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Syncromune® Announces First Patient Dosed in LEGION100 Phase 2a Trial of SYNC-T® Therapy SV-102 for Patients with Metastatic CastrationResistant Prostate Cancer

SYNC-T Therapy SV-102 combines partial tumor oncolysis with a multi-target biologic drug to provide a novel, personalized therapeutic approach for the treatment of metastatic solid tumor cancers

FORT LAUDERDALE, Fla. and WEST DES MOINES, Iowa, May 30, 2025 (GLOBE NEWSWIRE) -- Syncromune[®] Inc., a clinical-stage biopharmaceutical company focused on the development of SYNC-T, an *in situ* personalized combination immunotherapy platform optimized for solid tumor cancers, today announced that the first patient has been successfully dosed in the LEGION-100 trial, a two-part Phase 2a Dose Escalation and Dose Optimization trial of SYNC-T Therapy SV-102 for patients diagnosed with metastatic castration-resistant prostate cancer (mCRPC) (NCT06533644).

"Building on the encouraging results of the previous Phase 1 trial, we are pleased to have initiated LEGION-100, bringing SYNC-T Therapy SV-102 one step closer to potentially changing the treatment landscape in prostate cancer," said Eamonn Hobbs, President & CEO of Syncromune. "This milestone not only propels our clinical progress, but also underscores our continued commitment to delivering a meaningful therapeutic option to patients in need."

The LEGION-100 Phase 2a trial is now enrolling patients who have mCRPC and have failed prior therapies. The primary objectives of the trial are to evaluate the safety and tolerability of SYNC-T Therapy SV-102 and measure the overall response rate (ORR). Key secondary objectives include evaluating duration of response, overall survival (OS), and radiographic progression-free survival (rPFS).

Jason Hafron, M.D., Chief Medical Officer and Medical Director of Clinical Research at Michigan Institute of Urology, the site of the first patient dosed, added, "SYNC-T Therapy SV-102 is uniquely

designed to synchronize the location of three key components necessary to educate the immune system so it can recognize and attack cancer, offering a potential new treatment approach where current options may fall short. Our commitment at <u>Michigan Institute of Urology</u> is to rigorously evaluate this potential and strive toward breakthroughs that could fundamentally improve outcomes for patients."

Charles Link, M.D., Executive Chairman of Syncromune, added, "Today's milestone of dosing our first patient in the Phase 2a trial of SYNC-T Therapy SV-102 not only signifies a pivotal moment for Syncromune's journey in advancing cancer treatment it also brings a tangible sense of hope to patients battling metastatic castration-resistant prostate cancer".

Results from the previous Phase 1 study will be delivered in a podium presentation during the 2025 Annual American Society for Clinical Oncology (ASCO) Meeting on May 31.

For more information about the ongoing LEGION-100 trial for mCRPC, please visit www.legion100trial.com.

About Syncromune® and SYNC-T®

Syncromune is a privately held, clinical-stage biopharmaceutical company dedicated to the development of SYNC-T, a potentially first-in-class platform immunotherapy designed to address major unmet needs and treatment challenges of incurable metastatic solid tumor cancers. SYNC-T is an in situ personalized cancer therapy engineered to synchronize the location of three components critical to T cell activation and an anti-tumor immune response: tumor antigens, immune cells, and our multi-target biologic drug. SYNC-T features a novel proprietary device delivery system that is optimized for combination drug/device immunotherapy. First, the system lyses a portion of a target tumor to rupture tumor cells and release tumor antigens into the tumor microenvironment (TME) that help to activate the immune system. Next, the delivery system facilitates the infusion of our proprietary multi-target biologic drug directly into the tumor. This synchronization of location approach is designed to unite the three critical components together in the TME and lymphatics where the immune system optimally functions. The combination therapy targets numerous mechanisms of cancer, promoting in situ immune activation while also battling immune suppression and minimizing systemic drug exposure. The goal is to activate T cells, empowering the immune system to recognize and attack the patient's cancer throughout the body and defend with immune memory. Our lead candidate, SYNC-T Therapy SV-102 for metastatic castration-resistant prostate cancer (mCRPC), is being evaluated in a U.S., multicenter, Phase 2a trial. For more information, please visit <u>www.legion100trial.com</u>.

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