Checkmate Pharmaceuticals Granted FDA Fast Track Designation for CMP-001 Combined with PD-1 Blockade in the Treatment of Certain Types of Metastatic or Unresectable Melanoma

July 27, 2020

Checkmate Pharmaceuticals, Inc. (Checkmate), a clinical-stage biotechnology company focused on developing proprietary technology to harness the power of the immune system to combat cancer, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation to its product candidate, CMP-001, a differentiated Toll-like receptor 9 (TLR9) agonist, in combination with a programmed death receptor 1 (PD-1) blocking antibody (nivolumab or pembrolizumab) for two development programs, including:

- initial treatment of patients with unresectable Stage III or Stage IV melanoma to prolong the time to disease progression; and
- treatment of patients with unresectable or metastatic melanoma refractory to prior anti-PD-1 blockade to improve the overall tumor response rate.

The FDA previously granted Orphan Drug designation to CMP-001 for Stages IIb-IV melanoma.

Fast Track is a designation granted by the FDA to facilitate the development and review of a drug intended to treat a serious condition and for which available nonclinical or clinical data demonstrate the potential to address an unmet medical need. A product candidate granted Fast Track designation may be eligible for several benefits, including more frequent meetings and communications with the FDA review teams and, if relevant criteria are met, the potential for Priority Review or Rolling Review of a Biologics License Application (BLA) or a New Drug Application (NDA).

"These FDA designations for CMP-001 are testaments to the critical need for new drugs designed to treat patients with melanoma," said Barry Labinger, CEO of Checkmate. "We look forward to continued engagement with the FDA in advancing the development of CMP-001 in combination with PD-1 blockade in melanoma and head and neck squamous cell carcinoma."

About CMP-001

CMP-001 comprises a virus-like particle utilizing a CpG-A oligonucleotide. It is designed to trigger the body's innate immune system via TLR9 and infiltrate the tumor microenvironment by the subsequent induction of both innate and adaptive anti-tumor immune responses. Checkmate believes CMP-001 is the only compound utilizing a CpG-A class TLR9 agonist in clinical development. For information on CMP-001 trials that are currently recruiting patients, please visit www.clinicaltrials.gov.

About Melanoma

Melanoma is a serious form of skin cancer that arises from a particular skin cell type called a melanocyte. Melanoma is a particularly dangerous form of cancer because of its ability to spread to other organs rapidly if not surgically removed at an early stage, as well as low response rates and limited durability of response when treated with commonly used chemotherapeutics. In 2020, melanoma of the skin is estimated to be the fifth most diagnosed cancer, and accounts for approximately 1% of all skin cancers in the U.S. According to the American Cancer Society, there will be an estimated 100,350 new diagnoses and approximately 6,850 patients will die as a result of melanoma in the United States in 2020 alone.

About Checkmate Pharmaceuticals

Checkmate Pharmaceuticals is a clinical stage biotechnology company focused on developing proprietary technology to harness the power of the immune system to combat cancer. Checkmate's product candidate, CMP-001, is a differentiated TLR9 agonist delivered as a biologic virus-like particle designed to trigger the body's innate immune system to attack tumors in combination with other therapies. Checkmate's goal is to leverage its proprietary technology to discover, develop and commercialize transformative treatments to fight cancer. Information regarding Checkmate is available at www.checkmatepharma.com.

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Contacts

Kleem Chaudhary
Chief Business Officer
617-682-3625
kleem@checkmatepharma.com

Karen Sharma
MacDougall
781-235-3060
ksharma@macbiocom.com