Relay Therapeutics and Elevar Therapeutics Announce Exclusive Global Licensing Agreement for Lirafugratinib in FGFR2-Driven Cholangiocarcinoma and Other Solid Tumors

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Global licensing agreement grants Elevar Therapeutics worldwide rights to develop and commercialize lirafugratinib (RLY-4008)

Lirafugratinib is a potential best-in-class FGFR2 inhibitor that has shown differentiated efficacy in FGFR2-driven cholangiocarcinoma and demonstrated durable responses across multiple other types of FGFR2-altered solid tumors

Relay Therapeutics has potential to receive up to $500 million in upfront, regulatory and commercial milestone payments, including $75 million in upfront and regulatory milestones, plus up to double digit royalties on global sales

CAMBRIDGE, Mass. and FORT LEE, N.J., Dec. 03, 2024 (GLOBE NEWSWIRE) -- Relay Therapeutics, Inc. (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies, and Elevar Therapeutics, Inc., a majority-owned subsidiary of HLB Co., Ltd. and fully integrated biopharmaceutical company dedicated to elevating treatment outcomes for patients who have limited or inadequate therapeutic options, today announced an exclusive global licensing agreement for lirafugratinib (RLY-4008). Lirafugratinib is a selective oral small molecule inhibitor of fibroblast growth factor receptor 2 (FGFR2) that is being developed for patients with FGFR2-driven cholangiocarcinoma (CCA) and other FGFR2-altered solid tumors. The announcement of the partnership follows Relay's recent positive FDA interaction and previously reported differentiated data in cholangiocarcinoma and data across other solid tumors.

"Data to-date show that lirafugratinib has the potential to be an important novel medicine for patients with FGFR2-driven cholangiocarcinoma and other FGFR2-altered solid tumors. We are pleased that Elevar will continue its development and leverage their growing commercial capabilities to bring it to patients in need around the world," said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. "As a result of this agreement, we are able to remain fully focused on continuing to advance our PI3Kα programs, including initiating the RLY-2608 2L breast cancer pivotal trial and vascular malformations trial next year."

"Lirafugratinib is an NDA-ready therapy that has shown a potential best-in-class profile in both FGFR2-driven cholangiocarcinoma and in other FGFR2-altered solid tumors including in advanced stages where treatment options are limited," said Saeho Chong, Ph.D., chief executive officer of Elevar Therapeutics. "We are excited to diversify and expand our late-stage oncology pipeline with lirafugratinib, which is a strong strategic fit with our existing oncology portfolio and provides another opportunity to advance our mission of bringing life-changing medicines to cancer patients worldwide."

Lirafugratinib was granted breakthrough therapy designation and orphan drug designation by the FDA. Lirafugratinib is being investigated in the global ReFocus trial in patients with FGFR2-altered tumors. The study includes a pivotal cohort in patients with FGFR2-fusion CCA that was designed to support accelerated approval and is fully enrolled. Interim data from this cohort were presented at the European Society for Medical Oncology Congress in 2022. The study also includes cohorts in patients with other types of solid tumors, including gastric, pancreatic, and head and neck tumors. Interim data from these cohorts were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in 2023 and 2024. Earlier in 2024, Relay Therapeutics met with the U.S. Food and Drug Administration (FDA) to discuss data from the ReFocus trial and potential regulatory pathways. The FDA recommended that the company first file an NDA for FGFR2-driven CCA, followed by a supplemental NDA for FGFR2-altered other solid tumors with data from an expanded cohort of patients.

Cholangiocarcinoma (CCA) or bile duct cancer is a rare disease in which malignant cells form in the bile ducts. Approximately 8,000 people in the United States are diagnosed with CCA each year.

Terms of the Agreement

Under the terms of the agreement, Elevar will be granted global development and commercialization rights for lirafugratinib. Elevar will assume full responsibility for all further development activities, including submission of the NDAs, all subsequent clinical development, and global commercialization for FGFR2-driven CCA and FGFR2-altered other solid tumors.

Relay Therapeutics is eligible to receive up to $75 million in upfront and regulatory milestones, plus up to $425 million in potential commercial milestone payments, as well as tiered royalties up to the low-teens percentage.

Moelis & Company LLC is serving as exclusive financial advisor to Relay Therapeutics in the transaction. Goodwin Procter LLP is serving as exclusive legal advisor to Relay Therapeutics in the transaction.

