

OncoTherapy Science, Inc.

March 13, 2023

Announcement regarding Development of New Cancer Gene Panel Test
at Our Subsidiary Company, Cancer Precision Medicine, Inc.

OncoTherapy Science, Inc. (President & CEO: Junichi Shimada; hereinafter, “OncoTherapy”) announces that the subsidiary company, Cancer Precision Medicine, Inc. (CPM) decided to start development of a new cancer gene panel and testing method (hereinafter “new cancer gene panel” *1) using liquid biopsy that can be performed under the medical insurance.

Liquid biopsy is a technology that uses body fluids such as blood to diagnose diseases, choose treatment methods, and predict treatment effects. Since it is possible to detect even small amounts of genetic mutations released into the blood from cancer cells, it is believed to be useful for early detection of cancer, selection of appropriate therapeutic drugs, and monitoring of recurrence. Compared to conventional tissue biopsy, liquid biopsy is a non-invasive test, available for repeated examinations, and possible for real-time examination of the state in whole body.

The new cancer gene panel test is designed for gene mutations common to various solid tumors, and aims to comprehensive and inexpensive genetic analysis regarding the targets of therapeutic drugs. In addition, by including clonal hematopoiesis (*2) that are mutations not associated with cancer, it is also intended to evaluate false positives and monitoring the clonal hematopoiesis. Furthermore, aiming to the medical insurance coverage, we will consider alliances with medical device manufacturing and sales companies.

By developing this new cancer gene panel test, we aim to spread liquid biopsy, which can be used for repeated times and under the medical insurance, and believe to contribute in the detection of cancer at early stage, providing therapeutic drugs at appropriate time, and monitoring of cancer recurrence with high sensitivity.

*1) The cancer gene panel test is a test that uses next-generation sequencing technology to examine gene mutations in dozens to hundreds of cancer-related genes at once.

*2) Clonal hematopoiesis is accompanied genetic mutations in the proliferation process of hematopoietic stem cells, generally increases with age, and thus known as an issue in the liquid biopsy by being detected as a false-positive result. It is also increased by other factors like exposure to radiation and chemotherapy, and reported to increase the risk of various diseases development, such as blood cancer and cardiovascular disease.