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BrightPath Bio and Cellistic® Announces Process Development and Manufacturing Collaboration for Phase 1 Clinical Trial of iPSC-derived BCMA CAR-iNKT cell

Tokyo, Japan and Mont-Saint-Guibert, Belgium, – December 13th, 2024 – BrightPath Bio (Tokyo Stock Exchange Growth 4594, “BrightPath”), a pioneer in iPS cell-derived Natural Killer T (“NKT”) cell therapy, and Cellistic, a leader in advanced iPS cell therapy manufacturing, today announce a process development and manufacturing agreement to advance BrightPath’s novel allogeneic CAR-T cell therapy platform, utilizing iPSC-derived NKT cells, is progressing into clinical trials.

The strategic collaboration includes the use of Cellistic's innovative 3D bioreactor-based manufacturing platform, *Echo™*, to enable GMP-compliant, clinical-scale manufacturing for a Phase 1 trial of iPSC-derived BCMA-targeting CAR-NKT cells. This advancement establishes BrightPath as a first mover in this emerging field.

“The use of NKT cells as effectors in allogeneic CAR-T therapy represents a promising strategy, offering not only direct cytotoxicity but also indirect anti-tumor activity through the priming of host CD8+ T cells—a mechanism expected to evade host immune rejection and to enhance the durability of clinical responses. However, achieving clinical-scale manufacturing of such a rare subset of T cells, while preserving their original functionality, has traditionally been a significant challenge. Induced pluripotent stem (iPS) cell technology has overcome this barrier, making large-scale production feasible.” stated Ken Nagai, CEO of BrightPath.

“While we have established a robust 2D culture-based manufacturing process, we recognized the importance of anticipating the full scalability potential of the iPS cells from the commercial perspective at an early stage. To address this need, we are committed to implanting more scalable manufacturing solutions. Cellistic is well-positioned to meet this critical requirement with their unique 3D platform and extensive experiences in iPSC differentiation and scale-up of a variety of cell types,” Ken Nagai further noted. “We are delighted to partner with Cellistic, which has the most experience in culturing iPS cells using 3D bioreactors. This collaboration with Cellistic allows us to leverage their state-of-the-art development and manufacturing capabilities to accelerate the development of our BCMA CAR-NKT product.”

“We are excited to partner with BrightPath in the development of their revolutionary iPSC-derived cell therapy,” said Gustavo Mahler, CEO of Cellistic. “Our Echo manufacturing platform is designed to meet the unique challenges of cell therapy production, ensuring scalability, quality, and regulatory compliance. Together, we can advance the therapeutic potential of BCMA CAR-NKT cells and help BrightPath to bring innovative solutions to patients in need.”

The agreement marks a significant step forward in the industry’s pursuit of innovative and effective cell therapies, with both companies committed to advancing healthcare solutions that improve patient outcomes.

About BrightPath Biotherapeutics

BrightPath is a clinical stage biopharmaceutical company focused on the development of novel cancer immuno-therapies to transform cancer treatment for refractory or progressive cancers that cannot be treated with conventional standard therapies. BrightPath is actively involved in developing cell therapies, currently in clinical trials, and immunomodulatory antibodies.

For more information, visit www.brightpathbio.com/English

About Cellistic™

Cellistic specializes in process development and manufacture of immune cell therapies based on human induced pluripotent stem cell (iPSC) technology using their Pulse™ and Echo™ Platform. Its focus and expertise in iPSC reprogramming, gene editing using its proprietary STAR-CRISPR™ technology and differentiation development, positions the company to be the partner of choice for innovative cell therapy developers to advance into clinic. Leveraging more than a decade of scientific and technical knowledge and experience, Cellistic possesses unique capabilities for the design and optimization of proprietary manufacturing platforms for iPSC- based cell therapies.

For more information, visit www.cellistic.com.