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BrightPath Presents New Data on Preclinical Data on BP2301(HER2 CAR-T) at AACR 2022

Tokyo, Japan - April 11, 2022/ -- BrightPath Biotherapeutics (TSE Growth 4954), a clinical-stage biopharmaceutical company focused on developing novel immunotherapeutics, today announced that preclinical data on BP2301(HER2 CAR-T) are presented at the American Association for Cancer Research Annual Meeting (“AACR 2022”) on April 8-13. The data are being reported in a poster presentation entitled “**Development of *piggyBac* transposon-mediated HER2-CAR-T cells for the treatment of solid tumors (Ab No. 5570) ”**

The abstract for this presentation is available on the websites of the [AACR](#) and [BrightPath](#).

Key findings are as follows:

- * **A non-viral GMP manufacturing process of BP2301 has been optimized using *piggyBac* transposon system with antigen presenting feeder cells.**
- * **BP2301 exhibits stem cell memory phenotype and no significant T-cell exhaustion markers.**
- * ***In vitro*, BP2301 showed killing activity against the cell lines of sarcoma (RH30, RD-ES, SW-982), ovarian cancer (SK-OV-3) and endometrial serous adenocarcinoma (ARK1) and demonstrated durable cytotoxicity and resistance to exhaustion in a sequential killing assay.**
- * **In RH30 and SK-OV-3 xenograft models, BP2301 eradicated the inoculated tumors completely without recurrence, suggesting that BP2301 persisted and maintained anti-tumor activity in these mice.**

About BP2301

BP2301 (HER2 CAR-T cell) is a chimeric antigen receptor T (CAR-T) cell product targeting HER2, which is highly expressed in various solid tumors. The CAR transgene of BP2301 is transduced by a non-viral gene transfer method, piggyBac transposon system, and the product is successfully manufactured by using a method developed by the company, together with Professor Yozo Nakazawa and Professor Shigeki Yagyu of Shinshu University . BP2301 exhibits a dominant fraction of stem cell memory-like T cells (Tscm), which is less exhausted, having potential to proliferate, and long-lived *in vivo*. Tscm has been reported to be correlated with CAR-T clinical response in many literatures. An investigator-initiated Phase 1 clinical trial to

evaluate the safety and efficacy of BP2301 in patients with recurrent or advanced osteosarcoma, soft tissue sarcoma and gynecological cancer is going to be started in April-June 2022.

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.

Investor and Media Contact:

+81-3-5840-7697

irpr@brightpathbio.com

www.brightpathbio.com