

DNA Chip Research, Inc.

[May 21, 2021. Tokyo, JAPAN]

## **Notice of insurance coverage of the disease diagnosis program “EGFR Liquid” Gene Analysis Software in Japan**

DNA Chip Research Inc. (President and Representative Director Ryo Matoba) is pleased to announce that May 21, 2021 onward, a function of the “EGFR Liquid” Gene Analysis Software (test using unfixed tissue sample) will be covered by public insurance of Japan. The “EGFR Liquid” Gene Analysis Software is a disease diagnosis program for detecting mutations (exon 19 deletion and L858R) in the gene encoding epidermal growth factor receptor (*EGFR*) using DNA extracted from plasma samples or cancer tissues and determining drug efficacy of EGFR tyrosine kinase inhibitors (gefitinib, erlotinib hydrochloride, or afatinib maleate) in non-small-cell lung cancer patients. It was developed based on the research findings of the Nara Institute of Science and Technology and Osaka International Cancer Institute and approved for marketing in July 2020 as a companion diagnostic program.

The characteristics of non-small-cell lung cancer differ according to the type of genetic mutation. Drugs that can specifically target a certain type of gene have been developed. Approximately 50% of non-small-cell lung cancers have mutations in *EGFR gene* in Japan, highlighting the importance of genetic testing. This program will be used for the EGFR genetic mutation test (EGFR Liquid Test).

The EGFR Liquid Test can be used for plasma samples (isolated from blood) or unfixed tissue. Unfixed tissue-based tests are now covered by the Healthcare Insurance in Japan, while blood sample-based tests are expected to be covered by the insurance later.

DNA Chip Research Inc. is now developing gene panel tests using next-generation sequencing technology. We aim to acquire medical device manufacturing and marketing approvals and insurance coverage for lung cancer panel tests (oncogene panel tests for identifying multiple driver genes of lung cancer). Combining the effects of the clinical implementation of this panel test and the EGFR Liquid Test, we aim to increase sales in the diagnostic business and achieve profitability by 2023.

By meeting the needs of clinicians with advanced genetic analysis technologies, we aim to improve the treatment opportunities and quality of life (QOL) of patients.

Overview of test

Brand name: “EGFR Liquid” Gene Analysis Software

General name: Somatic gene mutation analysis program (for determining the effectiveness of anti-tumor drugs)

Approval number: 30200BZX00249000

Target country: Japan

Specimen: unfixed tissue (surgical specimen or biopsy sample) or plasma of patients with non-small-cell lung cancer

Target genetic mutation: *EGFR* exon 19 deletion, L858R

Drugs subject to companion diagnosis: gefitinib, erlotinib hydrochloride, afatinib maleate

Insurance coverage starting date: May 21, 2021

Laboratory fee: 2,500 points (unfixed tissue sample)

※ Results from plasma tests are awaited

Planned marketing date: June 1, 2021

DNA Chip Research Inc. was founded in April 1999, as a company 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 cutting edge 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.

For more information:

DNA Chip Research Inc.

1-15-1 Kaigan, Suzuebaydium 5F

Minato-ku, Tokyo 105-0022 JAPAN

Tel: 03-5777-1700

E-mail: [dnachip-support@dna-chip.co.jp](mailto:dnachip-support@dna-chip.co.jp)

HP: <https://www.dna-chip.co.jp/en/index.html>