

HepaRegeniX Completes Darizmetinib Treatment Phase for First Patient Undergoing Major Liver Resection in Phase 1b Liver Regeneration Study

HepaRegeniX to seamlessly advance darizmetinib's clinical development to Phase 2a following completion of the Phase 1b in 2026

Tuebingen, Germany, September 22, 2026 – [HepaRegeniX GmbH](#) (“HepaRegeniX”), a clinical-stage biotech company advancing novel therapies for acute and chronic liver diseases, today announced that the first patient undergoing major liver resection due to liver metastases originating from colorectal cancer has completed the 28 day treatment with darizmetinib (formerly HRX215) in the second pilot part of its ongoing Phase 1b/2a study. To date, darizmetinib has demonstrated a favorable safety profile, with no darizmetinib treatment related serious adverse events reported. The second Phase 1b pilot part of the study is expected to enroll 10 patients and be completed in the fourth quarter of 2026.

Following the Phase 1b safety review by an independent Data Safety Monitoring Board (DSMB), as planned per clinical study protocol, HepaRegeniX anticipates seamlessly advancing darizmetinib into the randomized Phase 2a portion of the study in the same patient population. This seamless Phase 1b/2a design has been reviewed and authorized by all relevant regulatory authorities (FDA, EMA, and the Israel Ministry of Health) as well as ethics committees and Institutional Review Boards (IRBs).

“Darizmetinib is progressing rapidly through the clinic, with the first of 10 patients having completed treatment in the second part of the Phase 1b study, and a favorable safety profile observed to date,” said **Linda Greenbaum, Chief Medical Officer at HepaRegeniX**. “The progress of the study reflects our streamlined trial design and the readiness of our clinical sites. The identical patient population planned for the Phase 2a allows us to build on the clinical experience generated in Phase 1b and maintain development momentum. While the study remains ongoing, we are encouraged by these early observations and by the potential of darizmetinib to address a significant unmet need for patients undergoing major liver resection.”

“Major liver resection is an important part of standard of care for patients with liver metastases, but postoperative recovery of liver function remains a critical challenge,” said **Prof. Niv Pencovich, Principal Investigator at Sheba Medical Center**. “Completing treatment of the first patient undergoing major liver resection in this part of the study marks a significant milestone. We are proud to contribute to the clinical evaluation of darizmetinib in this setting and look forward to the findings from the program.”

The ongoing Phase 1b ([NCT06638502](#)) builds on the successful completion of the first part of the study in patients after minor liver resection, in which darizmetinib demonstrated a favorable safety profile. Enrolled patients receive 250 mg of darizmetinib twice daily orally for 28 days. HepaRegeniX is conducting the study at multiple sites across the U.S., Germany, Spain, France, and Israel, with the same sites expected to support the subsequent seamless Phase 2a part.

About Darizmetinib (HRX215) 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.

Darizmetinib (formerly HRX215) is an orally available small molecule inhibitor of mitogen-activated protein kinase kinase 4 (MKK4), a key regulator of liver regeneration. In preclinical models, darizmetinib 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. Darizmetinib 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. HepaRegeniX's lead candidate, darizmetinib (HRX215), is an orally available small molecule that 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 advancing darizmetinib in a Phase 1b/2a trial to prevent post-hepatectomy liver failure, with potential applications in living donor liver transplantation and severe alcohol-associated hepatitis. Beyond liver diseases, the company is also developing HRX233 in oncology.

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.

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