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Syncromune® Inc. Presents Positive Results from SYNC-T™ SV-102 Phase 1 Trial at AACR Annual Meeting 2024

Initial clinical data demonstrate a very high 85% overall response rate in patients with metastatic castrate-resistant prostate cancer.

FORT LAUDERDALE, Fla., April 08, 2024 (GLOBE NEWSWIRE) -- Syncromune® Inc., a clinical-stage biopharmaceutical company focused on the development of SYNC-T™, an *in situ* personalized therapy optimized for solid tumor cancers, today announced the presentation of positive results from the SV-102 Phase 1 trial at the American Association for Cancer Research (AACR) Annual Meeting 2024. The trial, involving patients with metastatic castrate-resistant prostate cancer (mCRPC), showed an overall response rate (ORR) of 85%.

James Armitage, M.D., Chairman of Syncromune's Scientific Advisory Board, former President of ASCO and Joe Shapiro Professor of Medicine at the University of Nebraska Medical Center, commented on the results stating, "This is an innovative and exciting new therapeutic approach that shows promise with encouraging results in treating mCRPC. With minimal toxicity and high response rates in this debilitating cancer, SYNC-T holds significant potential as a viable treatment option for patients with mCRPC. I am incredibly eager to see how it progresses in future clinical trials."

SYNC-T is a novel and personalized *in situ* therapy that uses a combination of partial tumor lysis and intratumoral immunotherapy. First, lysis is performed via freezing to disrupt a portion of a target tumor which facilitates the release of cancer-specific signals and activation of the immune system, after which a fixed-dose multi-target drug, SV-102, is directly administered into the tumor site. This is intended to further stimulate the immune system and block mechanisms that suppress the immune response. This combination approach is intended to empower the immune system to recognize and attack patient-specific cancer throughout the body. Injecting SV-102 directly into the tumor enables significantly smaller doses in comparison to those required for systemic IV administration, which may contribute to fewer side effects and lower toxicity than current therapies.

George Prendergast, Ph.D., President and CEO of the Lankenau Institute for Medical Research (LIMR), part of Main Line Health, and former Editor-in-Chief of the AACR's flagship journal,*Cancer Research*, added, "This rate of clinical response in mCRPC is unprecedented, given it is a disease with few treatment options, high mortality rates, and for which current treatments have exhibited low response rates and high toxicity. Remarkably, one subject in the trial who enrolled with more than 50 metastatic bone lesions and significantly advanced disease experienced a complete response. This is a profound outcome given the subject's advanced bone metastases. Based on the clinical data and our observations to date, SYNC-T is emerging as a first-in-class therapy that warrants continued clinical trials."

The Phase 1 trial enrolled 15 mCRPC subjects, most of whom had diffuse bone metastases and had experienced failure with prior therapies. Subjects received SYNC-T therapy with the SV-102 multi-target biologic drug every four weeks for up to 12 cycles with response evaluation every eight weeks. SYNC-T demonstrated an ORR of 85% with five complete responses (CRs) and six partial responses (PRs) among the 13 evaluable subjects. The treatment was well tolerated, with minimal side effects and no significant safety concerns. The trial is ongoing, with results expected in the second half of 2024.

These encouraging results support the continued clinical development of the SYNC-T Therapy platform to potentially offer a new treatment option for patients with mCRPC and other solid

tumors. The trial's inclusion in AACR's press program highlights the interest of the oncology research community in these findings.

For more information about Syncromune and its ongoing clinical trials, please visit www.syncromune.com.

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 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 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 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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