

Attn: All Media

April 1, 2020

National Cancer Center

Sysmex Corporation

RIKEN GENESIS Co., Ltd.

Advanced Medical Care Approval for Cancer Gene Panel Testing at the Time of Initial Treatment

- Prospective Study to Assess the Feasibility and Clinical Utility of Comprehensive Genomic Profiling at the Time of Initial Treatment of Patients with Solid Tumors -

The “Prospective Study to Assess the Feasibility and Clinical Utility of Comprehensive Genomic Profiling at the Time of Initial Treatment in Patients with Solid Tumors” (the “Study”), which uses the OncoGuide™ NCC Oncopanel System¹ (the “System”, generic name: mutation analysis set for cancer genome profiling) developed through collaboration between the National Cancer Center (Location: Tokyo, Japan; President: Hitoshi Nakagama) and Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu), has been applied as Advanced Medical Care² on April 1, 2020. The start date of this test will be announced on the website as soon as preparations at the National Cancer Center are completed. (<https://www.ncc.go.jp/en/ncch/index.html>)

The System analyzes genetic alterations in cancer-specific genes in patients with solid tumors and provides the cancer genomic profile of the tumor to help determine the treatment strategy, including accurate diagnosis and the selection of anti-cancer drugs. Currently, the System is covered by the National Health Insurance (NHI) in patients who have already undergone the standard treatment. Personalized genomic medicine based on cancer genomic profiling from an early phase at the time of initial treatment could provide the patients with more opportunities for appropriate treatment, including matched therapy. However, the feasibility and clinical utility of the System at the time of initial treatment remains unclear.

On April 1, 2020, the “Prospective Study to Assess the Feasibility and Clinical Utility of Comprehensive Genomic Profiling at the Time of Initial Treatment in Patients with Solid Tumors” has been applied as Advanced Medical Care. The National Cancer Center will announce the start date of this test at the National Cancer Center Hospital on its website as soon as the National Cancer Center is ready. (<https://www.ncc.go.jp/en/ncch/index.html>).

The Study will include patients with six types of advanced or recurrent solid tumors, which could be treated with medication, including non-small-cell lung cancer, gastric cancer, colon cancer, breast cancer, pancreatic cancer, and biliary tract cancer (a total of 200 cases). We will evaluate whether personalized genomic medicine based on cancer genome profiling by the System at the time of initial treatment results in more opportunities of matched therapies compared to after standard treatment.

All collected samples will be analyzed at the Innovation Genome Center (Kawasaki Office) of RIKEN GENESIS Co., Ltd. (HQ: Tokyo, Japan; President and CEO: Naoto Kondo), a Sysmex subsidiary which provides lab assay services for gene analysis.

The National Cancer Center, Sysmex and RIKEN GENESIS will contribute to the implementation and development of personalized genomic medicine in Japan by providing high-value testing and diagnostic technologies for cancer patients.

Product Overview

Generic name: Gene mutation analysis set (for use in cancer genome profiling)
Name: OncoGuide™ NCC Oncopanel System
(medical equipment production sales authorization number:
23000BZX00398000)
Target institutions: Medical institutions that have in place diagnostic systems appropriate for cancer genome profiling
Target market: Japan

References

Press release dated December 25, 2018: “Sysmex Receives Manufacturing and Marketing Approval to Use the OncoGuide™ NCC Oncopanel System in Cancer Genome Profiling”
<https://www.sysmex.co.jp/en/news/2018/181225.html>

Press release dated May 31, 2019: “The OncoGuide™ NCC Oncopanel System Receives Insurance Coverage for Use in Cancer Genome Profiling”
<https://www.sysmex.co.jp/en/news/2019/190531.html>

Terminology

- 1 OncoGuide™ NCC Oncopanel System:
On December 25, 2018, Sysmex received manufacturing and marketing approval for the System as Japan’s first system for cancer genome profiling. This was also the first such system to be covered under the NHI, as of June 1, 2019.
The NHI coverage for D006-19 cancer genome profiling using the System includes patients with solid tumors for which no standard treatment exists and patients with solid tumors confirmed to have advanced locally or metastasized (including patients for which treatment is expected to conclude). Coverage is limited to cases in which the attending physician determines the potential for applying chemotherapy following this testing is high based on chemotherapy guidelines from related societies and the patient’s general status and organ function. The objective of Advanced Medical Care is to assess utility at the time of initial treatment.
- 2 Advanced Medical Care:
Refers to advanced healthcare technologies that have been approved by Japan’s Minister of Health, Labour and Welfare but are not yet covered by healthcare insurance. Based on

a Fundamental Accord in December 2004 between the Minister of Health, Labour and Welfare; the Cabinet Officer Minister of State in Charge of Special Missions (regulatory reform, industrial revitalization); the minister in charge of administrative reform; and the Minister in charge of Special Zones for Structural Reform and Regional revitalization, this system was approved in combination with healthcare insurance coverage from the perspective of ensuring the safety of patients in Japan, preventing patient burdens from increasing, expanding patient choices, and increasing convenience.

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