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Qiagen receives Japanese PMDA approval for cancer diagnostic kit

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This marks the first companion diagnostic approval for QIAGEN in Japan.

QIAGEN N.V. recently announced that the Japanese Pharmaceuticals and Medical Device Agency (PMDA) has approved the therascreen EGFR RGQ PCR Kit to allow its use as a companion diagnostic with Pfizer's VIZIMPRO (dacomitinib) for EGFR gene mutation-positive, inoperable or recurrent non-small cell lung cancer.

The therascreen EGFR RGQ PCR Kit is registered in more than 40 countries globally. This marks the first companion diagnostic approval for QIAGEN in Japan.

"As precision medicine becomes the standard of care in oncology, we are pleased to provide benefits to more lung cancer patients with our clinically proven therascreen EGFR RGQ PCR Kit. Our collaboration with Pfizer has made great strides already and will continue to improve personalized healthcare for patients around the world," said Jonathan Arnold, Vice President, Head of Oncology and Precision Diagnostics for QIAGEN. "In addition to detecting a comprehensive panel of EGFR mutations, the therascreen EGFR kit offers laboratories an efficient workflow on the Rotor-Gene Q MDx, the real-time PCR module in our widely-used QIAsymphony family of instruments."