

## **MEBGEN™ BRAF 3 Kit Receives MHLW Approval and Insurance Coverage as a Tumor Agnostic Companion Diagnostic**

Tokyo, Japan – November 8, 2023 - Medical and Biological Laboratories Co., Ltd. (CEO: Hiroki Ito, “MBL”), a JSR Life Sciences Company, announced that the MEBGEN™ BRAF 3 Kit, an in vitro diagnostic reagent, was approved for manufacturing and marketing by the Ministry of Health, Labour and Welfare (MHLW) on August 18, 2023, and received national health insurance coverage on November 1, 2023.

The MEBGEN™ BRAF 3 Kit was developed as a tumor-agnostic companion diagnostic for the detection of BRAF (v-raf murine sarcoma viral oncogene homolog B1) gene mutations (V600E). Clinical performance studies were conducted in solid tumors and hairy cell leukemia as part of the SCRUM-Japan MONSTAR-SCREEN, GI-SCREEN and GOZILA studies, which are collaborative industry-academic cancer genome screening projects led by the National Cancer Center Japan.

With MHLW approval and insurance coverage, the MEBGEN™ BRAF 3 Kit is expected to support personalized medicine based on its ability to detect the presence or absence of BRAF gene mutations in rare tumors (solid tumors including histiocytosis and hairy cell leukemia) for which treatment options are limited.

### **Product Information:**

Product Name: MEBGEN™ BRAF 3 Kit

Approval No.: 30500EZX00044000

Purpose of use: Detection of BRAF gene mutations (V600E) in DNA extracted from tumor tissue

Used as an aid in identifying patients with malignant tumor, etc. eligible for dabrafenib mesilate and trametinib dimethyl sulfoxide combination therapy

Reimbursement: 50,000JPY/test

Testing method: PCR-rSSO

Package Size: 48 tests/ kit

Shelf life : 12 months

### **Contact:**

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[PRESS RELEASE]

**MBL** MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.  
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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/>