November 17, 2022
DNA Chip Research, Inc.

Announcement of the Manufacturing and Sales Approval for "Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System" (Medical Device Program)

[Summary]
On November 16, 2022, DNA Chip Research, Inc. (President and Representative Director: Ryo Matoba) announced that the company has received specially-controlled medical device manufacturing and sales approval for a "Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System" (hereinafter, Lung Cancer Compact Panel). We have been working on the development of a highly sensitive multiple genetic test that specializes in key genes (driver genes[*1]) for lung cancer. With this manufacturing and sales approval for the Lung Cancer Compact Panel, the device can be used as a companion diagnostic test,[*2] especially for patients with non-small cell lung cancer,[*3] to detect mutations in four representative driver genes and determine the suitability of drugs to treat them. This product was developed based on the research results from the Nara Institute of Science and Technology and the Osaka International Cancer Institute.

In its study of driver genes of lung cancer, DNA Chip Research, Inc. is working on the commercialization of gene panel tests[*4] using next-generation sequencing (NGS) technology[*5] based on the concept of providing an easy-to-use and highly reliable companion diagnostic test that meets the needs of clinical practice in Japan. As a forerunner, the Lung Cancer Compact Panel was developed as a cancer gene panel test for eight representative driver genes (four CDx-approved genes and four additional druggable genes) of lung cancer, and is currently being introduced to clinical trials to elucidate its efficiency and suitability in the clinical setting. The features of this test are the efficient measurement of multiple major genes at once (multi-diagnosis), sensitive detection of partially degraded specimens and specimens with extremely small amounts of tumor cells (high sensitivity), and compatibility with liquid cytology specimens. Its usefulness in the clinical setting has been demonstrated in pilot studies conducted thus far. Compared to single-gene testing, conventional multi-gene testing requires tissue specimens containing sufficient amounts of cancer cells. We believe that a major step forward is the ability to perform companion diagnostic tests for mutations in the four approved genes in cases where only a small amount of cancer cells is available from tissue or cytological specimens. There is great anticipation that this product will help further promote precision and personalized medicine and improve treatment results as a test that addresses the unmet medical needs of lung cancer care.

In the field of lung cancer, a growing number of molecular-targeted drugs are being launched, and the corresponding companion diagnostics are becoming increasingly complex. Multiple companion diagnostic tests that cover all drugs would be ideal; however, each test has a different spectrum of drugs it is compatible for, and there remain cases where multiple genetic tests have to be performed. Our aim is to develop an all-in-one multiple companion diagnostic test for non-small cell lung cancer, and in the future, we plan to add a companion diagnostic function for three other gene mutations (total of seven genes) to this product, and aim to achieve additional approval and insurance coverage for the product.

We will continue to strive to contribute to the improvement in patient treatment results and quality of life by responding to the needs of the clinical scene with cutting-edge genetic analysis technology.

Test Outline

Market name: Lung Cancer Compact Panel Dx Multiplex Companion Diagnostic System

Generic name: Somatic Gene Mutation Analysis Program (for determining the suitability of anti-tumor drugs)

Approval No.: 30400BZX00263000

Target country: Japan

Target specimen: Tissue (FFPE tissue, unfixed tissue or cytology specimens) collected by surgery or biopsy from patients with non-small cell lung cancer

[Explanation of Terms]

*1 Driver gene:

A gene that directly causes or plays a direct role in carcinogenesis or cancer progression.

*2 Companion diagnosis test:

A test to detect genetic mutations before administering a specific drug (molecular-targeted drug). For example, if an EGFR gene mutation is detected, a tyrosine kinase inhibitor is administered and its therapeutic effect is anticipated.

*3 Non-small cell lung cancer:

Lung cancer is broadly classified into non-small cell and small cell carcinoma, with the former accounting for 85–90% of cases. Adenocarcinoma accounts for the majority of non-small cell lung cancer, and squamous cell and large cell carcinomas are also included.

*4 Gene panel test:

A test that simultaneously detects mutations in multiple genes using a next-generation sequencer. Applications are broadly divided into companion diagnostics and genomic profiling. Genomic profiling is used to assist treatment policy decisions for patients who have become refractory to standard treatments.

*5 Next Generation Sequencing (NGS):

Advanced technology to determine the base sequence of nucleic acids and analyze genetic information. Mutation analysis of a specific gene can be performed with high sensitivity and high efficiency in a multiplex system.

<For more information about this case>

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