DNA Chip Research Inc.
[July 10, 2019. Tokyo, JAPAN]

DNA CHIP RESEARCH INC. HAS DEVELOPED A HIGH SENSITIVITY TEST TO ANALYZE GENETIC ANOMALY IN LUNG CANCER AND HAS APPLIED TO THE PMDA FOR PRODUCT APPROVAL.

On July 10, 2019, Ryo Matoba, the president of DNA Chip Research Inc., announced that they have developed a high-sensitivity genetic test to detect a very small amount of abnormal (mutated) DNAs in blood for targeted therapies of lung cancer, and submitted its program, "EGFR Liquid" Gene Analysis Software for approval from Japanese authorities as a medical program. The genetic test can be used as companion diagnostic test in clinical practice after approval.

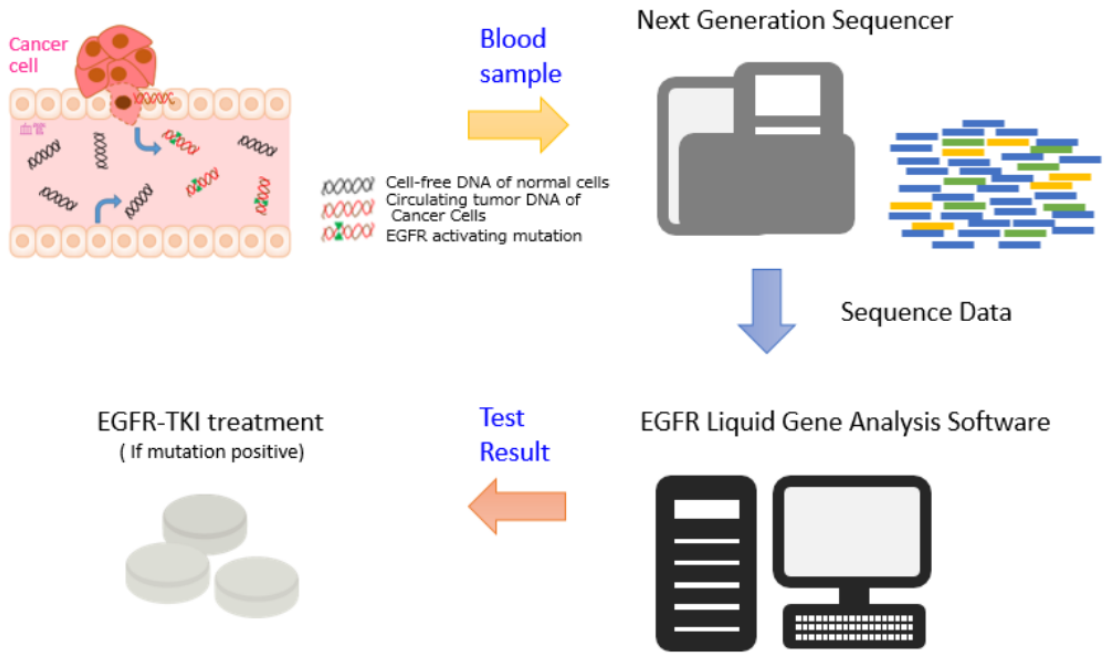
Drugs, such as gefitinib and afatinib, that inhibit epidermal growth factor receptor (EGFR) tyrosine kinase, are widely used to treat progressive lung cancer patients. However, the therapeutic effects are limited to patients with activating mutations of the EGFR gene. Hence, detection of such mutations is essential for drug selection and treatment. In Japan, approximately 50% of patients with non-small cell lung cancer (NSCLC) have EGFR mutations and more than 50,000 genetic tests of EGFR gene are performed annually.

Genetic testing of cancer in general, requires biopsy, a method to remove cancerous tissues from the body. However, it is usually painful and invasive for patients, and sometimes entails a higher risk of infection. In contrast, blood tests that analyze EGFR gene (ctDNA) released from lung cancer cells, can not only detect mutations but also decrease the physical and mental burden of patients. Such cancer genetic tests using blood as a sample, are called liquid biopsy, and research and development of this methodology are currently underway worldwide.

The genetic test we have developed uses next generation sequencing (NGS) technology and analyses more than 50,000 molecules of EGFR genes per blood sample to explore mutations. NGS is a very powerful gene analysis technology with which whole human genome sequence can be obtained within a few days. With such excellent performance, NGS has made it possible to detect very small amounts of mutated DNAs in samples (mutated genes with very low allele frequency) which otherwise would not have been detectable with conventional technology.

"Precision Medicine" has been drawing attention as a new medical concept which determines individual treatment method based on genetic anomaly, and it has also been mentioned in the State of the Union address of the former US president Barack Obama. Dr. Kikuya Kato at the Nara Institute of Science and Technology (NIST) says, "We think that this technology greatly accelerates precision medicine in Japan." This test has been developed based on the research performed at the

NIST and the Osaka International Cancer Institute (OICI). The technology submitted for the PMDA approval is the first liquid biopsy test based on national research and the application of domestic technology, and the second domestic next-generation sequencing test after Oncoguide™ NCC Oncopanel system (National Cancer Research Center and Sysmex), a cancer genetic test.



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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