May 13, 2025

BrightPath Presented Manufacturing Process Development Updates for iPS Cell-derived BCMA CAR-iNKT Cells (BP2202) at ASGCT 2025

Tokyo, Japan – May 13, 2025/ -- BrightPath Biotherapeutics ("BrightPath", TSE Growth 4954), a clinical-stage biopharmaceutical company focused on developing novel cancer therapeutics, today announced that it has presented the progress of manufacturing process development for its iPS cell-derived BCMA CAR-invariant Natural Killer T (iNKT) cells therapy, BP2202, at the 28th American Society of Gene & Cell Therapy Annual Meeting (ASGCT 2025, May 13-17, 2025, New Orleans). BrightPath is preparing BP2202 for Phase I clinical trial in patients with multiple myeloma.

The abstract and the electronic poster have been posted on the website of BrightPath after ASGCT 2025 was held.

(Abstract Number 812)
Title: Generation of functional BCMA CAR-iNKT cells from clinical-grade iPSCs via a GMP-compliant manufacturing process with capacity for linear scale-up
Date & Time: 6 p.m. - 7:30 p.m. CDT on May 13, 2025

BP2202 is an allogeneic CAR-T cell therapy derived from healthy donors and stored in advance, enabling rapid administration following diagnosis, unlike approved autologous CAR-Ts. Notably, BP2202 employs a highly standardized and scalable manufacturing approach using induced pluripotent stem cells (iPSCs) as a master cell bank, serving as the renewable source to consistently generate homogeneous CAR-T cells for off-the-shelf use.

In this study, BrightPath established a clinical-grade iPSC line through reprogramming and CRISPR/Cas-mediated gene editing under GMP-compliant conditions suitable for human use. A corresponding manufacturing process was also developed to differentiate the iPSC line into NKT cells and expand them to clinically relevant cell numbers, all under conditions meeting regulatory standards for human administration.

Using this platform, BrightPath successfully generated highly purified BCMA CAR-iNKT cells, which demonstrated robust anti-tumor activity in both *in vitro* and *in vivo*. The process supports efficient cell expansion to clinical scale and has been successfully transferred to a CDMO for GMP production of investigational materials. "Importantly, the process is designed to be linearly scalable, enabling efficient adaptation to clinical trial scale-up demands as the program advances from the planned Phase I trial to later stages," said Kenichi Nagai, CEO of BrightPath.

At ASGCT 2025, BrightPath presented these findings, validating the clinical readiness of both the iPSC line and the manufacturing process through the consistent production of functionally potent BCMA CAR-iNKT cells.

More detailed results are available on the websites of BrightPath.

About BrightPath Biotherapeutics

BrightPath is a clinical stage biopharmaceutical company focused on the development of novel cancer 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

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