hand, inhibits a viral enzyme that is not present in humans. Phase II clinical trial results published in 2012 showed good tolerability and efficacy for the compound – and piqued Big Pharma's interest. In October 2012, AiCuris licensed the compound to MSD, the trade name of Merck & Co., Inc., with headquarters in Rahway, N.J., USA, (NYSE: MRK). This deal earned the company €110 million – the largest upfront payment at the time for a research project from the German biotech scene – and potential milestone payments worth an extra €332.5 million.

The Phase III trials organized by MSD achieved their goal in 2016. They demonstrated that letermovir significantly reduced mortality after bone-marrow transplants. The FDA approved the compound under its accelerated pathway in November 2017. Meanwhile, its global sales under the brand name Prevymsis® total more than US\$400 million an-

nually. In 2018, Germany's president awarded the German Future Prize to Helga Rübsamen-Schaeff and AiCuris's then-CEO Holger Zimmermann for developing "the world's first and only drug to prevent a common virus from causing infections in bone-marrow transplant patients" and thus opening up new perspectives in transplantation medicine. In late 2022, letermovir was close to approval for a second indication: CMV prevention in kidney transplant recipients.

In February 2021, AiCuris, which now employs around 70 people, converted from a GmbH (limited liability company) to an Aktiengesellschaft (stock corporation). This move was made to open up additional growth opportunities. In the same year, the company launched its first self-organized Phase III trial to advance the compound pritelivir towards market approval for the treatment of resistant herpes simplex infections in immunocompromised patients. AiCuris is also developing a compound aimed at preventing transplant loss and lowering morbidity from the BK virus (BKV). Many people are asymptotically infected with this virus throughout their lives, but fall ill with BKV when their immune system stops functioning properly. In addition, the company's preclinical research is discovering new ways to fight other viruses as well as multiresistant bacteria. Through its development pipeline and its successes with novel compounds for patients with impaired immune systems, AiCuris shows impressively just how vital anti-infective research is to patients today and going forward.

