WEST SACRAMENTO, Calif., January, 2024 /PRNewswire/ -- Gemini Bioproducts, LLC ("GeminiBio"), a leading supplier of cell culture reagents and process liquids, a portfolio company of BelHealth Investment Partners, LLC ("BelHealth"), a Florida-based healthcare private equity firm, today announced the launch of a new human AB serum product for the cell therapy and regenerative medicine markets.

GeminiBio has an extensive history supporting the cell therapy research and development market, offering a portfolio of human serum products which are generally used in a growth medium for cell therapy biotechnologies such as chimeric antigen receptor T cell (CAR-T) therapies. As the cell therapy market has matured, including the successful US FDA approval of CAR-T therapies targeting blood cancers such as leukemia and lymphoma, the company has worked closely with customers to address evolving global regulatory requirements pertaining to ancillary products, such as human AB serum, used in the cell therapy manufacturing process.

To further support regulatory requirements in different regions around the world, GeminiBio is introducing a new human AB serum – GemCellTM Plus Xeno Free, World Grade. To meet specific regulatory requirements, including requirements within the United States and the European Union, the source plasma is collected from a maximum of 16 healthy male donors of the AB serotype. The donor material must also pass extensive viral testing requirements, and the manufacturing process includes defibrination of the source AB plasma using therapeutic grade recombinant human thrombin. GeminiBio manufactures all human serum products under cGMP.

"I am excited to offer our customers the new GemCellTM Plus Xeno Free, World Grade product", said Rob Perry, GeminiBio's Chief Scientific Officer, "as GeminiBio routinely supports our customers as they work to address questions from the various regulatory bodies. This new product represents an important addition to our product portfolio, as it allows customers to address the requirements for a limited number of donors in a pool without the cost or potential cell culture performance degradation associated with gamma irradiation, and with the benefit of large lot sizes."

GemCellTM Plus Xeno Free, World Grade comes standard in 125mL bottles, and can be custom manufactured to meet customer's unique fill size and containment requirements, including single use cryo-bags, which can streamline customer's manufacturing workflows and improve aseptic processes. About GeminiBio

Founded in 1985, GeminiBio serves the global biotechnology industry, from basic research to commercial production, with a focus on helping our customers accelerate the development of life enhancing biotherapeutics by streamlining and improving their cell culture and process liquid manufacturing workflows. The company's products are organized into two core verticals – Cell Culture Solutions and Process Liquid Solutions. Located in West Sacramento, California, GeminiBio has 57,000 square feet of cGMP manufacturing space that is segregated between animal origin free and animal component manufacturing. GeminiBio is an ISO 13485:2016 certified, FDA registered Class 1 Medical Device Manufacturer, aligned with 21 CFR Part 820. For more information, visit www.geminibio.com. Contact:

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