

Chugai Files for FoundationOne Liquid CDx Aiming to Provide Bloodbased Comprehensive Genomic Profiling for Solid Tumors

- Submitted the regulatory application for FoundationOne Liquid CDx, a liquid biopsy test for blood specimens
- By adding a blood-based comprehensive genomic profiling (CGP) test to FoundationOne CDx Cancer Genomic Profile, the tissue-based CGP test, Chugai aims at fulfilling medical needs and contributing to precision medicine for cancer patients based on genomic alterations

TOKYO, March 31, 2020 – <u>Chugai Pharmaceutical Co., Ltd.</u> (TOKYO: 4519) announced today that it has submitted the regulatory application for FoundationOne[®] Liquid CDx (overseas product name) to the Ministry of Health, Labour and Welfare (MHLW), as a liquid biopsy (LB) test that provides a comprehensive genomic profiling (CGP) for solid tumors.

"Since the national health insurance coverage for genomic testing has started in June 2019, cancer genomic medicine has become widely and increasingly recognized in our society as a new approach in cancer treatment. However, there is an increasing need for blood-based genomic testing in some patients who are unable to undergo invasive tumor biopsy," said Chugai's President and COO, Dr. Osamu Okuda. "FoundationOne Liquid CDx is a new tool that can help a physician determine treatment options by conducting comprehensive genomic profiling based on genomic alterations in a wider range of patients. We will continue our efforts to obtain approval for the product as soon as possible, and contribute to precision medicine."

Developed by <u>Foundation Medicine Inc.</u> based in Cambridge, USA, FoundationOne Liquid CDx is a next-generation sequencing based *in vitro* diagnostic device for advanced cancer patients with solid tumors. It is to identify genomic alterations in oncogenes through detection of blood circulating tumor DNA (ctDNA). In the U.S., Foundation Medicine received Breakthrough Device designation from the U.S. Food and Drug Administration for the LB test in April 2018.

As a leading company in the field of oncology, Chugai is committed to realize precision medicine in oncology and contribute to patients and healthcare professionals through improving access to CGP.

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