



Dracen Pharmaceutical's DRP-104 Granted U.S. FDA Fast Track Designation for the treatment of Non-Small Cell Lung Cancer

Dracen to work closely with FDA to advance the clinical program for the treatment of NSCLC with specific mutations

Dracen Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the Company's novel glutamine antagonist DRP-104 for the treatment of advanced, previously treated non-small cell lung cancer (NSCLC) patients whose tumors express mutations in KEAP1, NFE2L2 and/or STK11.

"The FDA's decision to grant Fast Track designation to the DRP-104 development program is an important scientific recognition of the unmet medical need in NSCLC with these specific mutations and of the potential for a glutamine antagonist to improve the outcome of therapy in this population," said Thomas Estok, CEO of Dracen Pharmaceuticals. "We look forward to working closely with the FDA to advance our ongoing clinical program."

"Innovative and accelerated registration approaches that advance novel agents with the potential to improve treatment outcomes are needed for the treatment of these genetically defined subsets of NSCLC patients," added Margaret Dugan, M.D., chief medical officer of Dracen Pharmaceuticals.

The FDA Fast Track designation is designed to facilitate the development and expedite the review of therapies and vaccines for serious conditions that fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application.

The single agent activity of DRP-104 in both genetically modified and patient derived xenograft mouse models of NSCLC with KEAP1 mutations was presented at the 2020 American Association for Cancer Research annual meeting. DRP-104 demonstrated consistent single agent anti-tumor activity across a broad panel of models with different KEAP1 mutations.

About DRP-104

Our lead glutamine antagonist, DRP -104, is currently in early stage clinical development. The mechanisms of action for DRP-104 include: a) direct irreversible 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 in animal models.

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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