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# Phase I clinical trial initiated for HER2-targeted CAR-T cell therapy BP2301

**Tokyo, Japan - May 9, 2022**/ -- BrightPath Biotherapeutics (TSE Growth 4954), a clinical-stage biopharmaceutical company focused on developing novel immunotherapeutics, today announced that the start of an investigator initiated phase I clinical trial testing the safety and efficacy of BP2301, a HER2 CAR-T cell product genetically modified with non-viral vectors , in patients with HER2-positive recurrent or progressive bone and soft tissue sarcomas and gynecologic malignancies at Shinshu University Hospital. BP2301 has been developed collaboratively by BrightPath and Shinshu University.

Pharmaceuticals and Medical Devices Agency (PMDA) accepted the clinical trial notification and the investigator initiated clinical trial of BP2301 starts as of May 6, 2022. Japan Agency for Medical Research and Development (AMED) gives financial supports for this clinical trial, using one of AMED's programs called the "Project for Regenerative/Cellular Medicine and Gene Therapies."

BP2301 is an autologous chimeric antigen receptor T(CAR-T) cell product targeting HER2 protein that is highly expressed in various types of solid tumors. CAR-T cell therapy has been approved globally with the excellent clinical performance in treatment of hematological malignancies. BP2301 is expected to open an opportunity to apply CAR-T cell therapy for a larger number of patients with solid tumors.

In general, solid tumors are more complex than hematologic tumors and have evolved multiple mechanism to keep them immunosuppressive. This has limited the use of CAR-T cells to treat solid tumors. CAR-T cells get exhausted and cannot perform durable anti-tumor function in the immunosuppressive tumor microenvironment. To overcome the T cell exhaustion barrier in solid tumors, we developed a new approach using piggyBac transposon system to manufacture CAR-T cells together with Professor Yozo Nakazawa, Department of Pediatrics, Shinshu University School of Medicine, and Professor Shigeki Yagyu, Shinshu University-Innovative Research & Liaison Organization. BP2301 exhibits a dominant fraction of stem cell memory-like T cells (Tscm)that are less exhausted, having continual proliferation capacity and ability of self-renewal, and long-lived *in vivo*. BP2301 is a promising solution to enhance resistance to T cell exhaustion and to achieve long-lasting anti-tumor effects against solid tumors. This novel method rests on the non-viral gene transfer method established by Professor Nakazawa.

**About BrightPath:**

BrightPath Biotherapeutics is an immuno-oncology focused biotech company dedicated to improving treatment and clinical outcomes for patients through cancer vaccine, therapeutic antibodies, and cell therapy that harness the immune system to fight cancer.

BrightPath's clinical-stage product, GRN-1201 is a new cancer vaccine in phase 2 trial in patients with melanoma and lung cancer in US. BP2201 in-collaboration with RIKEN, Japan is an iPSC (induced pluripotent stem cell)-derived NKT therapy and the phase 1 trial is currently ongoing in Japan.

BrightPath's broad pipeline of immunotherapy includes several potentially first-in-class and best-in-class clinical and preclinical candidates in cancers with high unmet medical need.

BrightPath has been a pioneer in immunotherapy by cancer vaccine and has expanded its expertise in the tumor microenvironment and immune cell development as well as antibody engineering. This innovative approach has resulted in a diversified proprietary portfolio of cancer vaccine, therapeutic antibody, and immune-cell therapy.

Based in Tokyo, Japan, BrightPath is listed on Tokyo Stock Exchange in Japan. For more information, visit www.brightpathbio.com

**Forward-Looking Statements:**

This news release contains forward-looking statements that are based on the current expectations and beliefs of BrightPath. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements. BrightPath cautions that these forward-looking statements do not guarantee our future financial results but involve risks and uncertainties that could cause actual results to differ materially from those discussed in the forward-looking statements. These forward-looking statements speak only as of the date of this press release and BrightPath assumes no duty to update forward-looking statements, except as may be required by law.

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