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Mie University  
BrightPath Biotherapeutics Co., Ltd.

## **Mie University and BrightPath Launch New Program for Neoantigen-based Personalized Cancer Immunotherapy**

Tokyo, February 15, 2018 – Mie University and BrightPath Biotherapeutics Co., Ltd. (“BrightPath”) have decided to launch a “Personalized Cancer Immunotherapy” Program (the “Program”) as an academia-industry collaboration. The Program is aimed at developing fully-personalized cancer immunotherapy that targets neoantigens. Under the framework of the Program, Mie University and BrightPath will commence collaborative research to establish a technology platform for detecting and identifying neoantigens and then developing appropriate modalities targeting them.\*1. \*2

Remarkable clinical outcomes using immune checkpoint inhibitors have recently opened a new paradigm in cancer treatment and have demonstrated two important aspects. First, T-cells, one of the various types of immune cells in the patient’s body, play a primary role in attacking cancer cells and demonstrate strong functionality to efficiently kill them. Second, neoantigens derived from gene mutations in the patient’s tumor serve as landmarks for T-cells to lock onto cancer cells. State-of-the-art technology in genome sequencing and analysis technologies spurred by the advent of next-generation DNA sequencers is making it possible to analyze cancer-specific genetic mutations and neoantigens that are completely unique to each patient.

The Program is intended to utilize such unique neoantigens from each patient as a tailored cancer immunotherapy. In this way, the conventional “one-size-fits-all” drugs that are currently used to treat millions of patients will evolve into a next-generation, fully “personalized” therapy that uses the patient’s own T-cells to recognize mutations that are unique to his/her cancer cells and that can adapt to individuality and variety.

Under the Program, we will establish methods for precise detection of gene mutations from patient tumor tissue and identification of epitopes (neoantigens) that strongly induce T-cell immune responses. Based on the technology platform for neoantigen identification, we will develop optimum forms of modalities for a new generation of cancer immunotherapies.

The Program is led by Dr. Hiroshi Shiku at Mie University Graduate School of Medicine. For many years, he has been engaged in the research and development of cancer immunotherapy, including cancer peptide vaccines and antigen receptor transduced T-cell therapy (TCR-T), ranging from exploratory through translational research to first-in-human clinical trials. With regard to fully-personalized cancer immunotherapy, which is the subject of the Program, Dr. Shiku has already been advancing exploratory research for over five years. In the last year of a four-year research program, a project organized by Ministry of Health, Labour and Welfare was implemented to formulate the series, “Guidance for Clinical Development of Cancer Immunotherapy,” with the participation of more than 50 academician cancer immunotherapy researchers and government officials in Japan. This guidance covers the entire field of the cancer immunotherapy and development process, from non-clinical to clinical trials. In this project, Dr. Shiku served as a project leader and played a key role in organizing and compiling the guidance. As the Program leader, Dr. Shiku will fully leverage his vast knowledge, technical expertise and experimental systems in pursuit of the Project’s successful conclusion.

Mie University and BrightPath are set to create new immunotherapies to enable

personalized cancer care to be developed in Japan and disseminated around the world.

- \*1. A neoantigen is defined as a tumor antigen generated from gene mutations present in cancer cells. The human immune system recognizes antigens, which induce immune responses. While the immune system does not strongly respond to the body's normal "self" antigens, a strong immune response is generated against "non-self" neoantigens since they are present only on tumor cells.
- \*2. Modality: A category of physical therapeutic agents such as small-molecule compounds, peptide vaccines, antibody drugs, nucleic acid therapy, and cell therapy

### **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 under clinical trials in Japan and 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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