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Syncromune® Inc. Presents Positive Results from SYNC-T® Therapy SV-102 Phase 1 Metastatic Prostate Cancer Trial at ASCO 2025

Presentation highlights deep and durable responses and radiographic resolution of bone metastases in patients with advanced prostate cancer

Final clinical data demonstrate an 87% overall response rate in patients with metastatic prostate cancer

Results support recent advancement into LEGION-100 Phase 2a clinical trial

FORT LAUDERDALE, Fla. and WEST DES MOINES, Iowa, June 02, 2025 (GLOBE NEWSWIRE) -- Syncromune, Inc., a clinical-stage biopharmaceutical company dedicated to the development of SYNC-T, an *in situ* platform combination immunotherapy optimized for solid tumor cancers, today announced the presentation of updated clinical data from a Phase 1 trial evaluating SYNC-T Therapy SV-102 for subjects with metastatic prostate cancer. The data were presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting by Ricky T. Tong, M.D., Ph.D., Clinical Assistant Professor at the Lankenau Institute for Medical Research, part of Main Line Health.

Final data showed an 87% overall response rate (ORR) and 53% complete response rate (CR) in subjects with metastatic castration resistant prostate cancer (mCRPC) or who had refused hormone therapy, which is nearly double that of current standard-of-care therapies for mCRPC. All subjects achieved disease control, highlighting the potential of SYNC-T for patients with advanced prostate cancer. The data support the recent initiation of the Company's Phase 2a LEGION-100 trial of SYNC-T Therapy SV-102, in which the first subject has been dosed at the Michigan Institute of Urology (NCT06533644).

Charles Link, M.D., Adjunct Professor at Lankenau Research Institute and Co-Founder and Executive Chairman of Syncromune added, "These updated data reinforce the promise of SYNC-T as a novel, localized approach to immunotherapy in solid tumors. Compared to current standard of care, these data suggest SYNC-T may offer a meaningful benefit for patients with mCRPC. The durability of response and strong safety profile reinforce our confidence as we actively enroll patients in our newly initiated LEGION-100 Phase 2a trial."

This Phase 1, open-label, single-arm study enrolled 15 subjects with histologically confirmed mCRPC or who had refused hormone therapy. Subjects received up to 12 cycles of SYNC-T Therapy SV-102 every four weeks, with response assessment at every 8 weeks.

Key Findings:

- **100% disease control rate**
    - 87% overall response rate among 15 evaluable subjects
    - 53% (8/15) had complete responses (resolution of all bone and soft tissue metastases)
    - 33% (5/15) had partial responses
    - 13% (2/15) had stable disease
- Durable clinical benefit with median duration of response of 12.1 months; 80% of subjects alive at median follow-up of 17.2 months
- Radiographic resolution of bone metastases in multiple subjects, including one case with over 50 lesions resolved
- Median radiographic progression-free survival (rPFS): 14.2 months
- SYNC-T was generally well tolerated, with 95% of treatment-emergent adverse events (TEAEs) being Grade 1 or 2 (most common: fever, hematuria) and no Grade 4 or 5 TEAEs reported
- Expanded biomarker data showed rapid post-treatment cytokine activation (IFNγ, TNFα, IL-6) and broad peripheral T-cell clonal expansion, suggesting sustained immune engagement
- Of note, an additional independent radiological review completed on 5/24/2025 reported an ORR of 87%, CR of 40%, and PR of 47%

“This Phase 1 experience has paved the way for us to proceed into our Phase 2a trial,” added Eamonn Hobbs, Co-Founder, President and Chief Executive Officer of Syncromune. “The speed and depth of response, combined with a safety profile that suggests minimal systemic drug exposure differentiates SYNC-T from current approaches in prostate cancer and gives us further certainty in advancing this program.”

Syncromune recently initiated its Phase 2a clinical trial, LEGION-100, a U.S., multicenter, dose-escalation and dose-optimization study evaluating SYNC-T Therapy SV-102 for patients with mCRPC. The trial is currently recruiting at multiple U.S. locations, including the Lankenau Institute for Medical Research, the Michigan Institute of Urology, and University of Pittsburgh Medical Center, 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 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 www.legion100trial.com.

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