



Teknova and Pluristyx Announce FDA Drug Master File for the PluriFreeze™ Cryopreservation System

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Developers of advanced therapies using PluriFreeze during preclinical stages can seamlessly scale to clinical manufacturing and cross-reference the Drug Master File in FDA submissions

HOLLISTER, Calif., Oct. 02, 2026 (GLOBE NEWSWIRE) -- Alpha Teknova, Inc. ("Teknova") (Nasdaq: TKNO), and Pluristyx, Inc. ("Pluristyx"), today announced that Pluristyx is completing a Type II Drug Master File (DMF) for the PluriFreeze™ cryopreservation system for submission to the U.S. Food and Drug Administration (FDA). The DMF will support drug makers seeking to incorporate PluriFreeze into their clinical development and manufacturing programs. Teknova is a leading producer of critical reagents for the discovery, development, and commercialization of novel therapies, vaccines, and molecular diagnostics, and is the exclusive manufacturer and distributor of PluriFreeze in the United States and Canada. Pluristyx is a leading provider of advanced induced pluripotent stem cell (iPSC) technologies and proprietary, genetically engineered solutions for drug discovery and the development of advanced therapies.

Developers who utilize PluriFreeze in preclinical stages can now request a letter of authorization (LOA) from Pluristyx and cross-reference the PluriFreeze DMF in their Investigational New Drug (IND) applications and Biologics License Applications (BLA). The comprehensive regulatory submission details chemistry, manufacturing, and controls (CMC) for the PluriFreeze system, helping to streamline regulatory submissions and accelerate the development of next-generation therapies.

"The PluriFreeze DMF gives advanced therapy developers more to build on than strong product performance: a documented regulatory position for their cryopreservation system, ready when they need it," said Stephen Gunstream, Teknova's President and Chief Executive Officer. "As the cell therapy industry has matured, and as more novel therapies move into clinical trials, our customers want to know that the reagents they've built their processes around can support them through clinical development and into commercialization. This file puts that documentation on record with the FDA, so they can seamlessly scale with confidence."

"Cryopreservation is a critical manufacturing step in cell therapy, but it is often overlooked during process development," said Dr. Jason Carstens, Chief Operating Officer and Co-Founder of Pluristyx. "PluriFreeze was designed for both cryopreservation performance and manufacturability, with a low-viscosity formulation that is easier to handle and scale as process volumes increase. That focus on low viscosity and manufacturing scalability is an important point of differentiation from other cryopreservation media, and the DMF now provides the regulatory documentation to support its use as programs advance toward the clinic."

Purpose-built for scalable manufacturing of cell-based products, the PluriFreeze system is a biopreservation media used to protect cells – from intermediate holds during manufacturing through long-term cryopreservation – helping cells remain viable and functional throughout the product lifecycle. Entirely synthetic and animal-origin-free, the system pairs a protective wash with a freezing medium: PluriFreeze Base is a cellular wash that mimics intracellular space and provides metabolic support across the workflow, while PluriFreeze PF10 is a low viscosity freezing medium with 10% dimethyl sulfoxide (DMSO) that simplifies scale-up and process automation. Both products are available for research use and GMP manufacturing applications and can be further customized to support specific cell types and workflow requirements.

In studies comparing PluriFreeze with an industry reference, PluriFreeze PF10 supported similar post-thaw viability, recovery, doubling times, expansion, and surface marker expression across multiple pluripotent stem cell lines and Natural Killer (NK) cells. The PluriFreeze system is stable for up to two years at 2 – 8 °C.

The DMF, which Pluristyx holds, builds on the companies' collaboration announced in March 2025, through which Teknova became the exclusive manufacturer and distributor of the PluriFreeze product line in the United States and Canada and subsequently contributed the manufacturing and quality content required to support the file. PluriFreeze products are manufactured at Teknova's ISO 13485 certified facilities in Hollister, California, on the same modular manufacturing platform that supports the Company's industry-leading turnaround times across research- and GMP-grade reagents.

For product specifications, quality documentation, and ordering information for PluriFreeze Base and PF10, visit teknova.com/pluristyx, email info@teknova.com, or call 1-800-209-4488. A Letter of Authorization can be requested directly from Pluristyx at info@pluristyx.com.

ABOUT TEKNOVA

Teknova makes solutions possible. Since 1996, Teknova has been innovating the manufacture of critical reagents for the life sciences industry to accelerate the discovery and development of novel breakthroughs that will help people live longer, healthier lives. We offer fully customizable solutions for every stage of the workflow, supporting industry leaders in genomics, molecular diagnostics, and emerging therapeutic modalities. Our fast turnaround of high-quality agar plates, microbial culture and cryopreservation media, buffers and reagents, and water helps our customers scale seamlessly from RUO to GMP. Headquartered in Hollister, California, with over 180,000 square feet of state-of-the-art facilities, Teknova's modular manufacturing platform was designed by our team of scientists, engineers, and quality control experts to efficiently produce the foundational ingredients for the discovery and commercialization of next-generation therapies.

ABOUT PLURISTYX

Pluristyx is the leading provider of advanced iPSC-based solutions for the cell and gene therapy industry, delivering a comprehensive platform designed to accelerate therapeutic development with unmatched speed, safety, and scalability. Leveraging proprietary mRNA bulk reprogramming and a polyclonal iPSC approach, Pluristyx produces genetically younger, more stable, engineerable, and highly expandable cells. The company's portfolio spans off-the-shelf, clinical-grade iPSC lines, custom gene editing and engineering, and safety and immune-evasion technologies, including the

FailSafe® safety switch and iACT® immune cloaking system. Beyond cell sourcing, Pluristyx supports the full development continuum, from organoid-based disease modeling and high-throughput drug screening to GMP-scale manufacturing, helping therapeutic developers streamline workflows, reduce risk and accelerate the path to clinic. For more information, visit www.pluristyx.com.

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