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Chugai Obtains Approval for FoundationOne Liquid CDx Cancer Genomic Profile to Provide Information on Detection of Copy Number Alterations of Cancer-Related Genes and bTMB Score

- Two important indicators that support cancer treatment decisions can be obtained by liquid biopsy as regulatory-approved information

TOKYO, May 27, 2024 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has obtained approval from the Ministry of Health, Labour and Welfare (MHLW) on May 23, 2024, for FoundationOne®Liquid CDx Cancer Genomic Profile to provide information on detection of copy number alterations of cancer-related genes and blood tumor mutational burden (bTMB) score. Copy number alterations and bTMB score in plasma samples are important indicators for predicting the efficacy of molecular target therapeutics such as immune checkpoint inhibitors. With this approval, our two comprehensive genomic profiling (CGP) tests using tissue and blood specimens, including FoundationOne®CDx Cancer Genomic Profile, can support diagnosis and treatment decisions based on regulatory-approved information.

“We are pleased that two important additions that support cancer treatment decisions have been approved for FoundationOne Liquid CDx Cancer Genome Profile based on blood specimens in addition to the FoundationOne CDx cancer genomic profile using tissue specimens,” said Chugai’s President and CEO, Dr. Osamu Okuda. “For patients with solid tumors for whom it is difficult to collect tissue samples, cancer genome profiling tests using blood specimens provide information on predicting the effectiveness of anticancer drug treatment, allowing for smooth consideration of treatment plans. We will continue our efforts to realize advanced personalized healthcare.”

As a leading company in the field of oncology, Chugai is committed to realizing advanced personalized healthcare in oncology and contributing to patients through the expansion of CGP.

About FoundationOne Liquid CDx Cancer Genomic Profile

Developed by Foundation Medicine Inc. based in Boston, USA, FoundationOne Liquid CDx Cancer Genomic Profile is a next-generation sequencing-based *in vitro* diagnostic device using blood samples for advanced cancer patients with solid tumors. By using circulating tumor DNA (ctDNA) in the blood of patients with advanced solid tumors, it is intended to identify genomic alterations (base substitutions, insertions/deletions, rearrangements, copy numbers alterations) in 324 cancer-related genes and calculate the bTMB score. It has been approved by the MHLW as a medical device program that has a genome profiling function for cancer-related genes and a companion diagnostic function for multiple molecular target drugs.

For the latest information about FoundationOne Liquid CDx Cancer Genomic Profile, please refer to the approval information.

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