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Chugai Files for Expanded Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic for Pemigatinib for Patients with *FGFR2* Fusion Positive Locally Advanced or Metastatic Cholangiocarcinoma

TOKYO, October 2, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed an application with the Ministry of Health, Labour and Welfare (MHLW) for the expanded use of FoundationOne® CDx Cancer Genomic Profile as a companion diagnostic (CDx) for the fibroblast growth factor receptor (FGFR) inhibitor pemigatinib for patients with *FGFR2* fusion positive locally advanced or metastatic cholangiocarcinoma on September 30,2020.

“Cholangiocarcinoma is a disease with high unmet medical needs that has limited treatment options. Currently, FGFR2 is identified as a driver gene for cholangiocarcinoma and molecular-targeted therapies are being evaluated to treat the disease,” said Dr. Osamu Okuda, Chugai’s President and COO. “We are committed to obtaining approval of FoundationOne CDx Cancer Genomic Profile as a CDx of pemigatinib as early as possible in order to contribute to treatment approaches for patients with the disease.”

The filing aims to expand the use as a companion diagnostic to identify patients who could benefit from pemigatinib for the treatment of *FGFR2* fusion positive locally advanced or metastatic cholangiocarcinoma by detecting *FGFR2* fusion genes. Incyte Biosciences Japan submitted an application for pemigatinib for the treatment of *FGFR2* fusion positive locally advanced or metastatic cholangiocarcinoma to the MHLW on September 14, 2020. The MHLW designated pemigatinib as an orphan drug for the indication.

As a leading company in the field of oncology, Chugai is committed to realizing advanced personalized oncology care and contributing to patients and healthcare professionals through improving access to comprehensive genomic profiling.

About FoundationeOne CDx Cancer Genomic Profile

Developed by Foundation Medicine Inc., FoundationOne CDx Cancer Genomic Profile is a next-generation sequencing based *in vitro* diagnostic device for the detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. The program is available as a companion diagnostic for multiple molecular-targeted drugs approved in Japan.

About FGFR

Fibroblast growth factor receptors (FGFRs) play an important role in tumor cell proliferation and survival, migration and angiogenesis (the formation of new blood vessels). Activating mutations, translocations and

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gene amplifications in FGFRs are closely correlated with the development of various cancers.

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