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FDA Clearance of Investigational New Drug Application for BP2202

TOKYO, Japan, August 3, 2026/ -- BrightPath Biotherapeutics Co., Ltd. (“BrightPath” , TSE Growth: 4594), a clinical-stage biopharmaceutical company developing next generation cell therapies for cancer therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for BP2202, a novel investigational iPSC-derived BCMA CAR-iNKT cell therapy. Following the clearance of the IND application, the Company may proceed first-in-human Phase 1 clinical trial in the United States in patients with relapsed/refractory multiple myeloma.

BP2202 is the Company’s lead investigational allogeneic CAR-iNKT cell therapy that targets B-cell maturation antigen (BCMA), a clinically validated therapeutic target for multiple myeloma, and uses induced pluripotent stem cell (iPSC)-derived invariant natural killer T (iNKT) cells as its cellular backbone. BP2202 is designed to combine CAR-mediated antitumor activity with native immunomodulatory functions of iNKT cells, with the goal of achieving durable clinical responses while providing a potent, readily available treatment option for patients with multiple myeloma, which remains difficult to cure.

Multiple myeloma is a hematologic malignancy characterized by the uncontrolled proliferation of abnormal plasma cells in the bone marrow, leading to bone lesions, renal impairment, anemia, and other serious complications. Although advances in treatment have improved patient outcomes, the disease remains incurable for most patients, who ultimately experience repeated cycles of relapse and subsequent treatment. In the United States, an estimated 203,000 people were living with multiple myeloma as of 2023,[*1] and approximately 36,000 new cases are expected to be diagnosed in 2026.[*1] These figures underscore the continued unmet need for additional treatment options.

The study is an open-label, dose-escalation, multicenter Phase 1 clinical trial in subjects with relapsed/refractory multiple myeloma. After a patient enrolls, premanufactured, ready-to-use BCMA CAR-iNKT cells will be administrated as three doses over a two-week period following a standard lymphodepleting conditioning regimen, and patients will subsequently undergo serial assessments of safety, tolerability, and response.

With the BP2202 IND now cleared, BrightPath is actively focused on opening clinical sites across the U.S. with the intention to begin patient dosing later this year. In parallel, upon completion of manufacturing and quality testing, the investigational product will be transferred from the CDMO to the participating clinical trial sites.

"The FDA's clearance of our IND is a major achievement for BrightPath and validates years of

work to advance our proprietary iPSC-derived CAR-iNKT platform into clinical development," said Kenichi Nagai, Chief Executive Officer of BrightPath Biotherapeutics. "We look forward to evaluating the safety and preliminary clinical activity of BP2202 and establishing a strong foundation for the broader application of our platform technology."

＜Sources＞

*1 National Cancer Institute. *SEER Cancer Stat Facts: Myeloma.* Bethesda, MD: National Cancer Institute. Accessed August 2, 2026

About BrightPath Biotherapeutics:

BrightPath (Tokyo Stock Exchange Growth: 4594) 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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