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Announcement on the Results of a Phase I Clinical Trial in Melanoma for Cancer Peptide Vaccine GRN-1201

Tokyo, August 9, 2019 — BrightPath Biotherapeutics Co., Ltd., an immuno-oncology company, announced that a Phase I clinical trial of cancer peptide vaccine GRN-1201 in patients with melanoma, which was conducted in the U.S. (hereinafter the "Trial"), has confirmed safety and tolerability, which are the primary endpoints, as well as an immune response, which is the secondary endpoint.

GRN-1201 is a cancer peptide vaccine consisting of four HLA-A2-compatible peptides derived from the tumor-associated antigens (TAA). HLA-A2 is a type of HLA* largely found in European and American populations. The Trial was conducted as monotherapy and enrolled a total of 18 melanoma patients who had resected, histologically proven, cutaneous melanoma determined to be Stage II or III.

Regarding the primary endpoints, a safety and tolerability profile was confirmed. Four grade 3 treatment-related adverse events were reported including face edema, pruritus and urticaria in 1 of the 6 subjects (16.7%) in the low-dose group, and headache in 1 of the 6 subjects (16.7%) in the middle-dose group. All other adverse events were grade 2 or lower, with no grade 4 or higher adverse events and no deaths occurring.

Since the main objective of the Trial is to evaluate safety, it was designed to have a limited number of doses, in contrast to the ongoing Phase II clinical trial whose objective is to evaluate the clinical efficacy of GRN-1201 in combination with pembrolizumab. Under these circumstances, the immune response seen in the Trial was positive in 2 of the 9 measurable subjects (22%) before vaccine administration and in 4 of the 10 measurable subjects (40%) after vaccine administration.

Immune response (Cellular immunity)

Dose		Before vaccine administration		After vaccine administration	
Group	Dose	Nos. of positive / measurable subjects	Positive rate	Nos. of positive / measurable subjects	Positive rate
Low dose (n=6)	0.1mg	1 / 3	33.3%	1 / 3	33.3%
Middle dose (n=6)	1mg	1 / 2	50.0%	2 / 4	50.0%
High dose (n=6)	3mg	0 / 4	0.0%	1 / 3	33.3%
Total		2 / 9	22.2%	4 / 10	40.0%

The above-described ability of GRN-1201 monotherapy to induce cellular immunity is considered to be

equivalent to the clinical research results of Kurume University.

While the above results were obtained using GRN-1201 as monotherapy, the ongoing Phase II clinical trial uses GRN-1201 in combination with pembrolizumab, and it is expected that vaccine-induced cytotoxic T cells specific to GRN-1201 antigens will be avoided from tumor-induced immunosuppression through PD1/PD-L1 signaling, thereby inducing stronger cancer immunity than in the case of monotherapy and leading to a better clinical outcome. The Phase II trial is currently enrolling subjects, and BrightPath is encouraged by the clinical results obtained to date.

[Glossary]

* HLA (Human Leukocyte Antigen): HLA is a marker that distinguishes between “self” and “non-self.” A wide variety of HLA types exist in order to distinguish “non-self” from “self.” Peptides bind to specific, but not to incompatible, HLA types.

BrightPath

BrightPath is a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies to transform cancer treatment for progressive or refractory cancers that cannot be treated using conventional standard therapies. In addition to the cancer peptide vaccines currently in clinical trials in the United States, BrightPath is actively involved in developing cell therapies, immunomodulatory antibodies and new drugs targeted toward cancer-specific neoantigens.

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