The Fibrolamellar Cancer Foundation (FCF) and Dracen Pharmaceuticals announce initiation of a phase I/II study of DRP-104 in combination with Durvalumab in patients with fibrolamellar carcinoma (FLC)

Greenwich, CT and San Diego, CA - February 14, 2024, The Fibrolamellar Cancer Foundation (FCF) and Dracen Pharmaceuticals Inc., a clinical stage biotech company, announced today the initiation of enrollment in a collaborative phase I/II study of the combination of subcutaneous **DRP-104** (sirpiglenastat) in combination with intravenous durvalumab in fibrolamellar carcinoma (FLC). FCF and Dracen recently launched a partnership to make the experimental prodrug DRP-104 available for clinical research in FLC.

Recent studies indicate that FLC tumors' characteristic DNAJB1-PRKACA fusion causes a metabolic rewiring of FLC cells. These metabolic aberrations “addict" FLC tumors to glutamine metabolism and lead to increased resistance to tumor-cell killing by immune cells. Researchers believe that FLC tumor cells may deplete glutamine from their vicinity and enrich the tumor environment with immunosuppressive metabolites including ammonia, thereby impairing a patient’s ability to launch an effective immune response to the cancer.

DRP-104 is a prodrug that broadly targets all 10 glutamine-metabolizing enzymes in tumors, leading to a profound anti-tumor activity related to both direct effects on tumor metabolism as well as immune mediated activity via remodeling of the tumor microenvironment. This unique mechanism of action shows promises for treating various tumor types. Dracen recently completed a Phase I clinical study which identified the DRP-104 dose and schedule which will be utilized in this new combination study with durvalumab in FLC patients.

Kurt Losert, CEO of FCF, commented, “We are proud of the teamwork between FCF, Dracen and our clinical partners that has quickly brought a promising investigational treatment to fibrolamellar patients who desperately need new therapies."

Enrollment for the new clinical trial is currently underway for patients diagnosed with unresectable or metastatic FLC whose disease has progressed on prior immune therapy. For further information about the study design, contacts, and location, please see National Clinical Trial Identifier: NCT06027086.

About the Fibrolamellar Cancer Foundation:
The principal purpose of the Fibrolamellar Cancer Foundation (FCF) is to encourage, drive and fund research that will substantially improve outcomes for patients with fibrolamellar carcinoma (FLC), a rare form of liver cancer that primarily occurs in adolescents and young adults who have no history of liver disease. FCF, a public 501(c)(3) nonprofit organization based in Greenwich, CT, was founded in 2009 by Tucker Davis, a FLC patient. Today, FCF is the leading non-governmental funder of FLC research. By supporting cutting-edge research, actively recruiting investigators, and working collaboratively to understand the origin and development of FLC, we hope to discover more effective therapies and ultimately a cure for the disease. 100% of all donations directly fund FLC-specific research. For more information, visit ***www.fibrofoundation.org*** and also interact with us on our social media channels: Facebook, Twitter and Instagram.

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About DRP-104
The glutamine antagonist, DRP-104 (sirpiglenastat), is currently in clinical development by Dracen Pharmaceuticals. The mechanisms of action for DRP-104 include a) direct inhibition of tumor cell addiction to glutamine metabolism 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, potentially 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; i&i Biotech Fund (i&i Bio); Osage University Partners; and The Institute of Organic Chemistry and Biochemistry of the CAS (IOCB Prague). Dracen has operations in San Diego, CA.

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