GeminiBio Submits Drug Master File (DMF) to FDA

Simplifying IND and BLA filings for cell therapy developers

West Sacramento, California, March 13th, 2025. Gemini Bioproducts, LLC ("GeminiBio"), a biopharma and advanced therapy raw materials supplier, and a portfolio company of BelHealth Investment Partners, LLC ("BelHealth"), a Fort Lauderdale-based healthcare private equity firm, announced today the submission of a Drug Master File (DMF) to the US FDA in support of the company's cGMP grade human serum products.

GeminiBio provides serum, customized media, buffers, and process liquids to biopharma and advanced therapy companies focused on the research and production of mRNA, AAV, monoclonal antibody, and cell therapy technologies. Human serum is a critical raw material supplement for cell therapy manufacturing and is used to support the expansion of human immune cells (e.g., T cells, NK cells, etc.) that form the backbone of the cell therapy industry.

With the filing of a DMF for GeminiBio's Human Serum with the FDA, GeminiBio has made it easier for cell therapy companies to progress towards commercialization. Because the FDA requires detailed information about human serum as part of their Investigational New Drug (IND) applications and Biologics License Applications (BLA), the DMF from GeminiBio reduces the burden for cell therapy companies in their regulatory submissions - enabling customers to incorporate manufacturing, quality, and compliance data with ease into their filings.

"As an ancillary product used in cell therapy manufacturing processes, human serum has very specific quality and safety requirements as communicated by various global regulatory agencies," said Robert Perry, Chief Scientific Officer at GeminiBio, "and, over the last several years we have seen a significant increase in the regulatory support required by our customers as the cell therapy industry has gained traction. This was the catalyst to compile and submit our DMF to the FDA."

Brian Parker, GeminiBio's CEO, added, "We are very excited to support cell therapy developers across the globe, and the company has hundreds of cell therapy customers spanning the clinical development process, including pre-clinical, phase I, phase II, and phase III." Mr. Parker continued, "We are particularly excited to see one of customers receive US FDA approval of their BLA and are currently supporting the commercialization of this product. The submission of our DMF will further simplify our customer's regulatory process and enable them to focus on progressing their advanced therapies."

For more information on GeminiBio, please visit: www.geminibio.com

About GeminiBio

GeminiBio is a portfolio company of BelHealth Investment Partners. GeminiBio was founded in 1985 and serves the global biopharma, cell and gene therapy industries. Its focus is on helping customers (from basic research to commercial production) accelerate the development of life-enhancing biotherapeutics by streamlining and improving their cell culture and process liquid manufacturing workflows.

The company provides critical raw materials used in cell therapy, gene therapy and biotherapeutics manufacturing – including serum, customized media and buffers solutions, and process liquids.

Located in West Sacramento, California, GeminiBio has 57,000 square feet of cGMP manufacturing space, 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.

Contact
Brian Parker (CEO)
Email: bparker@geminibio.com
Phone: +1(832) 541-9668
www.geminibio.com

About BelHealth Investment Partners

BelHealth Investment Partners, based in Fort Lauderdale, Florida, is a healthcare private equity firm focused on lower middle market companies. BelHealth acquires majority positions in entrepreneur-owned companies that it believes will benefit from its extensive investing, executive management and entrepreneurial experience.

Contact
Inder Tallur (Partner)
Email: itallur@belhealth.com
Phone: +1(917) 975-6604
www.belhealth.com