AmoyDx® Pan Lung Cancer PCR Panel submission for regulatory approval in Japan for the additional indication of Amivantamab in combination with chemotherapy

TOKYO and XIAMEN, October 8, 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") for the additional indication of Amivantamab in combination with chemotherapy in Japan.

This application is intended for patients with unresectable advanced or recurrent non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (*EGFR*) exon 20 insertion mutation in addition to the already approved (*EGFR*) exon 19 deletion or exon 21 L858R substitution mutation. Amivantamab is marketed by Johnson & Johnson, available worldwide including Japan. If approval is obtained for the additional indication of this product as a follow-on companion diagnostic (CDx) for Amivantamab plus chemotherapy, it is expected to contribute to expanding treatment opportunities for patients with unresectable advanced or recurrent non-small cell lung cancer (NSCLC) positive for *EGFR* gene exon20 insertion.

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 19 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.

"If this application is approved in the future, the AmoyDx® PLC Panel can be used as a CDx to identify advanced NSCLC patients with EGFR exon20 insertion mutation for treatment with Amivantamab plus chemo, 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.	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 19 antineoplastic agents for patients with NSCLC. ・***EGFR* gene mutation** Gefitinib, Erlotinib hydrochloride, Afatinib maleate, Osimertinib mesylate and Amivantamab plus Lazertinib mesylate hydrate ・***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.

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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