



## Oncocyte Selected as New “Day One” Launch Site for QIAGEN’s Companion Diagnostics Test to Identify Patients for Amgen’s Newly FDA-Approved Drug LUMAKRAS (Sotorasib) For Advanced Stage Lung Cancer

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*Oncocyte’s Nashville CLIA lab now offers the Therascreen RGQ KRAS test*

*Addition of the Therascreen RGQ KRAS test strengthens Oncocyte’s one-stop shop offering for lung cancer treatment decisions*

IRVINE, Calif., June 01, 2021 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NASDAQ: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, has signed an agreement with QIAGEN N.V. to support the launch of Amgen’s LUMAKRAS (Sotorasib). QIAGEN is the leading global provider of “Sample-to-Insight” solutions that enable customers to gain valuable molecular insights from tissue samples. LUMAKRAS™ (Sotorasib) is approved for patients with KRAS G12C-mutated locally advanced stage or metastatic Non-Small Cell Lung Cancer (NSCLC). QIAGEN was selected by Amgen to develop a tissue-based companion diagnostic (CDx) for the new therapy with indications in lung cancer, and QIAGEN selected Oncocyte as a “Day One” clinical lab for offering the QIAGEN *Therascreen* RGQ KRAS CDx test.

NSCLC accounts for approximately 84 percent of the 2.2 million new lung cancer diagnoses each year worldwide, including approximately 236,000 new cases in the U.S. Approximately 80% of patients are diagnosed with advanced stage or metastatic cancer. “The QIAGEN CDx for Amgen’s KRAS Inhibitor is a natural extension of Oncocyte’s growing capabilities as a central lab for biopharma, in particular in NSCLC, and complements our proprietary DetermaRx™ and DetermaIO™ tests. This agreement takes us one step closer to achieving our goal of being a one-stop lab, delivering all the relevant information physicians need to make the best treatment decisions for their patients,” said Ron Andrews, President and Chief Executive Officer of Oncocyte. “Our relationship with QIAGEN has been very exciting for the Nashville lab team and further validates our outstanding ability to support pharma in their effort to bring new drugs to market. We are in a terrific position to work closely with QIAGEN’s U.S. sales team to support AMGEN’s new drug launch and drive uptake of that innovative therapy.”

Detecting the G12C protein mutation in NSCLC is a prerequisite for treatment with LUMAKRAS (Sotorasib). NSCLC with this type of mutation comprises 25 percent of all NSCLC cases, and is a well-known unmet clinical need. In addition, the validation of new CDx tests is time consuming and can take up to nine months, emphasizing the importance of Day-One ready programs as new therapies receive approval by the U.S. Food and Drug Administration (FDA). Building on the FDA’s modernized regulatory approach, QIAGEN’s Day-One Lab Readiness program enables molecular diagnostic labs like Oncocyte’s

to begin implementing the activities necessary to prepare for commercial launch of new drugs and in-vitro diagnostics tests once FDA or other local regulatory approval is obtained.

Commenting on the commercial launch, Padma Sundar, Chief Commercial Officer of Oncocyte said, “We are excited to be selected as a companion diagnostic testing site by QIAGEN for the initial launch of their Therascreen test for LUMAKRAS. We now offer DetermaRx and an EGFR test for early-stage patients, and we plan to launch DetermaTx™ and DetermaIO for later stage patients in the second half of this year. Adding this new test from QIAGEN as a Day-One site is a terrific complement to our current menu in lung cancer and further strengthens our position as a leader in lung cancer treatment decisions across the care continuum.”

Amgen and QIAGEN originally initiated their collaboration to develop a tissue-based CDx for investigational cancer treatment with AMG 510, now named LUMAKRAS, which is the first KRAS G12C inhibitor to advance to the clinic targeting the KRAS G12C oncogene, one of the genes most frequently mutated in human cancers.

### **About Oncocyte Corporation**

Oncocyte is a molecular diagnostics company whose mission is to provide actionable answers at critical decision points across the cancer care continuum. The Company, through its proprietary tests and pharmaceutical services business, aims to help save lives and improve outcomes by accelerating and optimizing the diagnosis and treatment of cancer. The Company's tests and services present multiple opportunities to advance cancer care while also driving revenue growth for the Company. Oncocyte launched DetermaRx™, a test that identifies early-stage lung cancer patients who are at high risk for cancer recurrence post-resection and predicts benefit from adjuvant chemotherapy. Oncocyte has also launched DetermaIO™, a gene expression test that assesses the tumor microenvironment to predict response to immunotherapies, as a research use only tool for pharmaceutical and academic clinical trials. To complement DetermaIO™, the Company anticipates launching DetermaTx™ in the second half of 2021 as a test to assess mutational status of a tumor to help identify the appropriate targeted therapy. The Company recently completed the acquisition of Chronix Biomedical Inc. and its TheraSure™ CNI Monitor test, and plans to continue with the development of DetermaMx™ as the Company seeks to expand into the blood-based monitoring market. Oncocyte's pharmaceutical services provide pharmaceutical companies who are developing new cancer treatments a full suite of molecular testing services to support the drug development process.

DetermaRx, DetermaIO, DetermaMx, and DetermaTx are trademarks of Oncocyte Corporation. TheraSure™ is a trademark of Oncocyte's subsidiary Chronix Biomedical, Inc.

### **Oncocyte Forward Looking Statements**

Oncocyte cautions you that this press release contains forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates,” “may,” and similar expressions) are forward-looking statements. These statements include those pertaining to the Amgen's LUMAKRAS (Sotorasib), QIAGEN'S *Therascreen RGQ KRAS test*, our agreement and expected work with QIAGEN, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, the potential impact of COVID-19 on our or our subsidiaries' financial and operational results, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, and the need to obtain third party reimbursement for patients' use of any

diagnostic tests we or our subsidiaries commercialize, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Oncocyte, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Oncocyte's Securities and Exchange Commission filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Oncocyte undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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