Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/heidelberg-based-development-revolutionizes-hepatitis-d-therapy-worldwide-us-food-and-drug-administration-fda-approves-hepatitis

Heidelberg based development revolutionizes hepatitis D therapy worldwide: US Food and Drug Administration (FDA) approves hepatitis drug Hepcludex (bulevirtide)

Joint press release of the Heidelberg Faculty of Medicine at Heidelberg University and the German Center for Infection Research: With the FDA approval of Hepcludex (bulevirtide), a therapy for chronic hepatitis D developed at the Heidelberg Faculty of Medicine at Heidelberg University, Heidelberg University Hospital, and the German Center for Infection Research (DZIF) has now reached the world's most important pharmaceutical market.

The U.S. Food and Drug Administration (FDA) has approved Hepcludex (bulevirtide) for the treatment of chronic hepatitis D infection. The active substance was largely developed and advanced by Heidelberg virologist Professor Dr Dr h.c. Stephan Urban, Professor for „Translational Virology" at the Heidelberg Faculty of Medicine at Heidelberg University and researcher at the German Center for Infection Research (DZIF). With FDA approval, the therapy is now available in the most significant global pharmaceutical market. Hepcludex was first approved in Europe in 2020 as the world's first treatment for hepatitis D. It is estimated that more than 12 million people worldwide are living with chronic hepatitis D. This aggressive form of viral hepatitis frequently leads to liver cirrhosis and liver cancer.

"The FDA approval of Hepcludex marks an outstanding achievement within a series of important translational advances in viral hepatitis over recent years. It underscores the excellence of the "Infection Diseases" research profile at Heidelberg University's Faculty of Medicine. The approval clearly demonstrates how sustainable innovation can emerge directly from the Faculty.

This breakthrough would not have been possible without the outstanding contributions of Prof. Dr. Dr. h.c. Stephan Urban and his team, — also supported by close collaborations within major research networks such as the Collaborative Research Centre/Transregio 179 and the German Center for Infection Research (DZIF). I would like to express my sincere gratitude to all involved," says Prof. Dr. Michael Boutros, Dean, Heidelberg Faculty of Medicine; Heidelberg University.

In recent years, the drug has been approved not only in the European Union, but also in Switzerland and the United Kingdom, as well as in countries including Canada, Russia, and Israel.

"The development of Hepcludex demonstrates the potential of close integration between academic research, translational infrastructures, and industrial partners. Medical innovation does not arise in the laboratory alone—what is crucial is the consistent advancement of research through to application for patients," says Professor Dr Hanns-Peter Knaebel, Chief Executive Officer of Heidelberg University Hospital.

"With the FDA approval of Hepcludex (bulevirtide), thousands of patients in the United States now gain immediate access to a highly effective therapy for an otherwise often fatal liver disease. A major challenge for the future will be to identify those affected who remain undiagnosed and to create pathways to make the drug accessible in low-income countries. The development of this active substance from its discovery to clinical application was only possible through teamwork and funding mechanisms designed not for short-term gains, but with a long-term perspective," says Professor Urban.

From basic research to an effective medicine

The FDA approval was preceded by around 30 years of research. As a basic scientist, Stephan Urban initially sought to understand the mechanisms that enable hepatitis B and D viruses to target and infect liver cells so specifically. At the time, suitable human cell culture systems were not yet available, so initial studies were conducted using a related hepatitis virus in Pekin ducks. Together with his team, Urban eventually succeeded in blocking the viral entry pathway into liver cells using a fragment of a viral envelope protein, thereby preventing infection of the liver cells. Over many years, this concept was then successfully transferred to the human hepatitis virus.

The original focus was not on developing a drug, but on understanding why hepatitis viruses exclusively infect liver cells.

However, this work led to the concept of a so-called "entry inhibitor," which blocks the gateway used by hepatitis viruses to enter cells. The German Center for Infection Research (DZIF) recognized the potential of this candidate compound and supported its translational development through to clinical application. Urban has held the professorship of Translational Virology at Heidelberg Faculty of Medicine, Heidelberg University, since 2014.

This development is regarded as a successful example of collaboration between academic research and public funding with the aim of translational advancement. The biotechnology company MYR Pharmaceuticals recognized the potential of the substance at an early preclinical stage, secured exclusive licensing rights, and took over clinical development from Phase II onwards. Following EU approval, the pharmaceutical company Gilead assumed global commercialization. With FDA approval, the therapy has now achieved its final milestone, enabling its use worldwide against an otherwise often life-threatening infectious disease.

Statements from the Department of Molecular Virology at the Center for Infectious Diseases, Heidelberg University Hospital, on the FDA approval of Hepcludex (bulevirtide)

"I clearly recall recruiting Stephan Urban in 2002 to join my newly established Department of Molecular Virology in Heidelberg. Drawing on his strong biochemical expertise, he elucidated the mechanisms by which the hepatitis B virus infects hepatocytes and identified the critical viral structures required for this process. Particularly remarkable is that, on this foundation, he succeeded in developing a therapeutic agent that prevents infection—an achievement attained by only a few and one that now benefits countless patients. I take great pride in the fact that this breakthrough emerged from my department at the time. I extend my sincere congratulations to Stephan Urban on this outstanding achievement," says Professor Dr. Dr. h.c. Ralf Bartenschlager, Medical Director of the Department of Molecular Virology at the Center for Infectious Diseases, Heidelberg University Hospital.

*"The FDA approval of bulevirtide marks a historic milestone and provides compelling evidence of the impact of excellent basic research. Over more than three decades, Prof. Urban has advanced this project with scientific vision, persistence, and leadership, ultimately making a decisive contribution to the development of a therapy for millions of patients. For our department, this represents both validation and motivation. My sincere congratulations, Stephan,"*says Professor Dr. Mathias Munschauer, Medical Director of the Department of Molecular Virology at the Center for Infectious Diseases, Heidelberg University Hospital.

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