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Syncromune Granted FDA Fast-Track Designation for SYNC-T SV-102 for the Treatment of Metastatic Castrate-Resistant Prostate Cancer (mCRPC)

FORT LAUDERDALE, Fla., July 01, 2024 (GLOBE NEWSWIRE) -- Syncromune® Inc., a clinical-stage biopharmaceutical company dedicated to developing innovative therapies for solid tumor cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for SYNC-T SV-102 therapy, its lead candidate for the treatment of patients with metastatic castrate-resistant prostate cancer (mCRPC). SV-102 is part of Syncromune Inc.'s innovative SYNC-T platform, an *in situ* personalized therapy that uniquely employs a combination multi-target approach to cancer treatment, aiming to improve outcomes and quality of life for patients.

The Fast Track designation was granted based on the potential of SYNC-T SV-102 therapy to address the significant unmet need in treating patients with mCRPC. This advanced form of prostate cancer affects over 40,000 men in the U.S. alone and is associated with a very poor prognosis. The Fast Track process is designed to facilitate the development and expedite the review of therapies that treat serious conditions and fulfill an unmet medical need, with the goal of getting important new treatments to patients sooner. Fast Track designation provides Syncromune with several key benefits, including more frequent FDA interactions, eligibility for accelerated approval, and priority review.

“The Fast-Track designation for SYNC-T SV-102 therapy signifies another step forward in bringing our potentially groundbreaking therapy to patients who need it most,” said Eamonn Hobbs, Chief Executive Officer and co-founder of Syncromune. “This accomplishment builds upon the foundation of positive Phase 1 clinical data and recent IND clearance.”

Syncromune’s lead candidate, SYNC-T SV-102, is a platform therapy that combines an *in situ* vaccine via partial oncolysis of a tumor followed by intratumoral infusion of the SV-102 fixed-dose multi-target biologic drug into the lysed tumor. This combination is designed to provide both immune stimulation and block immune suppression to activate and proliferate T cells to elicit a systemic anti-tumor response. Interim data from a Phase 1 study of SV-102 in males with mCRPC demonstrated an overall response rate of 85% with a favorable safety profile and tolerability. The Fast-Track designation comes on the heels of clearance of the company’s investigational new drug (IND) application, with studies expected to begin in the US this year.

Charles Link, M.D., Executive Chairman of Syncromune added, “We believe that Fast-Track designation for SYNC-T SV-102 will significantly aid our development goals for this therapy for men with difficult to treat prostate cancer. We look forward to initiating trials at multiple US sites later this year to expand our efforts to develop the SYNC-T SV-102 Therapy.”

About Syncromune®
Syncromune is a privately held, clinical-stage biopharmaceutical company dedicated to the development of an *in situ* platform technology optimized for metastatic solid tumor cancers that aims to achieve high response rates with potentially improved survival. The company is currently developing SYNC-T, a novel and personalized combination multi-target biologic drug/device therapy platform. SYNC-T is designed to synchronize *in situ* patient-specific antigen T cell activation to enable the immune system to recognize and attack cancer throughout the body. The first two candidates, SV-101 and SV-102, are currently in Phase 1 trials. Syncromune is headquartered in Fort Lauderdale, FL, USA. For more information, please visit www.syncromune.com.

About SYNC-T

Syncromune® is developing SYNC-T, a personalized in situ combination multi-target biologic drug/device platform designed to activate T cells and stimulate the immune system to treat metastatic solid tumors. SYNC-T utilizes a combination approach of *in situ* vaccination via device-induced partial tumor oncolysis and intratumoral infusion of a multi-target biologic drug, aiming to synchronize the timing and location of tumor antigen release with the functional activation of immune cells. The therapy is designed to activate the immune system and combat immune suppression, resulting in patient-specific T cell activation. The proliferation of anti-cancer T cells can enable a systemic anti-tumor response, attacking cancer throughout the body.

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