

QIAGEN launches first FDA-approved tissue companion diagnostic to identify the *KRAS* G12C mutation in NSCLC tumours and expand precision medicine options in lung cancer

- The *therascreen*® *KRAS* RGQ PCR Kit receives U.S. regulatory approval from FDA for expanded scope to include use in guiding treatment with the newly approved therapy LUMAKRAS™ (sotorasib) from Amgen
- First tissue-based companion diagnostic to identify the *KRAS* G12C mutation in NSCLC
- Test will be available under QIAGEN's Day One Lab Readiness program

Germantown, Maryland, and Hilden, Germany, May 28, 2021 – QIAGEN N.V. (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced the launch of an expanded scope of companion diagnostic (CDx) claims for the *therascreen*® *KRAS* RGQ PCR Kit (*therascreen* *KRAS* Kit) after it received U.S. regulatory approval as a companion diagnostic to aid in the identification of non-small cell lung cancer (NSCLC) patients that may be eligible for treatment with LUMAKRAS™ (sotorasib), a newly approved therapy developed and marketed by Amgen Inc. (AMGN).

The *therascreen* *KRAS* Kit is the first companion diagnostic test to obtain premarket approval from the U.S. Food and Drug Administration (FDA) for use to identify the *KRAS* G12C mutation in samples of NSCLC tumour tissue. *KRAS* is one of the most frequently occurring mutation in this form of cancer, and is estimated to be present in up to 13% of cases of the disease. Until now *KRAS* G12C has not been actionable, and in fact had only previously been linked with resistance to therapies. The real-time qualitative PCR kit is used with the Rotor-Gene Q MDx instrument, a member of the modular QIASymphony family of automation solutions, and builds upon QIAGEN's nine years of experience in *KRAS* CDx test development and commercialization.

"We are pleased to announce this significant expansion in the scope of FDA-approved CDx claims for the *therascreen* *KRAS* Kit" said Jean-Pascal Viola, Senior Vice President and Head of QIAGEN's Molecular Diagnostics Business Area. "This new approval further expands our market-leading *therascreen* portfolio of companion diagnostic tests, and illustrates our determination to support the delivery of the latest innovations in precision healthcare to patients with NSCLC, for whom every new treatment option is extremely welcome."

"With advances in precision medicine, biomarker testing is critical for patients with non-small cell lung cancer because it informs treatment options during the course of their disease. It is important that patients and their healthcare providers know that *KRAS* G12C is now an actionable mutation and start testing for it," said Darryl Sleep, M.D., chief medical officer and senior vice president of Global Medical at Amgen. "With the approval of QIAGEN's companion diagnostic for LUMAKRAS, patients and clinicians will have more options and flexibility for biomarker testing."

Up to 13% of NSCLC-patients may have *KRAS* G12C positive tumours and hence be potentially eligible for treatment with LUMAKRAS™. To accelerate identification of these patients, following the FDA approval of this test QIAGEN is making testing of NSCLC tumour tissue samples with the *therascreen* *KRAS* Kit available immediately at leading laboratories across the U.S, through QIAGEN's Day-One Lab Readiness program for Precision Medicine.

QIAGEN's *therascreen* *KRAS* Kit was used to support the CodeBreak 100 clinical trial of sotorasib and the expansion of the Kit's CDx claims to include identification of the *KRAS* G12C mutation in NSCLC samples has been co-approved with LUMAKRAS by the FDA. The Amgen drug is a new inhibitor of the

G12C-mutated form of the KRAS (Kirsten rat sarcoma) protein, and is the first-in-class drug approved for treatment of this form of cancer. Further details about the Kit are available at www.qiagen.com/KRAS.

QIAGEN's Day-One Lab Readiness program builds on the FDA's modernized regulatory approach to benefit patients by accelerating the launch of advanced diagnostics. An updated list of U.S. laboratories offering testing of NSCLC samples for the KRAS G12C mutation using the *therascreen* KRAS test is available at www.qiagen.com/KRAS-lab-finder.

QIAGEN is a pioneer in Precision Medicine and the global leader in collaborations with pharmaceutical and biotechnology companies to co-develop companion diagnostics, which detect clinically relevant genetic abnormalities to provide insights that guide clinical decision-making in diseases such as cancer. QIAGEN has an unmatched depth and breadth of technologies from next-generation sequencing (NGS) to polymerase chain reaction (PCR) for companion diagnostic development. QIAGEN now has ten PCR based companion diagnostic indications that are FDA approved, including *therascreen* EGFR for non-small cell lung cancer, *therascreen* KRAS for colorectal cancer, *therascreen* FGFR for urothelial cancer, *therascreen* PIK3CA for breast cancer based on tissue or plasma samples and the *therascreen* BRAF kit for colorectal cancer.

Currently, QIAGEN is working under master collaboration agreements with more than 25 companies to develop and commercialize companion diagnostic tests for their drug candidates – a deep pipeline of potential future products to advance Precision Medicine for the benefit of patients. The *therascreen* KRAS Kit co-approval with LUMAKRAS™ marks the tenth FDA approval of a therapy partnered with a QIAGEN companion diagnostic assay.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare), Applied Testing (primarily forensics), Pharma (pharma and biotech companies) and Academia (life sciences research). As of March 31, 2020, QIAGEN employed approximately 5,700 people in over 35 locations worldwide. Further information can be found at <http://www.qiagen.com>.

Forward-Looking Statement

Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For further information, please refer to

the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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