AmoyDx® Pan Lung Cancer PCR Panel Approved in Japan as a Drug-agnostic Companion Diagnostic for *EGFR* Gene Mutations

TOKYO and XIAMEN, April 28, 2026 — 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 a partial change to the manufacturing and marketing authorization of the AmoyDx® Pan Lung Cancer PCR Panel (the "AmoyDx® PLC Panel") in Japan.

With this approval, the AmoyDx® PLC Panel can be used as a Drug-agnostic Companion Diagnostic (CDx) [*1] to support treatment selection across *EGFR* molecular targeted drugs approved for patients with non-small cell lung cancer (NSCLC) harboring *EGFR* gene mutations.

The AmoyDx® PLC Panel is based on real-time PCR, which covers seven key driver genes associated with NSCLC; *EGFR*, *ALK*, *ROS1*, *BRAF*, *MET*, *KRAS*, and *RET*. With this approval, the Panel can support drug-agnostic use for *EGFR* molecular target drug selection beyond its prior role as a companion diagnostic individually approved for each antineoplastic agent targeting *EGFR* gene mutations, and is expected to contribute to expanded treatment opportunities for patients with NSCLC.

"With this approval, the AmoyDx® PLC Panel can now be used to support treatment selection across multiple therapies targeting *EGFR* gene mutations in patients with NSCLC, reflecting the evolving regulatory framework for companion diagnostics and contributing to the advancement of precision medicine," said Yuko Oi, President and CEO of Riken Genesis; Li-Mou Zheng, Ph.D., Founder and Chairman of AmoyDx; and Vivian Liu, President and CEO of PREMIA.

[Notice]

*1 **Drug-agnostic Companion Diagnostics (CDx)** :

Based on the "Notification on Handling of In Vitro Diagnostics and Medical Device Products Aiming for Drug-agnostic Companion Diagnosis" (PSEHB/PED Notification No. 0331-1, PSEHB/MDED Notification No. 0331-1, PSEHB/PSD Notification No. 0331-1, dated March 31, 2022) (hereinafter referred to as "Drug-agnostic Use Notification"), products that meet the following 3 requirements.

-Requirement (1) More than one CDx product with the same intended use (i.e. the target disease (cancer type in the case of malignant tumors), biomarker and specimen type) is approved.

-Requirement (2) Therapeutic product(s) for which each CDx product is approved to be used as aid in identifying the eligible patients for treatment is (are) different.

-Requirement (3) It is considered scientifically reasonable to use the test results of any of the CDx products interchangeably to identify the eligible patients for treatment with relevant therapeutic products

About AmoyDx PLC Panel:

(1) Product name	AmoyDx® Pan Lung Cancer PCR Panel
(2) Approval No.	30300EZX00076000
(3) Purpose of use	Detection of *EGFR* gene mutations, *ALK* fusion genes, *ROS1* fusion genes, *BRAF* gene mutations, *MET*ex14 skipping mutations, *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 twenty antineoplastic agents for patients with NSCLC. ・***EGFR* mutations** Molecularly targeted drugs for *EGFR* ・***EGFR* exon 20 insertion mutation** Amivantamab (genetically engineered) (Drugs containing amivantamab (genetically engineered) are also covered) ・***ALK* fusion genes** Crizotinib, Alectinib hydrochloride, Brigatinib and Lorlatinib ・***ROS1* fusion genes** Crizotinib, Entrectinib, Repotrectinib and Taletrectinib adipate ・***BRAF* V600E mutation** Combined administration of Dabrafenib mesylate and Trametinib dimethyl sulfoxide ・***MET* exon 14 skipping mutations** Tepotinib hydrochloride hydrate, Capmatinib hydrochloride hydrate and Gumarontinib hydrate ・***KRAS* G12C mutation** Sotorasib ・***RET* 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.

***2 *EGFR* molecular targeted drugs**

Reports on the Drug-agnostic Companion Diagnostic and information on *EGFR* molecular target drugs for which indications can be determined using cross-classification CDx are available on the following website; https://www.pmda.go.jp/english/rs-sb-std/rs/0027.html

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 offers 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 26,000 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 and with sites planned for Indonesia and the Philippines in 2026. For more information, please visit www.premia-inc.com

Contacts:

Atsushi Tsuchiya

General Manager, Marketing department

Tel: +81-3-5759-6042

info2@rikengenesis.jp

Yash Nahata

Senior Director, International Business.

Info@amoydiagnostics.com

Vivian Liu

President and CEO

Tel: +81-3-5403-5973

info@premia-inc.com