

HepaRegeniX Completes Phase Ib Study of HRX-215 to Enhance Liver Regeneration in Patients Undergoing Minor Liver Resection

Tuebingen, Germany, February 11, 2026 – [HepaRegeniX GmbH](#) (“HepaRegeniX”), a clinical-stage biotech company advancing novel therapies for acute and chronic liver diseases, today announced the completion of the Phase Ib minor resection study of HRX-215. Five patients in the clinical trial were treated with HRX-215 for a period of 28 days after a minor liver resection ($\leq 30\%$) due to liver metastases originating from colorectal cancer. Following an interim safety analysis and having observed a clean safety profile for HRX-215, the independent Data Safety Monitoring Board (DSMB) recommended that the study continue as planned. HepaRegeniX is now moving forward with the Phase Ib study in patients requiring major liver resection (50-72%). By the end of 2026, the company plans to initiate the Phase IIa major resection part of the study, an international, multicenter, double-blind, placebo-controlled trial.

“While the liver has an inherent capacity to regenerate, its ability is significantly impaired in patients with advanced liver disease as a result of reduced functional capacity in combination with a small post-resection liver volume. By accelerating and enhancing liver regeneration, HRX-215 has the potential to improve post-operative outcomes and enable more patients to undergo lifesaving surgery,” said **Linda Greenbaum, Chief Medical Officer at HepaRegeniX**.

The first part of the Phase Ib study ([NCT06638502](#)), enrolling five patients, was conducted at a single site: the Mayo Clinic in the U.S. Patients received a twice-daily oral dose of 250 mg of HRX-215 for 28 days. The second part of the Phase Ib study will treat ten patients undergoing major liver resection with HRX-215 for the same treatment period of 28 days; patients will be recruited in the U.S., Europe, and Israel. With a favorable safety profile confirmed in Phase Ib, HRX-215 will next be evaluated in the Phase IIa part of the study in patients undergoing major liver resection. The Phase IIa results will inform the design of subsequent registrational studies and support development in additional liver indications and liver transplantation.

About HRX-215 and Liver Regeneration

For patients with colorectal cancer liver metastases (CRLM) and other cancers affecting the liver, surgical resection remains the most effective potentially curative treatment. Successful liver resection depends on the ability of the remaining liver, known as the future liver remnant (FLR), to sustain essential functions and regenerate. When the FLR is insufficient in volume or function, the risk of post-operative liver failure increases significantly, rendering many patients ineligible for potentially curative surgery.

HRX-215 is an orally available small molecule inhibitor of Mitogen-Activated Protein Kinase Kinase 4 (MKK4), a key regulator of liver regeneration. In preclinical models, HRX-215 has been shown to selectively inhibit MKK4, stabilizing and protecting hepatocytes while accelerating and enhancing regenerative processes, even in compromised or diseased livers. This therapeutic approach has the potential to expand surgical eligibility to patients requiring extended liver resection who would otherwise be deemed inoperable, offering a new path to potentially lifesaving treatment. HRX-215 can potentially transform the field of liver transplantation by preventing liver failure after the transplant of small liver grafts and thereby expand living donor

transplantations, as well as in acute and chronic late-stage liver diseases that often have limited therapeutic options.

About HepaRegeniX GmbH

HepaRegeniX is advancing therapies to treat acute and chronic liver diseases based on groundbreaking discoveries of a novel cellular target and small molecules that enable rapid liver regeneration. We do so by harnessing the liver's inherent regenerative power not only in healthy but also in diseased livers. The company's lead candidate, HRX-215, an orally available small molecule currently in a Phase Ib/Ila trial, selectively inhibits Mitogen-Activated Protein (MAP) Kinase Kinase 4 (MKK4), a master regulator of liver regeneration. Building on demonstrated safety in clinical trials, HepaRegeniX is progressing HRX-215 to prevent post-hepatectomy liver failure, facilitate transplantation of smaller living donor liver grafts, and treat severe alcohol-associated hepatitis. Beyond liver diseases, the company is also developing HRX-233 to target resistance to kinase inhibitors in KRAS-driven tumors.

HepaRegeniX is backed by experienced life science investors, including Vesalius Biocapital IV, Novo Holdings A/S, Boehringer Ingelheim Venture Fund (BIVF), Coparion, High-Tech Gründerfonds, Ascenion GmbH and Wellington Partners.

Visit our website at www.heparegenix.com to learn more about the company.

For further information, please contact:

HepaRegeniX GmbH

Elias Papatheodorou

Chief Executive Officer

info@heparegenix.com

Media Inquiries

Trophic Communications

Jacob Verghese or Gretchen Schweitzer

Tel: +49 151 7441 6179

Email: heparegenix@trophic.eu