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Syncromune® Presents SYNC-T™ Therapy: Image-Guided Cryolysis and Intratumoral Immunotherapy at CIRSE 2026

Invited speaker, Stephen Kee, M.D. reviews SYNC-T™ Therapy SV-102 mechanism, previously reported Phase 1 findings and ongoing Phase 2 LEGION-100 trial in metastatic prostate cancer

FORT LAUDERDALE, Fla. and WEST DES MOINES, Iowa, Sept. 09, 2026 (GLOBE NEWSWIRE) -- Syncromune®, Inc., a privately held clinical-stage biopharmaceutical company developing SYNC-T™, an investigational in situ multi-target immunotherapy platform for solid tumors, today announced that Stephen Kee, M.D., EVP, Clinical Medical & Business Operations, EMEA, presented the company's investigational SYNC-T Therapy SV-102 approach at CIRSE 2026 in Copenhagen, Denmark.

The presentation, titled "Cryolysis and Direct Immunotherapy Injection," reviewed the scientific and procedural rationale for combining image-guided partial tumor cryolysis with direct intratumoral immunotherapy, as well as previously reported Phase 1 clinical findings with SYNC-T Therapy SV-102 in metastatic prostate cancer.

Dr. Kee also reviewed previously reported preliminary results from Syncromune's 15-patient Phase 1 study in metastatic prostate cancer. In this small, early-stage study, investigators reported a 100% disease control rate and an investigator-assessed overall response rate of 87%, including complete responses in 53% of patients. Independent radiological review reported an 87% overall response rate, including 40% complete responses and 47% partial responses. Study imaging showed complete resolution of bone metastases in seven of the 13 patients (54%) who had bone metastases at baseline. Across the study, 95% of reported treatment-emergent adverse events were Grade 1 or 2 with no Grade 4 or 5 reported. These preliminary results should be interpreted in light of the study's small sample size and early-stage design. SYNC-T Therapy SV-102 remains investigational, and its safety and effectiveness have not been established. Results from this 15-patient study may not be predictive of results in larger or later-stage trials.

Prostate cancer remains difficult to treat with conventional systemic immunotherapies, underscoring the need for approaches designed to overcome local immune suppression. SYNC-T is designed to address this challenge through a localized, image-guided drug-device approach that integrates image-guided tumor intervention with direct intratumoral immunotherapy delivery. As presented at CIRSE, a portion of a target tumor undergoes partial cryolysis, disrupting tumor cells and releasing a heterogeneous population of patient-specific tumor antigens. The investigational fixed-dose, multi-target drug SV-102 is then infused directly into the treated area through the same device path.

SV-102 combines four immune modulators designed to inhibit immune-suppressive pathways while activating immune-stimulatory pathways. Combined with partial cryolysis, this approach is designed to synchronize tumor antigens, immunotherapy and immune cells within the tumor and locoregional tumor-draining lymphatics, with the goal of activating T cells capable of generating a systemic anti-tumor immune response while limiting systemic drug exposure.

“Interventional radiologists bring the imaging expertise and procedural capabilities needed to precisely access tumors throughout the body, creating an important opportunity to expand how image-guided intervention contributes to cancer treatment,” said Dr. Kee, EVP, Clinical Medical & Business Operations, EMEA. “SYNC-T combines a minimally invasive local procedure with direct intratumoral immunotherapy delivery designed to generate an immune response beyond the treated tumor itself. We were pleased to share both the technical approach and our clinical experience with the CIRSE community as we continue to expand our clinical program and advance the role of interventional radiology in intratumoral immunotherapy.”

“CIRSE represents an important opportunity to engage the interventional radiology community as we continue building the multidisciplinary clinical infrastructure to support SYNC-T,” said Charles Link, M.D., Executive Chairman and Chief Innovation Officer of Syncromune, and Adjunct Professor at the Lankenau Institute for Medical Research. “The encouraging preliminary findings generated in the Phase 1 study helped inform the development of LEGION-100, which is now advancing through Phase 2 dose optimization in the United States. At the same time, we are preparing to expand LEGION-100 into new regions outside the U.S.”

