

## MBL received MHLW approval for its AmoyDx® PIK3CA Mutation Detection Kit

Tokyo, Japan - March 23, 2026 - Medical & Biological Laboratories Co., Ltd. (CEO: Hiroki Ito), a group company of Tokuyama Corporation (President: Hiroshi Yokota), Amoy Diagnostics Co., Ltd. (Founder and Chairman: Li-Mou Zheng) and Precision Medicine Asia Co., Ltd. (President and CEO: Tatsuya Ikeda) today announced that MBL received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) on March 5, 2026 for the AmoyDx® PIK3CA Mutation Detection Kit in Japan. The approval in Japan marks an important milestone achieved through the close collaboration of MBL, AmoyDx and PREMIA.

This kit was developed as a companion diagnostic for the PI3K $\alpha$  (phosphatidylinositol 3-kinase  $\alpha$ ) inhibitor, Risovalisib (Risovalisib Mesilate Hydrate). The AmoyDx® PIK3CA Mutation Detection Kit is used to detect the presence or absence of PIK3CA gene mutations in patients with ovarian clear cell carcinoma (OCCC). It is expected to support personalized medicine by helping identify patients who may benefit from targeted therapy.

Risovalisib is developed by Haihe Biopharma Co., Ltd. (CEO: Haiying Liu). In Japan, Haihe Biopharma K.K. (President and Representative Director: Xuehua Li), a wholly owned affiliate of Haihe, received approval from the Japanese MHLW on March 23, 2026 for the approved indication of "advanced or recurrent ovarian clear cell carcinoma harboring PIK3CA gene mutations that has progressed after chemotherapy." and Taiho Pharmaceutical Co., Ltd. (President and Representative Director: Masayuki Kobayashi) will be responsible for providing medical information and managing the sales of Risovalisib.

### **Product information:**

[In Vitro Diagnostics]

Product name: AmoyDx® PIK3CA Mutation Detection Kit

Approval No.: 30800EZX00012000

Intended use: Detection of *PIK3CA* gene mutations in DNA extracted from tumor tissue

Used as an aid in identifying patients with ovarian clear cell carcinoma eligible for Risovalisib Mesilate Hydrate

Sample: FFPE tissue in which the presence of tumor cells was confirmed

Testing method: Real-time PCR

Package: 24 tests/kit

Shelf life: 12 months

Marketing Medical & Biological Laboratories Co., Ltd.

Authorization Holder:

Manufacturer: Amoy Diagnostics Co., Ltd

**About Medical & Biological Laboratories Co., Ltd.:**

Medical & Biological Laboratories (MBL) was established in 1969 as the first antibody manufacturer in Japan, and researches, develops, manufactures, and sells reagents of in vitro diagnostics (IVD) and reagents for basic research. It has now expanded its business not only to the immunological field but also to the field of genetic diagnosis.

In the IVD business, we develop and sell IVD reagents for autoimmune diseases, cancer, infectious diseases, etc. Particularly in the field of autoantibody diagnosis, we are expanding our product lineup as a top manufacturer in Japan and contributing to medical care in this field where there are many intractable diseases. In the field of oncology, we are contributing to personalized medicine by developing companion diagnostics that predict the effects of drugs. For more information, please visit <https://www.mblbio.com/e/>

**About Tokuyama Corporation:**

Since founding in 1918, Tokuyama has worked to accumulate technologies and create new products by developing our inorganic chemicals business, while, from the 1970s, we began addressing social issues by expanding the scope of businesses, mainly in organic and polymer chemistry.

Under its Medium-Term Management Plan 2025, Tokuyama has identified the “Electronics,” “Healthcare,” and “Environment” fields as growth businesses. As a part of efforts to transform our business portfolio, our plan is to increase the proportion of consolidated sales generated from growth businesses to more than 60% by FY2030. Taking the aforementioned into consideration, our intention is to position the newly acquired IVD businesses at the heart of our healthcare domain. For more information, please visit <https://www.tokuyama.co.jp/eng/>

**About Amoy Diagnostics Co., Ltd.:**

Amoy Diagnostics (AmoyDx) is at the forefront of championing molecular diagnostics for cancer, committed to enhancing patient outcomes worldwide through innovative diagnostic solutions and breaking barriers for global precision oncology adoption. The company is recognized for its excellence in precision medicine, driving advancements in cancer diagnosis through its extensive collaboration with pharmaceutical companies. For more information, please visit <https://www.amoydiagnostics.com/>

**About Precision Medicine Asia Co., Ltd.:**

Precision Medicine Asia (PREMIA) offer an integrated platform for the development of innovative oncology therapies and diagnostics in Asia, the fastest growing market for the pharmaceutical industry. PREMIA also manages a clinical-genomic lung cancer registry, the largest in the region, which includes more than

20,000 patients and allows an efficient patient identification process for clinical trial enrollment through participation by more than 200 hospitals in Japan, Taiwan, Malaysia and Thailand. For more information, please visit <https://www.premia-inc.com/>

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