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Chugai Obtains Approval for Use of FoundationOne CDx Cancer Genomic Profile as a Companion Diagnostic for Pemigatinib for Patients with *FGFR2* Fusion Positive Biliary Tract Cancer

TOKYO, February 16, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained approval from the Ministry of Health, Labour and Welfare (MHLW) for the 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 biliary tract cancer on February 15, 2021.

“We are very pleased that FoundationOne CDx Cancer Genomic Profile has been approved as a companion diagnostic for pemigatinib in patients with biliary tract cancer. The expanded use of FoundationOne CDx Cancer Genomic Profile for this new cancer type with high unmet medical needs underscores the value of comprehensive genomic profiling in cancer treatment,” said Dr. Osamu Okuda, Chugai’s President and COO. “We are committed to preparing for the use of the genomic profiling to identify those who may benefit from pemigatinib."

The approval allows the use of FoundationOne CDx Cancer Genomic Profile as a companion diagnostic to identify patients with *FGFR2* fusion positive locally advanced or metastatic biliary tract cancer who could benefit from treatment with pemigatinib. Incyte Biosciences Japan submitted a Japanese New Drug Application for pemigatinib for the treatment of *FGFR2* fusion positive locally advanced or metastatic cholangiocarcinoma with the MHLW on September 14, 2020 which is currently under review. The MHLW granted orphan drug designation to pemigatinib for this 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 of cancers.

Approval information The underlined part has been newly added.

Intended uses or indications

- The Product is used for comprehensive genomic profiling of tumor tissues in patients with solid cancers.
- The Product is used for detecting gene mutations and other alterations to support the assessment of drug indications listed in the table below.

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Alterations	Cancer type	Relevant drugs
Activated *EGFR* alterations	Non-small cell lung cancer (NSCLC)	afatinib dimaleate, erlotinib hydrochloride, gefitinib, osimertinib mesylate
EGFR exon 20 T790M alterations		osimertinib mesylate
ALK fusion genes		alectinib hydrochloride, crizotinib, ceritinib
ROS1 fusion genes		entrectinib
MET exon 14 skipping alterations		capmatinib hydrochloride hydrate
BRAF V600E and V600K alterations	Malignant melanoma	dabrafenib mesylate, trametinib dimethyl sulfoxide, vemurafenib
ERBB2 copy number alterations (HER2 gene amplification positive)	Breast cancer	trastuzumab (genetical recombination)
KRAS/*NRAS* wild-type	Colorectal cancer	cetuximab (genetical recombination), panitumumab (genetical recombination)
NTRK1/2/3 fusion gene	Solid tumors	entrectinib, larotrectinib sulfate
BRCA1/2 alterations	Ovarian cancer	olaparib
BRCA1/2 alterations	Prostate cancer	olaparib
FGFR2 fusion genes	Biliary tract cancer	pemigatinib

About FoundationOne 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 fibroblast growth factor receptors

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

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