Syncromune is currently evaluating SYNC-T Therapy SV-102 in LEGION-100 (NCT06533644), an ongoing multicenter Phase 2 trial in patients with metastatic castration-resistant prostate cancer (mCRPC) who have progressed following standard-of-care treatment. Part 1 dose escalation has been completed, and Part 2 dose optimization is underway.

For more information about LEGION-100, please visit www.legion100trial.com.

About Syncromune® and SYNC-T™ Therapy

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 medical needs and treatment challenges of metastatic solid tumor cancers. SYNC-T is an investigational *in situ* personalized cancer therapy engineered to synchronize the location of three components involved in T cell activation and an anti-tumor immune response. The platform features a novel proprietary needle-based device delivery system designed for combination drug/device immunotherapy. First, the system is designed to lyse a portion of a target tumor via a proprietary freeze/thaw method to rupture tumor cells and release patient-specific tumor antigens into the tumor microenvironment (TME), with the goal of activating the immune system. Next, the delivery system facilitates the infusion of our investigational multi-target immunomodulatory drug directly into the lysed area of the tumor. The volume of the infusion is intended to promote the flow of antigens and the drug into tumor-draining lymph nodes, where they are intended to co-localize with immune cells. This co-localization approach is designed to unite three components involved in T cell activation. The combination intratumoral therapy is designed to target multiple mechanisms of cancer, with the goal of promoting *in situ* immune activation, addressing immune suppression and limiting systemic drug exposure. The goal is to generate a systemic anti-tumor response that may recognize and attack both primary and metastatic tumors throughout the body and support immune memory. Our lead candidate, SYNC-T Therapy SV-102, is currently being evaluated in the U.S. in our multicenter Phase 2 LEGION-100 clinical trial for metastatic castration-resistant prostate cancer (mCRPC). For more information, please visit www.legion100trial.com.

This press release includes forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained in this press release or expressed orally in connection herewith that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, forward-looking statements can be identified by phrases such as “plans,” “intends,” “believes,” “expects,” “anticipates,” “foresees,” “forecasts,” “estimates” or other words or phrases of similar import. Similarly, statements herein that describe our business strategy, outlook, objectives, plans, intentions or goals also are forward-looking statements. Forward-looking statements in this release include statements regarding the clinical development, potential mechanism and effects of SYNC-T Therapy SV-102; the progress, timing and geographic expansion of LEGION-100; and the expansion of Syncromune’s pipeline and clinical infrastructure. These statements are subject to risks and uncertainties, including the risks that preliminary or early-stage clinical results may not be confirmed in later-stage or larger trials; adverse events or other safety issues may arise; patient enrollment, trial operations or regulatory review may be delayed; planned trial expansion may not occur on the anticipated timeline or at all; and Syncromune may not obtain regulatory approval for SYNC-T Therapy SV-102. Actual results could differ materially from those expressed or implied by the forward-looking statements. Accordingly, you should not place undue reliance on our forward-looking statements. The forward-looking statements contained in this press release or expressed orally in connection herewith are made only as of the date of this press release and we undertake no obligation to update these forward-looking statements to reflect subsequent events or circumstances, except as required by applicable law. This press release was prepared by us for informational purposes only and does not constitute an offer, or solicitation of an offer, to sell any securities at any time. None of Syncromune’s securities have been registered under the Securities Act of 1933, as amended, or any state securities law. Such securities have not been approved or disapproved by the Securities and Exchange Commission or by any state securities regulatory authority, nor has the Securities and Exchange Commission or any such state authority passed on the accuracy or adequacy of this press release. Any representation to the contrary is a criminal offense. Some of the information contained in this press release may be derived from information provided by industry sources. We believe that such information is accurate and that the sources from which it has been obtained are reliable; however, we cannot guarantee the accuracy of such information and have not independently verified such information.

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