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Syncromune Appoints Zhihong Li, Ph.D., as Chief Regulatory Affairs Officer to Lead Global Regulatory Strategy for Novel Oncology Immunotherapies

FORT LAUDERDALE, Fla. and WEST DES MOINES, Iowa, March 25, 2025 (GLOBE NEWSWIRE) -- Syncromune® Inc., a clinical-stage biopharmaceutical company developing SYNC-T, an *in situ* personalized immunotherapy platform optimized for solid tumor cancers, today announced the appointment of Zhihong Li, Ph.D., as Chief Regulatory Affairs Officer. Dr. Li brings 18 years of regulatory and drug development experience spanning the U.S. FDA, Pfizer, Biocytogen/Eucure and Belief Biomed. As Chief Regulatory Affairs Officer, he will oversee global regulatory strategy, ensuring compliance with FDA, EMA, and NMPA (China) requirements, and is expected to play a key role in advancing SYNC-T Therapy SV-102 through late-stage clinical development.

“Dr. Li brings invaluable expertise to our team, and we are confident that his vision and unique skillset will help us accelerate our mission to bring life-saving cancer therapies to patients,” said Charles Link, M.D., Executive Chairman of Syncromune. “His leadership will be pivotal in planning and executing multifactorial regulatory strategies for our SYNC-T platform.”

During his tenure at the FDA’s Center for Drug Evaluation and Research (CDER), Dr. Li conducted regulatory reviews of over 200 INDs, NDAs, and BLAs, providing critical insights into clinical trial design, expedited program applications, and regulatory approvals for oncology and immunotherapy products. In his industry roles, he successfully led multiple IND submissions in the U.S. and equivalent submissions in China, secured expedited program designations, and guided regulatory pathways for novel biologics, gene therapies, and oncology products. His leadership has helped transition multiple early-stage assets into clinical development and regulatory approval.

As former Chief Regulatory and Strategy Officer at Biocytogen/Eucure, Dr. Li has first-hand experience working with Syncromune’s licensed antibodies (CTLA-4, CD40, and OX40), which is expected to provide a unique advantage in advancing the company’s immuno-oncology portfolio. Additionally, his fluency in Mandarin and deep understanding of international regulatory environments will help strengthen Syncromune’s global partnerships.

"Dr. Li’s extensive experience in regulatory strategy and oncology drug development will be instrumental as we navigate the complex regulatory landscape for SYNC-T,” said Eamonn Hobbs, President & Chief Executive Officer of Syncromune. "With his deep knowledge of clinical pharmacology, regulatory expertise, and global regulatory frameworks, Dr. Li will play a critical role in shaping the regulatory path forward for SYNC-T and our broader pipeline."

"I am excited to join Syncromune at this pivotal time in the company’s growth and clinical advancement," said Dr. Li. "SYNC-T represents a highly innovative approach to immunotherapy, and I look forward to leveraging my regulatory experience to support the company’s mission of bringing transformative cancer therapies to patients worldwide.”

For more information about Syncromune and its clinical programs, 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 anti-tumor immune response: tumor antigens, immune

cells, and our multi-target biologic drug. SYNC-T features a proprietary delivery system that is optimized for combination drug/device immunotherapy. First, the system freezes a portion of a target tumor to kill 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 a proprietary multi-target biologic drug directly into the tumor. This synchronization approach is designed to unite the three critical components together in the TME and lymphatics where the immune system optimally functions. The combination therapy aims to target multiple 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 cancer throughout the body and defend with immune memory. Syncromune's lead candidate, SYNC-T Therapy SV-102 for metastatic castration-resistant prostate cancer (mCRPC), is being evaluated in Phase 2 trials. Syncromune is headquartered in Fort Lauderdale, FL, and West Des Moines, IA, USA. For more information, please visit www.syncromune.com.

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