AmoyDx® Pan Lung Cancer PCR Panel Approved in Japan as a Companion Diagnostic for Haiyitan® tablets (gumarontinib hydrate)

TOKYO and XIAMEN, July 25th, 2024 -- 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® Pan Lung Cancer PCR Panel (the "AmoyDx PLC Panel") as a companion diagnostic for Haiyitan® (gumarontinib hydrate), a product of Haihe Biopharma K.K. Haiyitan® in 50 mg tablet form, was approved by MHLW in June 2024 for patients with unresectable advanced or recurrent non-small cell lung cancer (NSCLC) with *MET* exon 14 (*MET*ex14) skipping mutations.

Engineered using cutting-edge PCR technology, the AmoyDx® 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*ex14 skipping, *KRAS*, *RET*) directly linked to sixteen targeted NSCLC therapies. This approval signifies a transformative step forward in precision cancer treatment, combining rapid, sensitive detection with the potential to significantly enhance patient outcomes.

"With this approval, the AmoyDx® PLC Panel can be used to identify advanced NSCLC patients harboring alterations leading to *MET*ex14 skipping for treatment with gumarontinib hydrate, 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	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. Used as an adjunct to determine the indications of the following fifteen antineoplastic agents for patients with NSCLC. ・***EGFR* gene mutation** Gefitinib, Erlotinib hydrochloride, Afatinib maleate and Osimertinib mesylate ・***ALK* fusion gene** Crizotinib, Alectinib hydrochloride and Brigatinib ・***ROS1* fusion gene** Crizotinib and Entrectinib ・***BRAF* V600E mutation** Combined administration of Dabrafenib mesylate and Trametinib dimethyl sulfoxide ・***MET* exon 14 skipping mutation** Tepotinib, Capmatinib 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 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

Contacts:

Tatsuro Saito
General Manager, Marketing department
Tel: +81-3-5759-6042
info2@rikengenesis.jp

Robson Ee
Director, International Business
Info@amoydiagnostics.com

Vivian Liu
Director, Corporate Operations
Tel: 852-3978-2288
vliu@premia-inc.com