

Syncromune Reports Long-Term Data from Phase 1 Study in Metastatic Prostate Cancer with Investigational SYNC-T Therapy SV-102

Data support potential for highly differentiated clinical impact for patients suffering from metastatic prostate cancer

- *50% of patients who achieved a complete response (n=6) remain disease-free more than two years after treatment*
- *80% of patients treated with SYNC-T Therapy SV-102 (n=15) alive at 24 months*
- *Median overall survival not reached at nearly 30 months of follow-up*
- *Phase 2a LEGION-100 trial now enrolling at 24 U.S. cancer centers and soon at multiple prestigious international sites*

FORT LAUDERDALE, Fla., and WEST DES MOINES, Iowa, Oct. 27, 2026 (GLOBE NEWSWIRE) -- For men with metastatic prostate cancer, current treatments are designed to slow the disease and manage symptoms, but they are not expected to cure it. All approved therapies for metastatic disease remain palliative. New long-term data presented at the European Society for Medical Oncology (ESMO) Congress 2026 suggest that Syncromune's investigational therapy may offer a different possibility: durable, disease-free survival that, should these data continue to be sustained over time, could represent a potential curative benefit in some patients.

Syncromune, Inc., a privately held clinical-stage biopharmaceutical company developing SYNC-T, an investigational multi-target immunotherapy platform for solid tumors, today announced updated overall survival results from a Phase 1 trial of its investigational SYNC-T Therapy SV-102 in patients with metastatic prostate cancer.

Dr. Carlos Vargas presented the maturing clinical data at ESMO 2026 in Madrid on October 23, 2026 (Presentation #2247P). As of the April 1, 2026 data cutoff, median overall survival has not been reached with a median follow-up of 29.6 months, and 80% of patients (12 of 15) treated with SYNC-T therapy SV-102 were alive at 24 months. Of the six patients who achieved a complete response in

the Phase 1 trial, three (50%) remain disease-free with follow-up ranging from 26.5 to 35.3 months. These findings, coupled with previously reported results showing an 87% objective response rate and a 40% complete response rate, further support the highly differentiated clinical activity of SYNC-T therapy SV-102.

“These results represent a significant step forward for patients with metastatic prostate cancer,” said Eamonn Hobbs, President and Chief Executive Officer of Syncromune. “With nearly 30 months of follow-up, median overall survival has not been reached, and half of the patients who achieved a complete response remain disease-free more than two years later. We believe these data demonstrate the potential of SYNC-T Therapy to deliver durable benefit where current treatments are only palliative, and we are excited to build on this promise in our Phase 2a LEGION-100 trial, now enrolling at leading cancer centers.”

These Phase 1 survival data in metastatic prostate cancer represent the longest follow-up reported to date for this platform and support continued investment in the LEGION-100 Phase 2 program in metastatic castration-resistant prostate cancer (mCRPC), as well as potential expansion into additional solid-tumor indications.

Updated Phase 1 Results

The open-label, single-arm Phase 1 study ([NCT05544227](https://clinicaltrials.gov/ct2/show/study/NCT05544227)) enrolled 15 patients with metastatic prostate cancer: 10 with metastatic castration-resistant prostate cancer (mCRPC) and 5 with metastatic hormone-sensitive prostate cancer (mHSPC) who had refused androgen deprivation therapy. Patients received up to 12 treatment cycles, each targeting a single lesion, administered every four weeks.

Key findings as of the April 1, 2026 data cutoff (all 15 patients evaluable for survival):

- **Overall population (n=15):** Median overall survival not reached (95% CI: 27.9–not reached). 24-month survival rate: 80% (12 of 15 patients alive).
- **mCRPC cohort (n=10):** Median overall survival 27.9 months (95% CI: 17.1–not reached); 24-month survival rate: 70%.
- **mHSPC cohort (n=5):** No deaths have occurred; median overall survival not reached; 24-month survival rate: 100%.
- **Durability of complete responses:** Of the six patients who achieved a complete response, three (50%) remain disease-free at follow-up ranging from 26.5 to 35.3 months.

SYNC-T Therapy SV-102 was generally well tolerated. Ninety-five percent of treatment-emergent adverse events were grade 1–2; there were no grade 4 or 5 events and no grade 3 or 4 immune-related toxicities.

“Follow-up imaging in some patients showed regression of distant metastases that were never directly treated,” said Carlos Vargas, MD, Principal Investigator of the Phase 1 trial. “The potential systemic effect suggested by these observations is what makes this approach distinctive.”

These Phase 1 results support the ongoing multicenter Phase 2a LEGION-100 trial (NCT06533644), which is evaluating SYNC-T Therapy SV-102 in patients with metastatic castration-resistant prostate cancer (mCRPC).

Phase 2a LEGION-100 Trial Now Enrolling Patients

Building on these Phase 1 results, the multicenter LEGION-100 trial is currently enrolling at 24 cancer centers across the United States and international sites are expected to open soon. Patients and caregivers interested in learning whether the trial may be an option can visit www.legion100trial.com or speak with their physician. Eligibility criteria and site locations are available on the trial website.

About SYNC-T Therapy

SYNC-T Therapy SV-102 is an investigational *in situ* (in the tumor) multi-target immunotherapy platform engineered to help the patient's immune system produce an anti-tumor response. The therapy utilizes a proprietary device and drug (SV-102) and is administered on an outpatient basis similar to an image-guided needle biopsy. The needle-like device is used to partially freeze and

thaw a small portion of a single tumor. This breaks open some of the cancer cells and releases patient-specific tumor proteins (antigens) that help the patient's immune system recognize cancer. Immediately following this, using the same needle-like device, a five-minute infusion of SV-102 is delivered directly into the treated tumor.

SV-102 contains four immune-modulating agents: abazistobart (anti-PD-1), futermestotug (anti-CTLA-4), ciltistotug (CD40 agonist), and sitmutolimod (TLR9 agonist). The goal is to concentrate these agents and the newly released tumor antigens in the tumor and its draining lymph nodes, where they can help train the immune system to recognize and attack cancer cells throughout the body—including metastases that are not directly treated—and produce an anti-tumor response throughout the body.

SYNC-T Therapy SV-102 is an investigational therapy and has not been approved by any regulatory authority. Its safety and efficacy have not been established.

About Syncromune

Syncromune is a privately held, clinical-stage biopharmaceutical company focused on SYNC-T, an investigational *in situ* personalized cancer therapy designed to synchronize tumor antigens, multi-target immunomodulatory drugs, and immune cells in the tumor microenvironment and draining lymph nodes. The platform uses a proprietary needle-based device to partially freeze and thaw a portion of a single target tumor, followed by immediate infusion of a proprietary multi-target drug combination with the goal of generating a systemic immune response capable of recognizing and attacking both treated and untreated tumors throughout the body, while supporting immune memory. Syncromune's lead candidate, SYNC-T Therapy SV-102, is being evaluated in the Phase 2a LEGION-100 trial for metastatic castration-resistant prostate cancer. For more information, visit www.legion100trial.com.

Headquartered in Fort Lauderdale, Florida, and West Des Moines, Iowa, Syncromune is led by an experienced management team with deep expertise in drug and device development as well as the design and clinical development of combination products.

For more information, please visit www.syncromune.com and follow us on [LinkedIn](#). Further information for qualified investors is available through the company contact below.

About Metastatic Prostate Cancer

Metastatic prostate cancer is an advanced form of disease that has spread beyond the prostate, most often to the bones and lymph nodes. Treatment usually begins with hormone therapy (also called androgen deprivation therapy or ADT), which reduces testosterone levels to slow the cancer's growth and help control symptoms. Over time, however, cancer can stop responding to hormone therapy and continue to grow despite other available treatments such as newer hormone medicines, chemotherapy, and other therapies. At this stage, treatment options become more limited and are mainly focused on managing the disease symptoms rather than curing it. Many people continue to experience challenges such as bone pain, fatigue, and other complications that can make daily life more difficult and affect their overall quality of life.

Forward-Looking Statements

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, including whether SV-102 is potentially curative. 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 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 these forward-looking statements to reflect subsequent events or circumstances, except as required by applicable law. This press release was

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Contacts

Company:

Kerri-Ann Millar
Chief Financial Officer
Syncromune, Inc.
kmillar@syncromune.com