

AmoyDx[®] Pan Lung Cancer PCR Panel
Approved in Japan as a Companion Diagnostic for
HERNEXEOS[®] (Zongertinib)

TOKYO and XIAMEN, August 17th, 2026 — Riken Genesis Co., Ltd. and Amoy Diagnostics Co., Ltd. (“AmoyDx”) 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 (CDx) for HERNEXEOS[®] in Japan.

HERNEXEOS[®], manufactured and marketed by Nippon Boehringer Ingelheim, is indicated for the treatment of patients with Unresectable, advanced or recurrent *HER2* mutation positive non-small cell lung cancer (NSCLC) that has progressed after cancer chemotherapy.

Developed using cutting-edge PCR technology, the AmoyDx[®] PLC Panel is a multiplex PCR gene detection test approved in Japan as a companion diagnostic for zongertinib. Within its approved intended use in Japan, the test will enable the simultaneous detection of actionable alterations in eight key driver genes: *EGFR*, *ALK*, *ROS1*, *BRAF*, *MET* exon 14 skipping, *KRAS*, *RET* and *HER2*, which are associated with more than 20 targeted therapies for NSCLC. The panel additionally provides reference information on *NTRK1*, *NTRK2*, and *NTRK3*, which are not included in its approved intended use in Japan. This approval marks a significant advancement in precision oncology, offering rapid and sensitive mutation detection that can substantially improve patient outcomes.

“With this approval, the AmoyDx[®] PLC Panel is now approved for use as a CDx to identify patients with unresectable advanced or recurrent *HER2* mutation positive NSCLC that has progressed after cancer chemotherapy who may benefit from treatment with zongertinib, thereby expanding their therapeutic options,” said Yuko Oi, President and CEO of Riken Genesis; and Li-Mou Zheng, Ph.D., Founder and Chairman of AmoyDx.

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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