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## **Syncromune, Inc. Announces FDA Clearance of IND Application for SYNC-T SV-102, a First-In-Class Combination Multi-Target Immunotherapy for Metastatic Castrate-Resistant Prostate Cancer**

*SYNC-T SV-102 Therapy combines partial tumor oncolysis with a fixed-dose combination multi-target biologic drug to provide a novel, personalized therapeutic approach for the treatment of metastatic castrate-resistant prostate cancer*

*Syncromune expects to initiate enrollment of patients with metastatic castrate-resistant prostate cancer in the LEGION-100 Phase 1b trial in the second half of 2024*

FORT LAUDERDALE, Fla., May 30, 2024 (GLOBE NEWSWIRE) -- Syncromune<sup>®</sup> Inc., a clinical-stage biopharmaceutical company focused on the development of SYNC-T, an *in situ* personalized therapy platform optimized for solid tumor cancers, today announced that the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for SYNC-T SV-102, its lead candidate for the treatment of patients with metastatic castrate-resistant prostate cancer.

"Receiving clearance of our IND is a significant milestone for Syncromune and will allow us to rapidly advance the clinical development of SYNC-T SV-102," said Syncromune's President and CEO, Eamonn Hobbs. "This clearance, following our [recent presentation at AACR](#) of data demonstrating unprecedented response rates, underscores the potential of SYNC-T SV-102 to change the landscape of prostate cancer treatment."

"We are thrilled to obtain clearance to advance the SYNC-T SV-102 Therapy and the company is well-positioned to achieve key program milestones," added Charles Link, M.D., Syncromune's Executive Chairman. "The prospects of this new combination multi-target approach and its broad potential applicability in the treatment of metastatic solid tumor cancers is incredibly exciting."

The SYNC-T platform is a novel and personalized *in situ* therapy that uses a unique combination approach of partial tumor oncolysis and a multi-target biologic drug comprised of four active pharmaceutical ingredients (APIs). First, oncolysis is performed via freezing to disrupt a portion of a target tumor which facilitates the release of cancer-specific signals and tumor antigens, activating the immune system and creating an *in situ* vaccine. Next, a fixed-dose combination multi-target biologic drug, SV-102, is directly infused into the tumor site. This is intended to further stimulate the immune system and block mechanisms that suppress the immune response. The combination approach is designed to promote T cell activation and proliferation, empowering the immune system to recognize and attack patient-specific cancer throughout the body.

In a Phase 1 trial conducted in metastatic castrate-resistant prostate cancer patients, SYNC-T SV-102 demonstrated an objective response rate (ORR) of 85% with five complete responses (CRs) and six partial responses (PRs) among the 13 evaluable subjects. Notably, 54% of the subjects demonstrated complete resolution of their bone metastases. The treatment was well tolerated, with a favorable side effect profile and no significant safety concerns.

For more information about Syncromune and its ongoing clinical trials, please visit [www.syncromune.com](http://www.syncromune.com).

### **About Syncromune<sup>®</sup>**

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 biologic drug/device therapy platform. SYNC-T is designed to synchronize *in situ* patient-specific antigen T cell activation and immunostimulation via intratumoral infusion, 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 I trials. Syncromune is headquartered in Fort Lauderdale, FL, USA. For more information, please visit [www.syncromune.com](http://www.syncromune.com).

### **About SYNC-T™**

Syncromune® is developing SYNC-T, a personalized *in situ* combination 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 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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