



Source: Syncromune

December 04, 2025 08:00 ET

Syncromune®, Inc. Presents Phase 1 Data Highlighting Resolution of Bone Metastases in Metastatic Prostate Cancer Patients at Society of Urological Oncology 26th Annual Meeting

FORT LAUDERDALE, Fla. and WEST DES MOINES, Iowa, Dec. 04, 2025 (GLOBE NEWSWIRE) -- Syncromune®, Inc., a clinical-stage biopharmaceutical company dedicated to the development of SYNC-T, an *in situ* platform combination therapy optimized for solid tumor cancers, today announced the presentation of findings from its Phase 1 clinical study of SYNC-T Therapy SV-102 in patients with metastatic castration-resistant prostate cancer (mCRPC) and metastatic hormone-sensitive prostate cancer (mHSPC). The data, featured at the 26th Annual Meeting of the Society of Urological Oncology (SUO), highlight compelling responses among patients with bone metastases, a common and challenging manifestation of advanced prostate cancer.

Among the 15 patients enrolled in the single-arm Phase 1 trial, 13 (87%) had skeletal metastases at baseline, and following SYNC-T therapy, all bone metastases resolved in seven (54%) of these patients. Responses were durable, with 57% of responders maintaining ongoing remission at the time of analysis. Across the full study cohort SYNC-T achieved an overall response rate (ORR) of 87%, including 53% complete responses (CR) and 33% partial responses (PR). The median response time was 2.9 months, and the median duration of response was 12.1 months. At a median follow-up of 17.2 months, 80% of patients remained alive, suggesting encouraging durability of clinical benefit in this heavily pretreated patient population. Of significance for advanced prostate cancer treatment, the therapy was well tolerated, with most treatment-emergent adverse events (TEAEs) being Grade 1-2 and transient.

Charles Link, M.D., Adjunct Professor at the Lankenau Institute for Medical Research (LIMR) and Co-Founder and Executive Chairman at Syncromune said, "Bone metastases remain a clear unmet clinical challenge in metastatic prostate cancer with few durable responses, despite being present

in more than 80% of advanced cases. Data demonstrating complete resolution of bone metastases at the rates we have observed is rare in this population and it reinforces the potential of SYNC-T to elicit a well-tolerated, systemic immune response through an *in situ* approach. We are encouraged by the trajectory of this program and continue to build on this foundation in our ongoing Phase 2 LEGION-100 trial.”

The open-label, single-arm trial enrolled 15 individuals with histologically verified metastatic prostate cancer who had experienced progression following at least one previous therapy. Patients received SYNC-T SV-102 on a four-week schedule for up to 12 cycles, with clinical assessments performed at 8-week intervals.

Gerald Andriole, M.D., Chief Medical Officer, Urology at Syncromune and presenter of the SUO data, added, “For men with advanced prostate cancer, bone metastases are not only a major driver of pain and disability, but also represent one of the hardest challenges we face as clinicians. Seeing these lesions resolve in a meaningful proportion of patients treated with SYNC-T is very encouraging. Equally important is that SYNC-T was well tolerated in these heavily pre-treated physiologically fragile patients, who often have few remaining options that don’t carry significant toxicity. These findings suggest that *in situ* immune activation may offer a new path forward for patients who urgently need better and more tolerable therapies.”

Syncromune is enrolling patients for its Phase 2 multicenter trial (LEGION-100, NCT06533644) at sites across the United States, including the Michigan Institute of Urology, the University of Arizona Cancer Center, the University of Pittsburgh Medical Center, the University of Nebraska Medical Center, and Mercy Hospital, St. Louis with additional sites to follow. Please visit www.legion100trial.com to learn more and explore if you or someone you love may qualify.

For more information about Syncromune, please visit www.syncromune.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 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. SYNC-T features a novel proprietary needle-like 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 patient-specific tumor antigens into the tumor microenvironment (TME) that helps to activate the immune system. Next, the delivery system facilitates the infusion of our proprietary multi-target biologic drug directly into the lysed area of the tumor. This approach of location synchronization is designed to unite the three critical components of patient-specific tumor antigens, immune cells, and our multi-target biologic drug together in the draining 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 educate the immune system and activate T cells that can recognize and attack 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 the LEGION-100 U.S., multicenter, Phase 2 trial. 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. All such forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those in 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 the forward-looking statements to reflect subsequent events or circumstances, except as

required by applicable law. None of Syncromune, Inc., its affiliates or their respective directors, officers, employees or agents gives any representation or warranty, express or implied, as to: (i) the achievement or reasonableness of future projections, management targets, estimates or prospects contained in this press release; or (ii) the accuracy or completeness of any information contained in this press release, any other written information or oral information provided in connection herewith or any data that any of them generates. 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.

Corporate Contact

Danielle Hobbs
EVP, Marketing & Commercial Strategy
Syncromune, Inc.
media@syncromune.com

Media Contact

Michael Tattory
LifeSci Communications
mtattory@lifescicomms.com