Announcement of "Cancer Precision Medicine"

The technology innovation emerging in the 21st century has enabled us to perform comprehensive analysis of genome, epigenome and proteome in individual patients. Accordingly, OncoTherapy Science, Inc. (Head office: Kawasaki city, Kanagawa; President & CEO: Masaharu Mori; hereinafter, "OncoTherapy") is confident that "Cancer Precision Medicine" (hereinafter, "CPM") which provides development of prevention, early detection, prediction of treatment response and development of novel therapy through the individual information using the aforementioned innovation. Prior to this announcement, OncoTherapy launched in last September the TCR analysis service, which derives from the state-of-the art technology of oncoimmunology field.

The CPM that OncoTherapy pursues is to analyze various samples obtained from cancer patients and to provide the guidance in three possible areas, i.e. 1) prediction of an appropriate molecular target drug(s), 2) monitoring relapse or recurrence of cancer by liquid biopsy, and 3) provide personalized vaccine (oncoantigen or neoantigen vaccine) if any molecular target drug is not applicable.

(1) Genetic Analysis and Diagnosis (for prediction of an appropriate drug(s) and suggestion to possible clinical trial)

Based on genetic mutations in individual patients through whole exome and transcriptome analysis obtained from various samples (surgical material and biopsy), CPM is to provide information on an appropriate molecular-targeted drug(s) which is expected to be effective to the patients, or to suggest applicable clinical trial to them. Furthermore, it will pursue establishing drug selection based on the outcome using patient-derived xenograft (PDX) model developed by cancer tissue or CTC (circulating tumor cells).

(2) Diagnosis of Cancer (screening and monitoring of relapse/recurrence)

CPM will aim to detect cancer-cell-derived somatic mutations by deep-sequencing or

other sensitive methods using liquid biopsy material using blood / urine / saliva. It can be applicable for cancer screening as well as early detection and relapse/metastasis of cancers.

(3) Immune Therapy (providing optimal vaccine treatment to patients)

For patients who have no appropriate molecular-targeted drug two types of peptide vaccine treatment can be applicable; one type is neoantigen, which is likely to induce very high level of cytotoxic T-cell lymphocyte (CTL), and the other type is oncoantigen, which is derived from cancer-testis or cancer-fetal antigens with oncogenic activity. CPM will conduct monitoring immune responses through TCR analysis of lymphocyte cells induced by neoantigen or oncoantigen. TCR that can recognize cancer-specific antigen can be applied for TCR-engineered T-cell treatment in the near future.