

HepaRegeniX raises €15 million Series C round to advance clinical development of HRX-215 for liver regeneration

HepaRegeniX GmbH, a clinical stage company developing a novel regenerative therapy for the treatment of acute and chronic liver diseases, today announced the closing of a Series C round led by Vesalius Biocapital IV with participation of existing investors Novo Holdings, Boehringer Ingelheim Venture Fund (BIVF), and High-Tech Gründerfonds (HTGF). The new funds of €15 million will be used to advance the clinical development of the Company's clinical candidate HRX-215.

As part of the financing, Fabienne Roussel, Partner at Vesalius Biocapital, joins the Non-Executive Board of Directors. Elias Papatheodorou will become Chief Executive Officer, moving from Chair of the Board.

Elias Papatheodorou, Chair of the Board, said: "We are thrilled to secure this significant financing, which underscores the confidence our investors have in our science and our capabilities to bring effective treatments to patients suffering from liver diseases. With the new funds, HepaRegeniX will advance with its clinical plans for a Phase Ib study in the US and an international Phase IIa study to enhance liver recovery and prevent liver failure."

HRX-215 is a small molecule inhibitor of Mitogen-Activated Protein (MAP) Kinase Kinase 4 (MKK4). Inhibition of MKK4 unlocks the regenerative capacity of hepatocytes and can strongly boost liver regeneration in patients. This is highly relevant for patients with liver metastases or primary liver tumors, as resection of the tumors is the only curative therapeutic approach. Liver regeneration is also key in liver transplant and especially in enabling left liver lobe living donor transplant. This strategy could significantly reduce waiting lists for liver transplant candidates. Promising preclinical data have confirmed HRX-215's capacity for liver regeneration, and HepaRegeniX has successfully completed a Phase I trial. These results have been published in the prestigious journal Cell.

"Vesalius Biocapital is excited to support HepaRegeniX as it progresses into the next phase of clinical development for HRX-215. There is an immense need for a treatment that can induce liver regeneration in patients suffering from liver damage, liver tumors, as well as in transplant settings. HRX-215 has potential to help these patients and make a meaningful impact on their lives. I look forward to working with HepaRegeniX' excellent leadership team to advance this promising treatment candidate," commented Fabienne Roussel, Partner at Vesalius Biocapital IV.

Importantly, to take HepaRegeniX through the next stages of clinical development and value creation, Dr. Linda Greenbaum is joining HepaRegeniX as Chief Medical Officer (CMO). She brings extensive expertise and experience in clinical development and translational medicine. She recently served as Executive Director, Translational Medicine at Novartis in the US. Before joining Novartis, she held the position of Director of Clinical Development at Janssen R&D and served on the faculty of Thomas Jefferson University and University of Pennsylvania where she led a research laboratory investigating liver regeneration and fibrosis. Dr. Greenbaum holds an MD from the Columbia University Vagelos College of Physicians and Surgeons.

"I am honored to join HepaRegeniX at such a critical juncture in its development," added Dr. Linda Greenbaum, Chief Medical Officer of HepaRegeniX. "MKK4 is a key regulator of liver regeneration, and MKK4 inhibition has been shown to induce liver regeneration after a partial hepatectomy. With this mode of action, HRX-215 has an immense potential to improve outcomes for patients who are currently not able to undergo potentially curative surgical resections due to liver tumors, and other patient groups affected by liver failure. I look forward to working with the talented team at HepaRegeniX to advance the clinical development of HRX-215 through Phase II trials and beyond, with the ultimate goal of improving outcomes for patients with liver diseases worldwide."

Elias Papatheodorou concluded: "It is a pleasure to welcome Dr. Linda Greenbaum to our leadership team. With her extensive knowledge and expertise, she will guide the future clinical development of HRX-215. With our new funding and the extension to our experienced leadership team, we hope to bring a much needed therapy to patients suffering from liver diseases."

About HepaRegeniX GmbH

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 Mitogen-Activated Protein (MAP) Kinase Kinase 4 (MKK4). The first MKK4 inhibitor HRX-215 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 Tuebingen, Germany. Investors in HepaRegeniX include Vesalius Biocapital IV, the Boehringer Ingelheim Venture Fund (BIVF), Novo Holdings A/S, Coparion, High-Tech Gründerfonds (HTGF) and Ascenion GmbH.

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Further information

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