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BIO-TECHNE ANNOUNCES SUBMISSION OF FDA DRUG MASTER FILE FOR EXCELLERATE GMP iPSC EXPANSION MEDIUM SUPPORTING STEM CELL THERAPY

MINNEAPOLIS, Dec. 20, 2023 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) today announced that it has filed a Drug Master File (DMF) with the U.S. Food and Drug Administration (FDA) for its ExCellerate™ GMP iPSC Expansion Medium, Animal Free ([CCM036-GMP](#)), supporting the development and manufacture of regenerative medicine and stem cell therapies.

ExCellerate GMP iPSC Expansion Medium is optimized to support robust expansion and maintenance of stem cell culture for enhanced consistency and reproducibility throughout the stem cell manufacturing process. The recently released GMP medium complements Bio-Techne's industry leading regenerative medicine therapy workflow solutions, which includes the widest range of GMP cytokines and growth factors available on the market. The ready-to-use media is manufactured without the use of animal components and is available in preclinical and GMP grades to simplify transition from research to clinic.

The DMF submission provides the FDA with detailed information about the facilities and processes used in the manufacturing, processing, packaging, and storing of ExCellerate GMP iPSC Expansion Medium. Regenerative medicine and stem cell therapy developers who integrate the medium into their GMP cell manufacturing workflows can easily reference these important details when filing Investigational New Drug (IND) applications with the FDA.

"Minimizing variability is the keystone to success when developing stem cell-based therapies. Our ExCellerate iPSC expansion media offer consistent, scalable performance, enabling our customers to develop life changing therapies faster," said Will Geist, President of Bio-Techne's Protein Sciences Segment. "We are proud to provide our cell therapy customers with reliable workflow solutions and analytics tools for consistent and precise cell manufacturing. This recent DMF submission is yet another example of our commitment to support our customers with the highest-quality reagents and the documentation required for regulatory approval of their novel stem cell-based therapeutics."

[About Bio-Techne Corporation](#) (NASDAQ: TECH)

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