

MEBGEN™ BRAF 2 Kit Receives MHLW Approval as a Companion Diagnostic for Use with Patients with Thyroid Cancer

Tokyo, Japan – March 25th, 2024 - Medical and Biological Laboratories Co., Ltd. (CEO: Hiroki Ito, “MBL”), a JSR Life Sciences Company, announced that the MEBGEN™ BRAF 2 Kit was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) on February 21, 2024.

The MEBGEN™ BRAF 2 Kit is a companion diagnostic*¹ for encorafenib and binimetinib, for which Ono Pharmaceutical Co., Ltd. has submitted an application for partial change in manufacturing and marketing approval, for an additional indication of “the treatment of radically unresectable BRAF-mutant*² thyroid cancer”. By detecting BRAF gene mutations (V600E, V600K, V600D, V600R, and V600M) in DNA extracted from thyroid cancer tissue, the MEBGEN™ BRAF 2 Kit will be used as an aid in identifying thyroid cancer patients eligible for encorafenib and binimetinib combination therapy.

With this approval, the MEBGEN™ BRAF 2 Kit is expected to contribute to the timely personalized treatment of patients with radically unresectable thyroid cancer based on the presence or absence of the BRAF gene mutations. MBL will continue to pursue national health insurance coverage for the MEBGEN™ BRAF 2 Kit.

Product Information:

Product Name: MEBGEN™ BRAF 2 Kit

Approval No.: 30600EZX00005000

Purpose of use: Detection of BRAF gene mutations (V600E, V600K, V600D, V600R and V600M) in DNA extracted from cancer tissue

Used as an aid in identifying thyroid cancer patients eligible for encorafenib and binimetinib combination therapy

Testing method: PCR-rSSO

Package Size: 48 tests/ kit

Shelf life : 12 months

***1...What is a companion diagnostic?**

Companion diagnostics refers to testing a particular drug in advance of treatment to determine whether it will be effective for the patient and whether there is a significant risk of side effects.

MBL offers services for the development of companion diagnostics. For more information, please visit <https://www.mblbio.com/cdx/>

***2...What is BRAF gene mutation?**

BRAF protein is a serine/threonine kinase that is a component of the Ras/Raf/MEK/ERK signaling pathway.

[PRESS RELEASE]

When the BRAF gene mutation results in the production of abnormal BRAF protein, unregulated cell proliferation leads to cancer.

Combination therapy with encorafenib and binimetinib is expected to be a promising therapeutic option for radically unresectable BRAF-mutant thyroid cancer, as BRAF V600 mutations are widely observed in thyroid cancer.

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About Medical and Biological Laboratories Co., Ltd.

MBL was established in 1969 as the first antibody manufacturer in Japan, and researches, develops, manufactures, and sells reagents of in vitro diagnostics and reagents for basic research. MBL has now expanded its business not only to the immunological field but also to the field of genetic diagnosis. In the field of oncology, MBL is contributing to personalized medicine by developing companion diagnostics. For more information, please visit <https://www.mblbio.com/cdx/>