FDA Acceptance of Auransa's IND Application for AU409 for Treatment of Patients with Hepatocellular Carcinoma

First compound to enter clinical trial stage from a pipeline of research programs based upon Auransa's proprietary AI platform

PALO ALTO, CA, UNITED STATES, November 3, 2022 /EINPresswire.com/ -- Auransa Inc., a clinical stage drug development company using propriety AI drug discovery platform to identify novel drug candidates for oncology, CNS and inflammatory diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for AU409, a novel, orally active agent showing anticancer activity in preclinical studies of hepatocellular carcinoma (HCC). Initial clinical studies will focus on patients with advanced primary liver cancers and patients with advanced solid tumor with liver predominant metastatic disease.

"The FDA's acceptance of the IND for AU409 is an important milestone for Auransa's AI drug discovery platform. We look forward to initiating the Phase 1 study, our first-in-human trial of a compound derived from Auransa's proprietary SMarTR™ Engine." said Pek Lum, Ph.D., founder and chief executive officer of Auransa.

"AU409's anti-cancer activity in preclinical models is through a mechanism of action distinct from currently available, FDA approved tyrosine kinase inhibitors used for hepatocellular carcinoma making this an important new opportunity for clinical testing." said Andrew Protter, Ph.D. Auransa's Chief Scientific Officer.

About AU409
AU409 is a novel small molecule with oral active in models of hepatocellular carcinoma. In preclinical studies, AU409 has been shown to modulate transcription of certain genes thereby altering the gene expression profile of liver cancer cells. The mechanism of action of AU409 is distinct from that of current drugs approved for HCC including the tyrosine kinase inhibitors (TKIs) such as sorafenib or regorafenib. Non-clinical safety, toxicology and genetic toxicology studies support the first in human clinical studies being proposed.

About Hepatocellular Carcinoma
Despite major improvements in the treatment of primary liver cancers including hepatocellular carcinoma, patients with advanced disease continue to have limited median overall survival due

to primary or secondary resistance to existing therapies. While chronic hepatitis B and C infections continue to be important risk factors for liver cancer, the rising prevalence of obesity, non-alcoholic steatohepatitis (NASH) and alcohol consumption are becoming the dominant risk factors for liver cancer in the United States as well as the rest of the world. Liver cancer has recently been estimated to be the third most common cancer related death worldwide.

About Auransa
Auransa is an artificial intelligence (AI)-driven pharmaceutical company developing precision medicines in areas of significant unmet need. The company is working to redefine medicine, by combining a sophisticated, proprietary, and predictive computational platform with traditional pharmaceutical experience. The company's SMarTR™ Engine has proprietary machine learning, advanced analytics, and mathematics in an AI framework to generate insights from molecular data for a deep understanding of disease biology at subtype resolution. Auransa has successfully generated a broad pipeline of drug candidates focusing on cancer and cancer care. Learn more at www.auransa.com.

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