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Regulus Therapeutics Collaborates With Bio-Techne For Biomarker Development

MINNEAPOLIS, Dec. 2, 2020 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) and Regulus Therapeutics (NASDAQ: RGLS) announced a collaboration to support Regulus with biomarker analysis for the clinical development of RGLS4326, an Autosomal Dominant Polycystic Kidney Disease (ADPKD) treatment.

Regulus has utilized two Bio-Techne branded product lines, ProteinSimple and Exosome Diagnostics, to aid in their clinical trial patient testing. RGLS4326 is a first in class anti-miR-17 therapy currently in Phase 1b clinical development in ADPKD patients. The Phase 1b trial is an adaptive design, open-label, multiple dose study in up to three cohorts of patients with ADPKD. This study will evaluate RGLS4326 for safety, pharmacokinetics, and pharmacodynamic effects on the levels of polycystin 1 (PC1) and polycystin 2 (PC2). Due to a mutation in the PKD genes, patients with ADPKD have been reported to have low levels of PC1 and PC2, the proteins encoded by the PKD1 and PKD2 genes, respectively. This study is designed to assess whether different dose levels of RGLS4326 can increase levels of PC1 and PC2 in ADPKD patients. Regulus has elected to collaborate with Bio-Techne for the development of high-performance biomarker assays to support the assessment of PC1 and PC2 levels using the fully automated Simple Western instrument as a read-out. The first cohort is expected to enroll up to nine patients who will receive RGLS4326 every two weeks over a six-week period. The Company anticipates availability of results from the first cohort by the end of Q1 2021.

Bio-Techne's product portfolio also includes protein analysis solutions, sold under the ProteinSimple brand name, offering researchers efficient and streamlined options for fully automated CE-Western blot, multiplexed ELISA workflow and tools to assess the identity, purity and heterogeneity profiles of therapeutic proteins. ProteinSimple's instruments enable researchers to reveal new insights into proteins and their role in diseases while driving productivity within the research lab.

Exosome Diagnostics is a world leader in developing liquid biopsy-based diagnostics. The company has clinical laboratories in Waltham, MA (US) and Munich (DE) to support its diagnostics and biopharma segments. The company isolates and analyzes Exosomes to measure RNA, cell-free DNA, and proteins with their proprietary technology to explore and identify biomarkers.

"Our Exosome Diagnostics technology in combination with the Simple Western platform are powerful tools in biomarker discovery and assay development processes," commented Chuck Kummeth, President and Chief Executive Officer of Bio-Techne. "Regulus adds to a large list of cutting-edge biopharmaceutical companies leveraging Bio-Techne's broad portfolio of life science tools to enable scientific discoveries and drug discovery efforts."

"Regulus is pleased to enter this collaboration with Bio-Techne," said Jay Hagan, Chief Executive Officer of Regulus. "We recently initiated the dosing of patients in our Phase 1b

ADPKD study and our ability to determine PC1 and PC2 levels via urinary exosomes is intended to advance our understanding of the potential differentiation of RGLS4326 as a disease modifying treatment for ADPKD patients. We are excited to collaborate with Bio-Techne and employ their expert diagnostic capabilities towards generating this important clinical data."

About Bio-Techne Corporation (NASDAQ: TECH)

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