About Lirafugratinib

Lirafugratinib (RLY-4008) is a potent, selective and oral small molecule inhibitor of FGFR2, a receptor tyrosine kinase that is frequently altered in certain cancers. FGFR2 is one of four members of the FGFR family, a set of closely related proteins with highly similar protein sequences and properties. Preclinically, lirafugratinib demonstrated FGFR2-dependent killing in cancer cell lines and induced regression in in vivo models with minimal inhibition of other targets, including other members of the FGFR family. In addition, lirafugratinib demonstrated strong activity against known clinical on-target resistance mutations in cellular and in vivo preclinical models. Lirafugratinib is currently being evaluated in a clinical trial in patients with advanced or metastatic FGFR2-altered solid tumors with a single arm, potentially registration-enabling cohort for FGFRi-naïve FGFR2-fusion CCA. To learn more about the clinical trial of lirafugratinib, please visit here.

About Relay Therapeutics

Relay Therapeutics is a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies with the goal of bringing life-changing therapies to patients. As the first of a new breed of biotech created at the intersection of complementary techniques and technologies, Relay Therapeutics aims to push the boundaries of what's possible in drug discovery. Its Dynamo® platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable or inadequately addressed. Relay Therapeutics' initial focus is on enhancing small molecule therapeutic discovery in targeted oncology and genetic disease indications. For more information, please visit www.relaytx.com or follow us on Twitter.

About Elevar Therapeutics

Elevar Therapeutics, Inc. is a fully integrated biopharmaceutical company built on the promise of elevating treatment outcomes for patients who have limited or inadequate therapeutic options. With expertise rooted in oncology, Elevar is focused on identifying and developing promising medicines for complex yet under-treated health conditions. Elevar's lead proprietary drug candidate is rivoceranib. The NDA for rivoceranib in combination with camrelizumab as a therapy for advanced or metastatic hepatocellular carcinoma (HCC) is currently under review by the FDA with a PDUFA action date scheduled for March 20, 2025. Additional information is available at Press Releases - Elevar Therapeutics.

About HLB Group

The HLB Group is comprised of HLB Inc. (KOSDAQ:028300) and its affiliates with a diverse portfolio across biopharma, lifestyle, marine business, semiconductor and energy, united by the mission of improving all aspects of human life. Members of the HLB Group include HLB Innovation (KOSDAQ: 024850), HLB BioStep (KOSDAQ:278650), HLB Pharmaceutical (KOSDAQ:047920), HLB Life Science (KOSDAQ:067630), HLB Therapeutics (KOSDAQ:115450), HLB Panagene (KOSDAQ:046210) and HLB Global (KOSDAQ:003580). HLB Group's overseas affiliates include Elevar Therapeutics, Immunomic Therapeutics, a nucleic acid immunotherapy platform company, and Verismo Therapeutics, a CAR T platform oncology company, all of which are based in the United States.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Relay Therapeutics' strategy, business plans and focus; the progress and timing of the preclinical and clinical development of the programs across Relay Therapeutics' portfolio; the expected therapeutic benefits and potential efficacy and tolerability of its programs, including lirafugratinib; the timing and success of interactions with regulatory authorities and any related approvals; the potential market opportunity for lirafugratinib; and the expected strategic benefits under the exclusive global licensing agreement between Relay Therapeutics and Elevar Therapeutics. The words "may," "might," "will," "could," "would," "should," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions, or the negative thereof, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the impact of global economic uncertainty, geopolitical instability and conflicts, or public health epidemics or outbreaks of an infectious disease on countries or regions in which Relay Therapeutics has operations or does business, as well as on the timing and anticipated results of its clinical trials, strategy, future operations and profitability; the delay or pause of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary or interim results of its preclinical or clinical trials may not be predictive of future or final results in connection with future clinical trials of its product candidates and that interim and early clinical data may change as more patient data become available and are subject to audit and verification procedures; Relay Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of its planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Relay Therapeutics' most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Relay Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Relay Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Relay Therapeutics:
Contact:
Megan Goulart
617-322-0814
mgoulart@relaytx.com

Media:
Dan Budwick
1AB
973-271-6085
dan@1abmedia.com

Elevar Therapeutics:
Media Contact:
Jeanette Bressi
Head, Corporate Communications
jbressi@elevartherapeutics.com
609-439-3997

Investor Relations Contact:
Wade Smith

Chief Financial & Business Officer
wsmith@elevartherapeutics.com