

**AmoyDx[®] Pan Lung Cancer PCR Panel submission for
regulatory approval in Japan for the additional indication of
Amivantamab plus Lazertinib combination Therapy**

TOKYO and XIAMEN, March 28, 2025 -- Riken Genesis Co., Ltd., and Amoy Diagnostics Co., Ltd. (“AmoyDx”) 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 plus Lazertinib combination Therapy 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 19 deletion or exon 21 L858R substitution mutation. Amivantamab and lazertinib are marketed by Johnson & Johnson under licensed rights, available worldwide including Japan. In Korea, lazertinib is marketed by Yuhan Corporation.

If approval is obtained for the additional indication of this product as a follow-on companion diagnostic (CDx) for Amivantamab plus Lazertinib, 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 common mutation.

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 common EGFR mutation for treatment with Amivantamab plus Lazertinib, thereby expanding their therapeutic options.” said Kenji Iwakabe, President and Chief Executive Officer of Riken Genesis and Li-Mou Zheng, Ph.D., Founder and Chairman of AmoyDx.

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.

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