AmoyDx® Pan Lung Cancer PCR Panel Approved in Japan as a Companion Diagnostic for LORBRENA® (Lorlatinib)

TOKYO and XIAMEN, August 21, 2025 — Riken Genesis Co., Ltd., Amoy Diagnostics Co., Ltd. ("AmoyDx"), and Precision Medicine Asia Co., Ltd. ("PREMIA") today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved the AmoyDx® Pan Lung Cancer PCR Panel (the "AmoyDx PLC Panel") as a companion diagnostic (CDx) for LORBRENA® (Lorlatinib). This approval applies to patients with unresectable, advanced, or recurrent non-small cell lung cancer (NSCLC) harboring an ALK fusion gene. LORBRENA®, developed by Pfizer, is available globally, including in Japan, in 25 mg and 100 mg tablet formulations.

Developed using cutting-edge PCR technology, the AmoyDx® PLC Panel enables the simultaneous detection of activating alterations in 11 key driver genes: EGFR, ALK, ROS1, KRAS, BRAF, HER2, RET, MET, NTRK1, NTRK2, and NTRK3. It also identifies actionable mutations in seven of these genes (EGFR, ALK, ROS1, BRAF, MET exon 14 skipping, KRAS, and RET) that are directly associated with 18 targeted therapies for NSCLC. This approval marks a significant advancement in precision oncology, offering rapid and sensitive mutation detection that can substantially improve patient outcomes.

"With this approval, the AmoyDx® PLC Panel is now authorized for use as a CDx to identify patients with unresectable, advanced, or recurrent NSCLC harboring ALK fusions who may benefit from treatment with Lorlatinib, thereby expanding their therapeutic options," said Yuko Oi, President and CEO of Riken Genesis; Li-Mou Zheng, Ph.D., Founder and Chairman of AmoyDx; and Tatsuya Ikeda, President and CEO of PREMIA.

About AmoyDx PLC Panel:

(1) Product name	AmoyDx® Pan Lung Cancer PCR Panel
(2) Approval No.	30300EZX00069000
(3) Purpose of use	Detection of *EGFR* gene mutations, *ALK* fusion gene, *ROS1* fusion gene, *BRAF* gene mutations, *MET*ex14 skipping mutation, *KRAS* gene mutations and *RET* fusion genes in nucleic acids extracted from cancer tissue. Used as an adjunct to determine the indications of the following 18 antineoplastic agents for patients with NSCLC. ・***EGFR* gene mutation** Gefitinib, Erlotinib hydrochloride, Afatinib maleate, Osimertinib mesylate and Amivantamab plus Lazertinib mesylate hydrate ・***ALK* fusion gene** Crizotinib, Alectinib hydrochloride, Brigatinib and Lorlatinib ・***ROS1* fusion gene** Crizotinib, Entrectinib and Repotrectinib ・***BRAF* V600E mutation** Combined administration of Dabrafenib mesylate and Trametinib dimethyl sulfoxide ・***MET* exon 14 skipping mutation** Tepotinib, Capmatinib and Gumarontinib hydrate ・**KRAS G12C mutation** Sotorasib ・***RET* fusion gene** Selpercatinib
(4) Method	Real-time PCR
(5) Specimen	FFPE tissue and fresh frozen tissue in which the presence of tumor cells was confirmed
(6) Package size	12 tests / kit
(7) Marketing Authorization Holder	Riken Genesis Co., Ltd.
(8) Manufacturer	Amoy Diagnostics Co., Ltd.

Acknowledgements

We would like to express our sincere gratitude to the patients and staff at NHO Kyushu Cancer Center and Kanagawa Cancer Center for their tremendous cooperation in the development of this product.

About Riken Genesis Co., Ltd.

RIKEN GENESIS, founded in October 2007, provides lab-assay services as well as products for genetic testing based on cutting-edge gene analysis technologies and bioinformatics, and has experience in the field of personalized medicine. The company provides highly reliable tests based on international quality standards, as demonstrated by its CLIA certification, being the first organization in Japan to meet this U.S. quality control standard for clinical laboratories. For more information, please visit www. rikengenesis.jp

About Amoy Diagnostics Co., Ltd. (AmoyDx, SZSE: 300685)

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 www.amoydiagnostics.com.

About Precision Medicine Asia (PREMIA)

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 www.premia-inc.com

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