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ASIA EDITION

Chugai obtains approval for Genomic Mutation Analysis Program

December 27, 2018 | News

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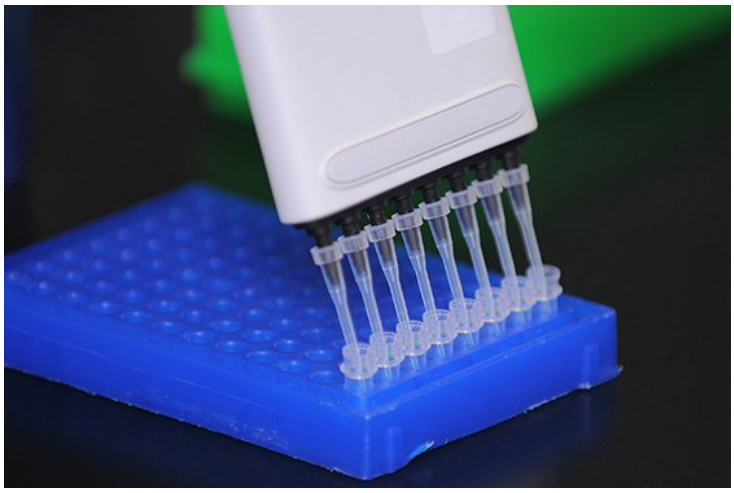

Chugai Pharma has announced today that it has obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for “FoundationOne® CDx Cancer Genomic Profile,” which is a next-generation sequencing based program for the purpose of gene mutation analysis program (for use in cancer genome profiling) for solid tumors and somatic gene mutation analysis program (for use in assessing anticancer drug indications).

This is the first cancer genomic test granted expedited review in May 2018 and approved by the MHLW with the two functions of cancer genomic profiling and companion diagnostics for molecular-targeted drugs.

As a function of comprehensive genomic profiling of cancer-related genes, FoundationOne CDx Cancer Genomic Profile allows to identify mutation status of 324 cancer-related genes for solid tumors at once by using the patient’s tumor tissues. As a comprehensive companion diagnostic function, it can be used as a companion diagnostic for the domestically approved molecular-targeted drugs listed in the following table.

The report provided from this program includes information that supports physicians’ decisions to develop treatment strategies for patients, and provides a summary of gene-mutation data, information on the relevant molecular-targeted drugs, their approval status and ongoing clinical studies as well as the relevant references.

Tatsuro Kosaka, Chugai’s President and CEO said, “It is said that cancer is a disease caused by gene mutation, and the gene mutation status is different from patient to patient. Clarifying the profile of each cancer enables us to understand the characteristics of cancer, and is very important in order to select appropriate treatment approaches.”

“The conventional concept of cancer treatment is based on the treatment for each tumor organ. However, we will have a completely new approach since comprehensive genomic profiling would provide tumor agnostic treatment tailored to each patient’s gene mutation. In order to realize more advanced personalized healthcare through this paradigm shift, we seek to

obtain the national health insurance reimbursement coverage for this program in view of the universal healthcare system in Japan in order to contribute to many healthcare professionals and patients", he added.

Melanie Nallicheri, chief business officer and head of biopharma at Foundation Medicine said, "The approval of FoundationOne CDx in Japan is yet another testament to its validation and is critical to enabling patient access to comprehensive genomic profiling. Similar to our FDA approval in the United States, the MHLW has approved FoundationOne CDx as a comprehensive genomic profiling tool for all solid tumors and a broad companion diagnostic, a first of its kind comprehensive diagnostic test for individuals living with cancer in Japan. This is also an important milestone for our biopharma partners who can leverage FoundationOne CDx to accelerate companion diagnostic development and improve access to personalized oncology care in Japan."

Foundation Medicine is a molecular information company where treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer.