Dracen Announces DRP-104 (sirpiglenastat) Presentation at ASCO 2021 Virtual Annual Meeting

Trial in progress poster: Phase 1 & Phase 2a, first-in-human study (FIH) of DRP-104, a broad glutamine antagonist, in adult patients with advanced solid tumors

Dracen Pharmaceuticals Inc., announced today that a poster presentation updating the ongoing Phase 1/2a, FIH study of DRP-104, a broad glutamine antagonist, in adult patients with advanced solid tumors will be presented during the trial in progress session at the ASCO virtual meeting June 4th- 8th, 2021.

The presentation details are as follows:

Title: Phase 1 & Phase 2a, first-in-human study (FIH) of DRP-104, a broad glutamine antagonist, in adult patients with
advanced solid tumors
Session Type: E-Poster Session
Session Title: Trial in progress
Permanent Abstract Number: TPS3149

DRP-104 is a novel broad-acting glutamine antagonist that has been shown to directly target tumor metabolism and thereby induce a strong anti-tumor response. In addition, DRP-104 leads to profound remodeling of the tumor microenvironment leading to stimulation of both the innate as well as the adaptive immune systems, resulting in a synergy with immune checkpoint inhibitors.

“We continue to make progress in the clinical development of DRP-104. The pharmacokinetic and clinical safety profiles from the dose-escalation portion of this ongoing study are similar to what we observed in our comprehensive preclinical program. Our prodrug approach of delivering the glutamine antagonist to the tumor while limiting the systemic and GI tissue exposure has been confirmed and is translating well into the clinic,” said Margaret Dugan, M.D., chief medical officer, Dracen Pharmaceuticals, Inc. “Based on the findings of this study, we are on track to declare the recommended phase 2 dose in Q4 2021 and advance seamlessly to phase 2, investigating the treatment of advanced NSCLC patients whose tumors express genetic mutations in KEAP-1, NFE2L2 and/or STK11, for which we were granted a Fast Track Designation by the US Food and Drug Administration.”

The Phase 1/2a study, is a multicenter, open-label, FIH Phase 1, 1b and 2a study of DRP-104 either as a single agent or in combination with an agent targeting checkpoint inhibition in adult patients with advanced solid cancers (excluding central nervous system and hepatocellular tumors). The study consists of 4 parts:

PART 1: DRP-104 single agent intravenous (IV) and subcutaneous (subQ) Dose Escalation in 8 US sites and 1 German site
PART 2: DRP-104 single agent dose Expansion with 3 cohorts:
- Cohort 1: Phase 1 Safety Expansion single agent IV and subQ in minimum of 14 and up to 20 adult patients/route of administration with advanced solid tumors. The remaining 2 cohorts begin with the selected route of administration selected after the maximum tolerated dose has been determined for both formulations in Part 1.
- Cohort 2: Phase 2a single agent: 55 patients with locally advanced or metastatic Non-Small Cell Lung Cancer

(NSCLC) with KEAP1, NFE2L2 and/or STK11 mutations
- Cohort 3: Phase 2a single agent: up to 25 pts with recurrent, un-resectable or metastatic Squamous Cell Carcinoma of the Head and Neck
PART 3: Phase 1 combination Dose Escalation followed by
PART 4: Phase 1 Safety Expansion of DRP-104 with an agent targeting checkpoint inhibition

About DRP-104
Our lead glutamine antagonist, DRP-104 (sirpiglenastat), is currently in early-stage clinical development. The mechanisms of action for DRP-104 include: a) direct inhibition of tumor cell addiction to glutamine leading to substantial single agent activity and tumor regression; b) broad metabolic remodeling of the tumor microenvironment leading to enhanced anti-tumor immune activity; and c) stimulation of T effector, NK and NKT cells and inhibition of immunosuppressive MDSC and macrophage cells, leading to greater long-term durable responses and survival.

About Dracen Pharmaceuticals
Dracen Pharmaceuticals, Inc. is a privately held biotech company developing proprietary anti-cancer drugs that target immuno-metabolism. Dracen's investors include Deerfield Management; Osage University Partners; and The Institute of Organic Chemistry and Biochemistry of the CAS (IOCB Prague). Dracen is headquartered in New York, NY with research operations in San Diego, CA.

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