

DNA Chip Research, Inc.

[July 31, 2020. Tokyo, JAPAN]

**ANNOUNCEMENT OF SPECIALLY-CONTROLLED MEDICAL
DEVICE MANUFACTURING AND SALES APPROVAL FOR THE
"EGFR Liquid" GENE ANALYSIS SOFTWARE, AS A DISEASE
DIAGNOSIS PROGRAM
~CONTRIBUTING TO PRECISION CANCER THERAPY
THROUGH PATIENT-FRIENDLY GENETIC TESTING~**

On July 31st, 2020, 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 diagnostic program (market name "EGFR Liquid" Gene Analysis Software), which detects EGFR genetic mutations (exon 19 deletion and L858R) in DNA samples extracted from cancer tissue or blood plasma, and helps to determine the suitability of EGFR tyrosine kinase inhibitors (gefitinib, erlotinib hydrochloride, or afatinib maleate) for patients with non-small cell lung cancer. This product was developed based on research results from the Nara Institute of Science and Technology and the Osaka International Cancer Institute. An application was made in July, last year to the Ministry of Health, Labor, and Welfare for manufacture and sales approval of the product as a companion diagnostic, and now the approval has been issued.

Non-small cell lung cancer, a type of lung cancer, is known to differ in its characteristics depending on the type of genetic mutation involved. Thus, such treatment drugs have been developed for this cancer type that specifically target the different genetic mutation types. In Japanese people, in particular, EGFR (epidermal growth factor receptor) genetic mutations have been reported in approximately 50 % of the non-small cell lung cancer cases, conducting genetic testing would thus be extremely important.

In general, cancer genetic testing requires a biopsy (an operation of cancer tissue collection for testing) to acquire cancer tissue but this method is painful and physically invasive. However, detecting mutations became possible while reducing the burden on the patient by analyzing the circulating tumor DNA (ctDNA), which is released from lung cancer cells into the blood. This blood-based type of genetic testing, called liquid biopsy, is currently in the focus of enthusiastic research and development worldwide.

This test is also considered as a liquid biopsy, applying next-generation sequencing technology to analyze more than 10,000 EGFR amplicons (amplified DNA fragments) from the blood and search for the presence of mutations. This allows the detection of

mutations even in small quantities, which is difficult using conventional technologies. The detection of mutations increases the possibility of medication. More than 50,000 EGFR genetic tests are performed each year in Japan, based on estimations. Introducing this test to the market would hopefully contribute to “precision medicine,” offering an optimized therapy for each individual and pathology types.

In the future, DNA Chip Research, Inc. aims at covering the test by insurance and is working to develop a cancer gene panel test for multiple driver genes using the next-generation sequencing technology and make it commercially available to healthcare institutions.

Test Outline

Market name: “EGFR Liquid” Gene Analysis Software

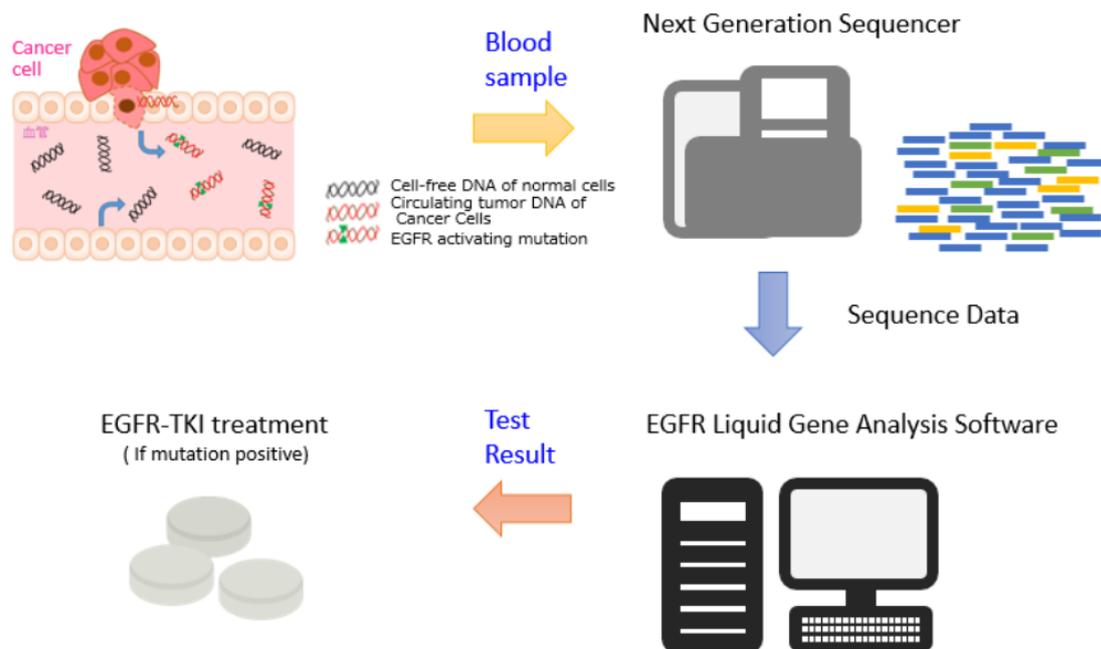
Generic name: Somatic Gene Mutation Analysis Program (for determining the suitability of anti-tumor drugs)

Target country: Japan

Target specimen: blood or unfixed tissue (surgery specimens, biopsies) from patients with non-small cell lung cancer

Target genetic mutation: exon 19 deletion, L858R

Companion diagnostic target drugs: gefitinib, erlotinib hydrochloride, afatinib maleate



DNA Chip Research Inc. was founded in April 1999, specializing in development of DNA microarrays. Since then, we have consistently been engaging in various research projects and services that involve gene analysis and related technologies. To stay on top of this rapidly developing field, we have always engaged ourselves with the latest technology, and our own innovations. We constantly strive to provide exceptional quality of service by consolidating our knowledge on bioinformatics, techniques on automation of sample processing, and nanoscale sample analysis. Currently, our major business is focused on research and development, contract research service, and diagnostic support service.

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