



NEWS RELEASE

Elevar Therapeutics Resubmits New Drug Application to FDA for Combination of Camrelizumab plus Rivoceranib as First-Line Treatment Option for Unresectable Hepatocellular Carcinoma Boosted by CARES-310 Leading Overall Survival Analysis

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FORT LEE, N.J., Sept. 23, 2024 (GLOBE NEWSWIRE) -- Elevar Therapeutics, Inc., a majority-owned subsidiary of HLB Co., Ltd., today announced the resubmission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its investigational drug rivoceranib, an oral VEGF-TKI, in combination with camrelizumab, a PD-1 inhibitor, as a first-line systemic treatment option for unresectable hepatocellular carcinoma (uHCC).

In May, the FDA issued a Complete Response Letter (CRL) for the original NDA submitted in May 2023. The CRL cited GMP deficiencies at the Hengrui Pharma facility where camrelizumab is manufactured and incomplete Bioresearch Monitoring (BIMO) clinical inspections due to FDA travel restrictions. The FDA did not indicate any issues related to clinical data or with the manufacturing site for rivoceranib. During a Type A meeting with the FDA in July, the FDA confirmed the responses to observations at the Hengrui manufacturing site were sufficient, resubmission could occur without further delay and BIMO inspections may occur after resubmission.

“Elevar’s timely resubmission of the NDA for the combination of camrelizumab and rivoceranib marks a critical milestone in our mission to bring a novel combination therapy for uHCC to patients and healthcare providers. HCC remains an area of significant unmet medical need,” said Dr. Saeho Chong, chief executive officer of Elevar Therapeutics. “This achievement would not have been realized without the extraordinary dedication of Elevar’s



teams. We are eager to work with the FDA in the coming months as we focus on the commercialization of our combination therapy.”

The resubmission is supported by the Phase 3 **CARES-310 study landmark analysis** presented during the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting on June 1, which reported median overall survival (mOS) of 23.8 months, the longest mOS for any treatment in a global Phase 3 trial for patients with uHCC, confirming the combination of camrelizumab and rivoceranib continued to show sustained long-term survival as a first-line treatment for uHCC.

“The combination of camrelizumab and rivoceranib shows distinct promise as a potential therapy for patients suffering from advanced hepatocellular carcinoma with efficacy results generally consistent across all subgroups,” commented Ahmed Omar Kaseb, M.D., professor, Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center in Houston. “The resubmission is strengthened by the recent CARES-310 landmark analysis, which reported the longest median overall survival for any treatment in a global Phase 3 trial in the uHCC setting.”

About Hepatocellular Carcinoma

Worldwide each year more than 800,000 people are diagnosed with liver cancer and the disease is the cause of more than 830,000 deaths.ⁱⁱ Hepatocellular Carcinoma (HCC) is the most common type of liver cancer and most frequently develops in people with chronic underlying liver inflammation which may be from viral and non-viral causes. HCC typically has a poor prognosis with limited treatment options and continues to be a diagnosis with an ongoing urgent medical need.

About Rivoceranib

Rivoceranib, a small-molecule tyrosine kinase inhibitor (TKI), is a highly potent inhibitor of vascular endothelial growth factor receptor (VEGFR), a primary pathway for tumor angiogenesis. VEGFR inhibition is a clinically validated target to limit tumor growth and disease progression. Rivoceranib is currently being studied as a monotherapy and in combination with chemotherapy and immunotherapy in various solid tumor indications. Ongoing clinical studies include uHCC (in combination with camrelizumab), gastric cancer (as a monotherapy and in combination with paclitaxel), adenoid cystic carcinoma (as a monotherapy) and colorectal cancer (in combination with Lonsurf®). Rivoceranib was the first TKI approved in gastric cancer in China (November 2014). It is also approved in China in combination with camrelizumab as a first-line treatment for uHCC (January 2023). The drug has been studied in more than 6,000 patients worldwide and was well tolerated in clinical trials with a comparable safety profile to other TKIs and VEGF inhibitors. Orphan drug designations have been granted in gastric cancer (U.S., EU and South Korea), in adenoid cystic carcinoma (U.S.) and in uHCC (U.S. and EU). Elevar Therapeutics, Inc. holds the global rights

(excluding China) to rivoceranib and has partnered for its development and marketing with HLB-LS in South Korea. Rivoceranib, under the name apatinib, is also approved in China for advanced gastric cancer and in second-line advanced HCC by the Chinese -territory license-holder, Jiangsu Hengrui Pharmaceuticals Company Ltd., (Hengrui Pharma), under the brand name Aitan®.

About Camrelizumab

Camrelizumab (SHR-1210) is a humanized monoclonal antibody that binds to the programmed death-1 (PD-1) receptor. Blockade of the PD-1/PD-L1 signaling pathway is a therapeutic strategy showing success in a wide variety of solid and hematological cancers. Camrelizumab is developed by Hengrui Pharma and has been studied in more than 5,000 patients. Currently, 50 clinical trials are underway in a broad range of tumors (including liver cancer, lung cancer, gastric cancer, and breast cancer, etc.) and treatment settings. Camrelizumab, under the brand name AiRuiKa®, is currently approved for eight indications in China, including monotherapy for the treatment of HCC (second-line), in combination with rivoceranib as a treatment for uHCC (first-line), relapsed/refractory classic Hodgkin's lymphoma (third-line), esophageal squamous cell carcinoma (second-line) and nasopharyngeal carcinoma (third-line or further) and in combination with chemotherapy for the treatment of non-small cell lung cancer (non-squamous and squamous), esophageal squamous cell carcinoma and nasopharyngeal carcinoma in the first-line setting. The U.S. Food and Drug Administration granted Orphan Drug Designation to camrelizumab for advanced HCC in April 2021 and by the EMA in August 2024.

In October 2023, Elevar licensed camrelizumab, an anti-PD-1 antibody, for commercialization from Jiangsu Hengrui Pharmaceuticals Co., Ltd. (Hengrui Pharma) worldwide excluding Greater China and Korea.

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i Key Statistics About Liver Cancer | American Cancer Society

ii Key Statistics About Liver Cancer | American Cancer Society

Source: Elevar Therapeutics