HepaRegeniX reports positive topline results of its Phase 1 Clinical Trial of HRX-0215, a First-In-Class MKK4 inhibitor

HRX-0215 proved to be safe and well tolerated in healthy volunteers

Tübingen (Germany), May 12, 2022 – HepaRegeniX GmbH, a clinical stage company developing novel regenerative therapy approaches for the treatment of acute and chronic liver diseases, announced today the successful conclusion and top-line results of its Phase 1 clinical trial for its lead drug candidate HRX-0215. HRX-0215 is a small molecule inhibitor of **M**itogen-Activated Protein (MAP) **K**inase **K**inase **4** (MKK4), a key regulator of liver regeneration. Suppression of MKK4 unlocks the regenerative capacity of hepatocytes even in severely diseased livers.

During the Phase 1 trial, HRX-0215 was well tolerated at all doses with no drug-related adverse events being observed. Moreover, no clinically relevant changes of any clinical or laboratory parameters were observed. Vital signs were stable and ECG parameter inconspicuous. HRX-0215 is thus considered to be safe and well tolerated.

Within a given dosing strength, pharmacokinetics revealed a dose-proportional increase of exposure with very low interindividual variability. HepaRegeniX plans to further investigate HRX-0215 in Phase 2 trials. Preclinical results underlining the therapeutic effect of MKK4 inhibition and its potential in liver regeneration were recently presented at international scientific conferences.

"We are very proud to have successfully concluded the clinical Phase 1 with HRX-0215, our first-in-class MKK4 inhibitor for unlocking regeneration in severely damaged livers," commented **Dr. Wolfgang Albrecht, Managing Director and COO of HepaRegeniX.** "Especially as this trial investigated inhibition of MKK4 first-in-human, confirming safety and tolerability is a very important clinical milestone. We will continue our work on improving the currently poor prognosis and very few therapeutic options of the ever-increasing number of people living with severe liver diseases."

The single-center, double-blind, randomized, placebo-controlled trial (EUDRA-CT No. 2021-000193-28) enrolled 48 healthy male volunteers. The trial assessed the safety, tolerability, and pharmacokinetics of HRX-0215 and was designed as a single and multiple dose escalation study (SAD/MAD). Previous extensive preclinical studies had demonstrated compelling efficacy of HRX-0215 in both acute and chronic degenerative liver disease models.

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About HepaRegeniX GmbH – www.heparegenix.com
Since 2017, HepaRegeniX has successfully discovered and developed several drug candidates for the treatment of acute and chronic liver diseases based on a novel proprietary molecular target **M**itogen-Activated Protein (MAP) **K**inase **K**inase **4** (MKK4). The first MKK4 inhibitor HRX-0215 recently completed Phase 1 clinical testing. 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.