



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

TOKYO and XIAMEN, February 6th, 2025 -- Riken Genesis Co., Ltd., Amoy Diagnostics Co., Ltd. ("AmoyDx"), and Precision Medicine Asia Co., Ltd. ("PREMIA") today announced that they have submitted a partial change application to the MHLW (Ministry of Health, Labour and Welfare) for the AmoyDx® Pan Lung Cancer PCR Panel (the "AmoyDx PLC Panel") as a companion diagnostic (CDx) for LORBRENA® (Lorlatinib tablets) in Japan.

This application is intended for patients with unresectable advanced or recurrent non-small cell lung cancer (NSCLC) with the ALK fusion gene. LORBRENA® is a product of Pfizer and is marketed worldwide including Japan in 25 mg and 100 mg tablet dosage forms.

If approval is obtained for the additional indication of this product as a CDx for Lorlatinib tablets, it is expected to contribute to expanding treatment opportunities for patients with unresectable advanced or recurrent non-small cell lung cancer (NSCLC) positive for ALK fusion gene.

Engineered using cutting-edge PCR technology, the AmoyDx® PLC Panel enables the simultaneous detection of activation alterations across 11 critical driver genes (*EGFR, ALK, ROS1, KRAS, BRAF, HER2, RET, MET, NTRK1, NTRK2, NTRK3*) and identifies actionable mutations in seven of these genes (*EGFR, ALK, ROS1, BRAF, MET, KRAS, RET*) directly linked to sixteen targeted NSCLC therapies.

"If this application is approved in the future, the AmoyDx® PLC Panel can be used as a CDx to identify advanced NSCLC patients with ALK fusion for treatment with Lorlatinib, thereby expanding their therapeutic options." said Kenji Iwakabe, President and Chief Executive Officer of Riken Genesis, Li-Mou Zheng, Ph.D., Founder and Chairman of AmoyDx and Wenn Sun, Ph.D., Founder and President of PREMIA.

About AmoyDx PLC Panel:

(1) Product name	AmoyDx® Pan Lung Cancer PCR Panel
(2) Approval No.	30300EZX00069000
(3) Purpose of use	<p>Detection of <i>EGFR</i> gene mutations, <i>ALK</i> fusion genes, <i>ROS1</i> fusion genes, <i>BRAF</i> gene mutations, <i>MET</i>ex14 skipping mutations, <i>KRAS</i> gene mutations and <i>RET</i> fusion genes in nucleic acids extracted from cancer tissue.</p> <p>Used as an adjunct to determine the indications of the following sixteen antineoplastic agents for patients with NSCLC.</p> <ul style="list-style-type: none"> • <i>EGFR</i> gene mutation Gefitinib, Erlotinib hydrochloride, Afatinib maleate and Osimertinib mesylate • <i>ALK</i> fusion genes Crizotinib, Alectinib hydrochloride and Brigatinib • <i>ROS1</i> fusion genes Crizotinib, Entrectinib and Repotrectinib • <i>BRAF</i> V600E mutation Combined administration of Dabrafenib mesylate and Trametinib dimethyl sulfoxide • <i>MET</i> exon 14 skipping mutations Tepotinib hydrochloride hydrate, Capmatinib hydrochloride hydrate and Gumarontinib hydrate • <i>KRAS</i> G12C mutation Sotorasib • <i>RET</i> fusion gene Selpercatinib
(4) Testing method	Real-time PCR
(5) Sample	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.

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

Contacts:

Tatsuro Saito

General Manager, Marketing department

Tel: +81-3-5759-6042

info2@rikengenesis.jp



Robson Ee

Senior Director, International Business.

Info@amoydiagnostics.com



Vivian Liu

Director, Corporate Operations

Tel: 852-3978-2288

vliu@premia-inc.com

