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Bio-Techne's Simple Western™ Technology Utilized in Recent FDA Approval of ZEVASKYN™ Cell-Based Gene Therapy

MINNEAPOLIS, July 14, 2025 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) today announced that its Simple Western™ Technology played a key role in supporting the FDA approval of ZEVASKYN™ (prademagene zamikeracel), the first autologous cell-based gene therapy for patients with recessive dystrophic epidermolysis bullosa (RDEB), developed by Abeona Therapeutics® (NASDAQ: ABEO). Throughout clinical development, Simple Western enabled precise identification and quantification of Collagen VII, a complex therapeutic target critical to ZEVASKYN's potency, supporting lot release testing for the viral vector and the cell therapy in a GMP setting.

Abeona selected Simple Western over competing methods like traditional western blot for its speed, reproducibility, picogram-level sensitivity, and minimal sample volume requirements. The platform effectively detected both the trimeric and monomeric forms of Collagen VII, addressing the analytical challenges posed by the protein's size and structure and supporting the regulatory requirements for potency and consistency.

RDEB is a rare and debilitating genetic skin disorder caused by mutations in the *COL7A1* gene, which leads to the misfolding of Collagen VII, a protein essential for skin integrity. Patients with RDEB suffer from severe blistering, chronic wounds, scarring, and are at significantly increased risk of life-threatening complications such as squamous cell carcinoma. The current standard of care focuses on symptomatic management, with no durable therapies available until now.

The Simple Western platform provided quantifiable, GMP-compliant data to ensure consistency of each autologous ZEVASKYN product lot, overcoming key challenges in analytical standardization, limited sample availability, and complex assay development. Abeona's final assay design was optimized through rigorous antibody selection, assay optimization, and use of an appropriate reference standard – enabled by Simple Western's automated and high-throughput capabilities.

"ZEVASKYN represents a significant milestone for patients with RDEB and for the field of cell-based gene therapy," said Will Geist, Bio-Techne's President, Protein Sciences Segment. "We are honored that our Simple Western platform helped Abeona develop and validate critical potency assays that supported FDA approval of this first-in-class therapy."

"Potency method development and validation were critical components in the clinical development and regulatory approval of ZEVASKYN," said Dr. Ann Durbin, Senior Director of Quality Control at Abeona Therapeutics. "The Simple Western platform was the best choice for our quality control laboratories due to the reproducibility, time-to-result, and GMP

compliance of the platform. We collaborated with Bio-Techne's ProteinSimple to address the challenges of our large molecular weight analyte, Collagen VII, and our requirement to evaluate the protein's tertiary structure under non-denaturing conditions. With the capillary electrophoresis platform, our validated assay efficiently quantifies Collagen VII to support both release testing of autologous ZEVASKYN lots, and the release and stability testing of our viral vector. The partnership of scientists at Abeona and at ProteinSimple was instrumental in advancing ZEVASKYN as the first approved cell-based gene therapy for patients with RDEB."

About Bio-Techne

Bio-Techne Corporation (NASDAQ: TECH) is a global life sciences company providing innovative tools and bioactive reagents for the research and clinical diagnostic communities. Bio-Techne products assist scientific investigations into biological processes and the nature and progress of specific diseases. They aid in drug discovery efforts and provide the means for accurate clinical tests and diagnoses. With hundreds of thousands of products in its portfolio, Bio-Techne generated approximately $1.2 billion in net sales in fiscal 2024 and has approximately 3,100 employees worldwide. For more information on Bio-Techne and its brands, please visit http://www.bio-techne.com or follow the Company on social media at Facebook, LinkedIn, Twitter or YouTube.

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About Abeona Therapeutics

Abeona Therapeutics Inc. is a commercial-stage biopharmaceutical company developing cell and gene therapies for serious diseases. Abeona's ZEVASKYN™ (prademagene zamikeracel) is the first and only autologous cell-based gene therapy for the treatment of wounds in adults and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB). The Company's fully integrated cell and gene therapy cGMP manufacturing facility in Cleveland, Ohio serves as the manufacturing site for ZEVASKYN commercial production. The Company's development portfolio features adeno-associated virus (AAV)-based gene therapies for ophthalmic diseases with high unmet medical need. Abeona's novel, next-generation AAV capsids are being evaluated to improve tropism profiles for a variety of devastating diseases. For more information, visit www.abeonatherapeutics.com.

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