



**AmoyDx<sup>®</sup> Pan Lung Cancer PCR Panel  
Approved in Japan as a Companion Diagnostic  
for selpercatinib RET fusion positive NSCLC**

TOKYO and XIAMEN, March 27<sup>th</sup>, 2023 -- 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<sup>®</sup> Pan Lung Cancer PCR Panel (the “AmoyDx PLC Panel”) as a companion diagnostic for *RET* fusion-positive non-small cell lung cancer (“NSCLC”), for selpercatinib capsules 40 mg and 80 mg .

The AmoyDx<sup>®</sup> PLC Panel is based on polymerase chain reaction (PCR) technology and can simultaneously evaluate the presence of activation alterations in 11 driver genes (EGFR/ ALK/ ROS1/ KRAS/ BRAF/ HER2/ RET/ MET/ NTRK1/ NTRK2/ NTRK3 genes) when all genes on the panel are approved as companion diagnostics. The AmoyDx<sup>®</sup> PLC Panel has received approval for the identification of activating alterations in seven driver genes (EGFR, ALK, ROS1, BRAF, MET exon 14 skipping, KRAS, and RET) for twelve (12) associated targeted therapies in NSCLC. With its high sensitivity and short turnaround time, the AmoyDx<sup>®</sup> PLC Panel is expected to be an important clinical diagnostic in guiding treatment opportunities for NSCLC patients.

“With this approval, the AmoyDx<sup>®</sup> PLC Panel can now be used to identify *RET* fusion-positive NSCLC patients for treatment with selpercatinib, thereby expanding their therapeutic options. We look forward to developing and commercializing additional, new therapy options for Japanese patients,” said Kenji Iwakabe, President and Chief Executive Officer of Riken Genesis, Li-Mou Zheng, Ph.D., Founder and Chief Executive Officer 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 EGFR gene mutations, ALK fusion gene, ROS1 fusion gene, BRAF gene mutations, MET exon 14 skipping mutation, KRAS gene mutations and RET fusion genes in nucleic acids extracted from cancer tissue</p> <p>Used as an adjunct to determine the indications of the following nine antineoplastic agents for patients with NSCLC.</p> <ul style="list-style-type: none"><li>• <b>EGFR gene mutation</b> Gefitinib, Erlotinib hydrochloride, Afatinib maleate, Osimertinib mesylate</li><li>• <b>ALK fusion gene</b> Crizotinib, Alectinib hydrochloride, and Brigatinib</li><li>• <b>ROS1 fusion gene</b> Crizotinib</li><li>• <b>BRAF V600E mutation</b> Combined administration of Dabrafenib mesylate and Trametinib dimethyl sulfoxide</li><li>• <b>MET exon 14 skipping mutation</b> Tepotinib</li><li>• <b>KRAS G12C mutation</b> Sotorasib</li><li>• <b>RET fusion gene</b> Selpercatinib</li></ul>
(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](http://www.rikengenesis.jp)

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

Amoy Diagnostics Co., Ltd. is a pioneer and globally leading company in the field of molecular diagnostics for precision oncology, focusing on companion diagnostics product development and commercialization. A rich product portfolio has been established with more than 20 products approved by China NMPA, EU authority, Japan MHLW, South Korea MFDS, etc. Patients in more than 60 countries are benefiting from AmoyDx products. With multiple technological platforms and full capability for companion diagnostics product development and commercialization, AmoyDx has become an important diagnostics partner of many pharmaceutical companies over the globe. For more information, please visit [www.amoydiagnostics.com](http://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 19,000 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](http://www.premia-inc.com)

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