Oncocyte Receives Final Pricing Decision for DetermaRx™ Molecular Test for Lung Cancer from Centers for Medicare and Medicaid Services

Sep 09, 2020

Pricing in line with comparable high-value molecular tests for oncology indications

Consistent growth in testing volumes now provides immediate and consistent revenue for Oncocyte

DetermaRx is the only test available today for therapeutic decisions in early stage NSCLC, addressing an estimated global market of $450M - $500M

IRVINE, Calif., Sept. 09, 2020 (GLOBE NEWSWIRE) -- Oncocyte Corporation (NYSE American: OCX), a molecular diagnostics company with a mission to provide actionable answers at critical decision points across the cancer care continuum, today announced that it has received a pricing decision from Centers for Medicare and Medicaid Services (CMS) for DetermaRx™, the Company's treatment stratification test that identifies which early stage lung cancer patients are at high risk for lung cancer recurrence post-surgery. This is the first and only testing available for this indication.

The pricing decision is in line with similar high-value molecular tests in oncology and is within the range of the Company's previously communicated pricing expectations. This CMS pricing decision establishes an immediate path to consistent revenue growth for Oncocyte. In addition, Oncocyte already has begun to receive payment from commercial payers including Blue Shield of California, Cigna and Anthem. The Company believes that the receipt of the final Medicare local coverage determination (LCD) for DetermaRx™, announced on July 20, 2020, and the receipt of this pricing decision, will drive favorable payment decisions from additional commercial payors.

"This CMS pricing decision provides important validation of DetermaRx's ability to improve patient outcomes and healthcare economics," said Ron Andrews, Chief Executive Officer and President of Oncocyte. "We are thrilled to have received a pricing decision in line with our expectations, and we continue to be encouraged by the solid market uptake of the DetermaRx test. Despite the current headwinds created by the COVID-19 pandemic, we are on track to test between 250 to 300 patient samples by year end, which is representative of 100% quarter over quarter growth. With this pricing decision and the continued growth in orders, DetermaRx represents a rapidly growing source of revenue and cash flow for Oncocyte."

Mr. Andrews continued, "Medicare patients account for approximately 70 percent of eligible patients for DetermaRx, and we are pleased to be able to provide this important, potentially life-saving test to Medicare patients at no out-of-pocket cost. We are also excited by the growing support of key opinion leaders, which in combination with the high value pricing, we believe will provide a catalyst to increase our sales efforts around the world to take advantage of our first-mover status in the test's approximately $450M - $500M global market opportunity, subject to pricing and adoption rates. We look forward to

building on this success as we continue to expand the adoption of DetermaRx while also advancing our commercially available for research use test, DetermaIO™, toward clinical use in 2021."

In published clinical studies, patients identified as high risk by DetermaRx who did not receive chemotherapy treatment had a 49% five year disease free survival rate versus a 92% five year disease free survival rate for those who were high risk and received a standard chemotherapy, a significant improvement. Conversely, in these studies, none of the low risk patients received chemotherapy. These low-risk patients reported a 94% five year disease-free survival rate, which suggests that DetermaRx may also help low risk patients avoid the toxic side effects associated with unnecessary chemotherapy.

Physician adoption of DetermaRx has continued to grow throughout 2020 despite the continued challenges associated with the global COVID-19 pandemic. Through August, Oncocyte has onboarded 55 hospitals across the United States, increasing the number of onboarded accounts by 60 percent since the second quarter of 2020. In addition, the test is already included in the diagnostic ordering systems of several large community health center networks, including Florida Cancer Specialists & Research Institute. DetermaRx test volume has grown rapidly since it was commercialized early in 2020, and the Company projects third quarter volumes to grow approximately 100 percent compared to second quarter volumes. The physician reorder rate has remained consistently high, and was approximately 60 percent through August.

The table below summarizes the hospital adoption, physician adoption and volume growth of DetermaRx since its commercialization early in 2020. It is provided for illustrative purposes only. Revenue recognition and cash payments to Oncocyte are determined by accounting principles and contractual agreements, and therefore do not necessarily correlate with volume statistics during individual quarters.

	Q1 2020	Q2 2020	July and August
Cumulative sites onboarded	14	36	55
Physician reorder rate	Not Tracked	60%	~60%
Billable Patients tested	33	64	Tracking to 100% QoverQ growth

About DetermaRx

DetermaRx is the first and only predictive test for the identification of patients with Stage I-IIA non-squamous non-small cell lung cancer who are at high risk for recurrence following surgery and who may benefit from adjuvant chemotherapy.

There are an estimated 40,000 Stage I and IIA non squamous NSCLC patients in the United States each year. With an estimated 350,000 patients potentially eligible for the test on an annual basis globally, the Company believes there may be a total addressable market opportunity of approximately $450M to $500 million for the test, subject to pricing and adoption rates. Oncocyte recently announced that it has agreements in place for the distribution of the test in India, the Middle East, Africa and Israel.

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, with the goal of improving patient outcomes by accelerating and optimizing diagnosis and treatment. The Company recently launched DetermaRx™, a treatment stratification test that enables the identification of early-stage lung cancer patients at high risk for recurrence post-resection, allowing them to be treated when their cancer may be more responsive to adjuvant chemotherapy. Oncocyte is also developing DetermaIO™, a gene expression test that identifies patients more likely to respond to checkpoint immunotherapies.

DetermaRx and DetermaIO are trademarks of Oncocyte Corporation.

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 commercial launch of DetermaRx, development of DetermaIO, unexpected expenditures or assumed liabilities or other unanticipated difficulties resulting from acquisitions, implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for Oncocyte, along with 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 financial and operational results, risks inherent in the development and/or commercialization of potential 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 our supply chain, the need and ability to obtain future capital, maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients’ use of any diagnostic tests we commercialize, and risks inherent in acquisitions such as failure to realize anticipated benefits, unexpected expenditures or assumed liabilities, unanticipated difficulties in conforming business practices including accounting policies, procedures and internal controls, greater than estimated allocations of resources to develop and commercialize technologies, or 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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Source: Oncocyte Corporation