

Al-Biopharma Auransa Announces Successful First Patient Dosed in Phase 1 Clinical Trial for Liver Cancer

Liver cancer, one of the fastest-growing cancers worldwide, is currently treated with on-market therapies that do not meet the needs of all patients

PALO ALTO, CA, USA, September 14, 2023 /EINPresswire.com/ -- PALO ALTO, CALIF. – Sept. 14, 2023 – <u>Auransa</u>, a clinical-stage, Al-native biopharma that mines massive data for therapeutic gold, today announced dosing of the first patient in its Phase 1 clinical trial to evaluate AU-409 as a treatment for patients with advanced liver cancers or solid tumors affecting the liver. The patient was treated at the USC Norris Comprehensive Cancer Center where Anthony El-Khoueiry, MD is the principal investigator on the trial.

Specifically, the Phase 1 trial will evaluate the safety and pharmacokinetics of single agent AU-409 in cancer patients and help define potential doses for follow-on Phase 2 studies. For more information you can view the trial on <u>ClinicalTrials.gov here</u>.

"Our focus is on advancing novel therapies that raise the standard of care for cancer patients, leveraging AI and massive, available data," said Pek Lum, PhD, Founder-CEO, Auransa. "Too many patients are still treated with drugs that were not designed for them, will not completely reverse their cancer, and can lead to dangerous side effects. With the first patient dosed in our Phase 1 clinical trial for liver cancer, we take one step closer to helping these patients and proving the AI platform that discovered AU-409 will generate more novel treatments for cancer and cancer-related diseases."

Patients with advanced liver cancer, such as hepatocellular carcinoma and biliary tract cancer, continue to have limited survival rates and despite advances in treatment. For hepatocellular carcinoma, immunotherapy combinations, such as atezolizumab and bevacizumab, have become standard, first-line treatment options. Historically tyrosine kinase inhibitors (TKIs) were the standard of treatment.

"Despite the higher response rates seen with immunotherapy combinations, when compared to TKIs, most patients will develop resistance to treatment," said Dr. El-Khoueiry. "In second line treatment and beyond, TKIs like sorafenib offer limited efficacy and the potential for significant toxicity. This leaves a substantial gap for new, improved therapies for liver cancer. We look forward to seeing how the AU-409 program progresses to address these unmet patient needs."

Beyond AU-409 for liver cancer, Auransa has a growing pipeline of therapies for cancer and cancer-related diseases, with the goal of advancing towards the investigational new drug application stage, a critical entry point for FDA trials. This includes programs for heart-safe chemotherapy, late-stage prostate cancer, triple negative breast cancer, and head and neck cancer.

To build its pipeline, Auransa takes a fundamentally different approach from other TechBio companies using AI to decode biology. Instead of generating its own data on which to train algorithms, Auransa harnesses publicly available human disease data, applies algorithms that separate "signal from noise" by looking for recurrent disease signatures, and discovers novel compounds, targets, and disease models for the patient populations that will respond best. The goal is smarter, more efficient drug discovery that maximizes the chances of success in clinical trials and generates precision medicines for patients in need of a better standard of care.

For more information on Auransa, its pipeline and partnerships, please visit <u>www.auransa.com</u>.

About AU-409 for liver cancer

AU-409 is a novel small molecule with oral activity in models of liver cancer. In preclinical studies, AU-409 has been shown to modulate transcription of certain genes thereby altering the gene expression profile of liver cancer cells. The mechanism of action of AU-409 is distinct from that of current drugs approved for liver cancer, including tyrosine kinase inhibitors (TKIs) such as sorafenib or regorafenib. Non-clinical safety, toxicology and genetic toxicology studies support the first in-human clinical studies of AU-409.

About the AU-409 clinical program

AU-409-Clinical-2022-01 is the first-in-human study titled: First in Human Dose Escalation Study of AU-409 in Patients with Advanced Primary Liver Cancers or Advanced Solid Tumor with Liver Predominant Metastatic Disease, now being conducted at the USC Norris Comprehensive Cancer Center with Principal Investigator Anthony El-Khoueiry, MD. Primary objectives of the study include: (1) determine the maximum tolerated dose of AU-409 and the recommended Phase 2 dose and (2) characterize the safety and tolerability of AU-409 by assessing toxicities. Secondary objectives include: (1) determine the pharmacokinetics of AU-409 in patients with advanced-stage solid tumors treated with AU-409 and (2) obtain a preliminary assessment of anti-tumor activity of AU-409. If the trial is successful, USC may receive royalty payments under the collaboration agreement with Auransa.

For more information you can view the Phase 1 trial on ClinicalTrials.Gov here.

About Auransa

Auransa is a clinical-stage, Al-native biopharma that mines massive data for therapeutic gold to raise the standard of cancer care. The company's platform uses Al and available human disease data to uncover novel drug candidates for the most responsive patients, leading to smarter drug discovery that maximizes clinical trial success. Auransa is focused on advancing better therapies for cancers and cancer-related diseases, including liver cancer, heart-safe chemotherapy, late-stage prostate cancer, triple negative breast cancer, and head and neck cancer. For more information visit www.auransa.com.

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