

October 27, 2017  
National Cancer Center Japan  
BrightPath Biotherapeutics Co., Ltd.

## Collaborative Research on Fully-personalized Cancer Neoantigen Vaccine

Tokyo, October 27, 2017 – The National Cancer Center Japan (“NCC”) and BrightPath Biotherapeutics Co., Ltd. (“BrightPath”) hereby announced that they have entered into a collaborative research agreement on fully-personalized cancer neoantigen\* vaccine as novel cancer immunotherapy.

Cancer immunotherapy is aimed at refractory and progressive cancers, which are difficult to treat with the conventional standard therapies, and it has recently driven remarkable achievements in cancer treatment. In the field of cancer immunotherapy, personalized medicine has come to the fore in recent years thanks to drastic advances in DNA sequencing technology. This approach provides cancer immunotherapy tailored for each patient based on the analysis of characteristics such as the patient’s immune response, cancer cells and tumor microenvironment.

Cancer cells proliferate when they lose normal proliferation control due to genetic mutations. They accumulate gene mutations attributable to genomic instability of tumors in the course of proliferation. The advent of a new-generation sequencer has enabled precise analysis of genetic mutations in the cancer cells of each patient. Immune system distinguishes self from non-self and recognizes genetic mutations as “non-self” since they have gene sequences different from normal genes. The genetic mutation thus becomes an antigen, a target of immune system that strongly induces an immune response, and thus a candidate for vaccination in cancer treatment. So-called tumor neoantigen are unique to each patient’s tumor, thus necessitating personalized treatment.

In the collaborative research, we will develop a methodology to quickly identify a target set of neoantigens that truly induce immune response of each patient from the mutated gene sequence data. We aim at developing fully-personalized cancer vaccines targeted at neoantigens unique to each patient.

Taking the initiative on the collaborative research will be Dr. Tetsuya Nakatsura, the Chief of Division of Cancer Immunotherapy at the Exploratory Oncology Research & Clinical Trial Center of the NCC, which is promoting cancer immunotherapy study centered on cancer peptide vaccines. At the same time, BrightPath will cooperate with NCC in the joint research to achieve clinical application of truly personalized neoantigen-based cancer vaccine—a promising next-generation cancer treatment. The company is currently conducting clinical trials on two cancer peptide vaccines: a late-stage clinical trial of personalized peptide vaccine in Japan, and an early-stage clinical in combination with the immune checkpoint inhibitors in the United States.

\*Neoantigen: Newly formed mutated proteins that arise as a result of the genomic instability of tumors. The human immune system recognizes and respond to antigen, and cancer immunity is induced by utilizing the antigen presented on the surface of cancer cells. While the immune system does not react to normal “self” antigens, neoantigen does not exist in normal cells and recognized as “non-self,” and thus is a target of a strong immune response.

### **The National Cancer Center Japan**

Founded in 1962 as a hub for cancer treatment research in Japan, the NCC has since become the national institute and a strong leader in the field. The NCC is actively involved in studies to clarify pathologies of cancers, conducts advanced studies to develop new therapies based on the clarified pathologies, and promotes uniform accessibility to medical services. The NCC boasts the highest number of clinical trials and actively implements phase I clinical trials and investigator-initiated trials.

Its Hospital and Hospital East are certified as core hospitals for clinical research under the Medical Care Act and are dedicated as playing an essential role in worldwide clinical trials and investigator-initiated trials to promote high-quality clinical studies and trials required to develop innovative pharmaceutical products, medical devices and medical technologies.

### **BrightPath**

BrightPath is a clinical stage biopharmaceutical company focused on development of novel cancer immunotherapy, to transform the cancer treatment for refractory or progressive cancers that cannot be treated with conventional standard therapies. In addition to the cancer peptide vaccines currently under clinical trials in Japan and the United States, BrightPath is actively involved in developing cell therapy by applying iPS-cell technology to cancer immunotherapy, immunomodulatory antibodies and new drugs targeted at cancer specific neoantigen.

### **Contacts**

- **National Cancer Center Japan**

Office of Public Relations, Strategic Planning Bureau (Kashiwa Campus)

Phone: +81-4-7133-1111 / Fax: +81-4-7130-0195 / e-mail: ncc-admin@ncc.go.jp

- **BrightPath Biotherapeutics Co., Ltd.**

Business Administration

Phone: +81-3-5840-7697 / Fax: +81-3-5840-7716