AmoyDx® Pan Lung Cancer PCR Panel Receives MHLW Approval as Companion Diagnostic for 9 Targeted Therapies for Use in Patients with Advanced Non-Small Cell Lung Cancer

TOKYO and XIAMEN, June 30, 2021 (GLOBE NEWSWIRE) -- Riken Genesis Co., Ltd., Amoy Diagnostics Co., Ltd., ("AmoyDx") and Precision Medicine Asia Co., Ltd. ("PREMIA") today announced that the AmoyDx® Pan Lung Cancer PCR Panel (the "AmoyDx PLC Panel"), an in vitro diagnostic reagent developed as a companion diagnostic for multiple anti-cancer agents, was approved by Ministry of Health, Labour and Welfare (MHLW) for production and marketing in Japan on June 25, 2021.

The AmoyDx® PLC Panel is based on polymerase chain reaction (PCR) technology, and can simultaneously evaluate the presence of 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® PLC Panel has received approval for four driver genes (EGFR, ALK, ROS1, and BRAF) for nine associated targeted therapies in NSCLC. With its high sensitivity and short turnaround time, The AmoyDx® PLC Panel is expected to be an important clinical diagnostic in guiding treatment opportunities for NSCLC patients.

"We are pleased to collaborate with AmoyDx and PREMIA in obtaining approval of the AmoyDx® PLC Panel in Japan. We will continue to make every effort so that it can be delivered to patients and clinicians in Japan as soon as possible." said Kenji Iwakabe, president and chief executive officer of Riken Genesis.

"Both AmoyDx and Riken Genesis have been our long term partners, previously collaborating on the approval of the single ROS1 CDx for Xalkori in Japan. It is extremely gratifying to have this opportunity to collaborate again on this fit-for-purpose test that offers accurate and timely diagnosis of actionable genetic alterations, and designed to lead to better treatment options for patients," said Wenn Sun, president and founder of PREMIA.

"The approval of the AmoyDx PLC Panel marks the time that Japanese patients will have direct access to a locally administered multi-gene PCR CDx with a very short turnaround time from sample to diagnosis." said Li-Mou Zheng, Ph.D., Founder and CEO of AmoyDx. "Our goal at AmoyDx has always been to develop the highest regulatory-grade cancer diagnostics which have greatest impact in a clinical setting. We are grateful for this collaboration with our regional partners Riken Genesis and PREMIA to help expand access to timely therapy options for Japanese patients."

About AmoyDx PLC Panel:

(1) Product name	AmoyDx® Pan Lung Cancer PCR Panel
(2) Approval No.	30300EZX00059000
(3) Purpose of use	Detection of EGFR gene mutations, ALK fusion gene, ROS1 fusion gene, and BRAF gene mutations in nucleic acids extracted from cancer tissue Used as an adjunct to determine the indications of the following nine antineoplastic agents for patients with NSCLC • **EGFR gene mutation** Gefitinib, Erlotinib hydrochloride, Afatinib maleate, Osimertinib mesylate • **ALK fusion gene** Crizotinib, Alectinib hydrochloride, and Brigatinib • **ROS1 fusion gene** Crizotinib • **BRAF V600E mutation** Combined administration of Dabrafenib mesilate and Trametinib dimethyl sulfoxide
(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 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 twenty f 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.

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 Japan's nation-wide, clinical-genomic lung cancer registry, the only such database in Asia. The registry currently includes more than 13,000 patients and allows an efficient patient identification process for clinical trial enrollment through participation by more than 200 hospitals in Japan and Taiwan, with the expected addition of hospitals in Southeast Asia during 2021. For more information, please visit www.premia-inc.com

Contacts:

Yuko Oi
General Manager, Marketing department
Tel: +81-5759-6042
yuko.oi@rikengenesis.jp
rikengenesis

Paul Huang
Director, International business
Tel: + 86-592-6806058
paulhuang@amoydx.com
AmoyDx
Better life with AmoyDx

Vivian Liu
Director, Corporate Operation
Tel: 852-3978-2288
vliu@premia-inc.com
PREMIA
PRECISION MEDICINE ASIA