

HepaRegeniX initiates first-in-man Phase 1 trial for its lead MKK4 inhibitor HRX-0215

HRX-0215 is the first compound from the company's small molecule-based drug discovery platform ready for clinical testing

Tubingen (Germany), August 10, 2021 – HepaRegeniX GmbH, a clinical stage company developing novel therapies for the treatment of acute and chronic liver diseases, announced today the first dosing of its lead drug candidate HRX-0215 in a Phase 1 clinical trial. HRX-0215 is a small molecule inhibitor of **Mitogen-Activated Protein (MAP) Kinase Kinase 4 (MKK4)**, a key regulator of liver regeneration. Suppression of MKK4 unlocks the regenerative capacity of hepatocytes even in severely diseased livers.

The single-center, double-blind, randomized, placebo-controlled trial plans to enroll 48 healthy male volunteers. The trial will assess the safety, tolerability, and pharmacokinetics of HRX-0215 and is designed as a single and multiple dose escalation study (SAD/MAD). HepaRegeniX expects the first results later this year. Previous extensive preclinical studies demonstrated compelling efficacy of HRX-0215 in both acute and chronic liver disease models.

“It is exciting to see the first MKK4 inhibitor now entering clinical development only four years after the synthesis of our very first small molecule compound,” said **Dr. Wolfgang Albrecht, Chief Operating Officer and Co-Founder of HepaRegeniX**. “This start of clinical development is backed by a large dataset showing the potential of our MKK4 inhibitor improving key liver parameters in a number of preclinical models plus an encouraging safety profile in 4-week general toxicology studies.”

“We are very proud to announce this important milestone for HepaRegeniX and our lead compound HRX-0215 representing a completely new first-in-class approach for enhancing liver regeneration through MKK4 inhibition,” added **Dr. Michael Lutz, CEO of HepaRegeniX**. “The first of our MKK4 inhibitors now advancing to the next level of pharmaceutical development contributes to our objective to improve the prognosis of patients with advanced liver diseases who currently have very few therapeutic options in the years to come.”

Liver diseases account for a huge unmet medical need worldwide with millions of people affected and severely impaired in their quality of life. At least 250.000 patients are suffering from an acute disease per year in EU5 and the U.S, and 700.000 patients from chronic liver diseases per year in EU5 and the U.S.¹ Chronic liver diseases are the major risk factor for hepatocellular carcinoma, which, with 2 million or 3.5 % of worldwide deaths per year, represents the fifth most common cancer and the third leading cause of cancer-related death in the United States.^{2,3}

References

¹ Fingas CD et al., CLD 2016; 8(5):119-122; DOI: <https://doi.org/10.1002/cld.585>

² Asrani SK et al., J Hepatol. 2019 Jan;70(1):151-171. DOI: <https://doi.org/10.1016/j.jhep.2018.09.014>

³ Wüstefeld T et al., Cell 2013; 153(2):389-401; DOI: <https://doi.org/10.1016/j.cell.2013.03.026>

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About HRX-0215

The lead candidate HRX-0215 is a potent and selective inhibitor of MKK4 and demonstrated preclinical efficacy in acute and chronic liver disease models. HRX-0215 was well tolerated in 4-week general toxicology studies and no geno-toxicological liabilities were detected. HRX-0215 was discovered by HepaRegeniX in collaboration with Prof. Stefan Laufer's group from the University of Tuebingen (Germany).

About HepaRegeniX GmbH – www.heparegenix.com

Since 2017, HepaRegeniX has successfully discovered and developed several preclinical drug candidates for the treatment of acute and chronic liver diseases based on a novel proprietary molecular target **Mitogen-Activated Protein (MAP) Kinase Kinase 4 (MKK4)**. MKK4 is a key regulator of liver regeneration and suppression of MKK4 unlocks the regenerative capacity of hepatocytes even in severely diseased livers. This new and unique therapeutic concept was discovered by Prof. Lars Zender and his research group at the University Hospital Tubingen, Germany. Investors in HepaRegeniX include the Boehringer Ingelheim Venture Fund (BIVF), Novo Holdings A/S, Coparion, High-Tech Gruenderfonds and Ascenion GmbH.