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Labcorp, QIAGEN announce companion diagnostic for metastatic breast cancer

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Piqray, in combination with fulvestrant, and therascreen PIK3CA PCR mutation analysis assay received approval from the U.S. Food and Drug Administration (FDA) on May 24, 2019.

LabCorp, a leading global life sciences company that is deeply integrated in guiding patient care has announced a new companion diagnostic called *therascreen* PIK3CA PCR mutation analysis, which is now available through LabCorp and its Integrated Oncology specialty laboratory.

The test, developed by QIAGEN, a world leader in Sample to Insight solutions for molecular testing, identifies whether a patient has the specific gene mutation that is a prerequisite for treatment with Piqray (aplelisib), a new therapy from Novartis for the treatment of postmenopausal women and all men with hormone receptor-positive, human epidermal growth factor receptor-2 negative (HR+/HER2-), PIK3CA-mutated, advanced or metastatic breast cancer, as detected by an FDA-approved test following progression on or after an endocrine-based regimen. Piqray, in combination with fulvestrant, and*therascreen* PIK3CA PCR mutation analysis assay received approval from the U.S. Food and Drug Administration (FDA) on May 24, 2019. LabCorp is able to make the test available quickly after FDA approval through its participation in QIAGEN's Day-One Lab Readiness program, under which LabCorp began test validation and development of operating protocols while the test was under regulatory review and is therefore able to make the test available to patients just two weeks after approval.

"Piqray (aplelisib), from Novartis, is the first and only therapy for HR+/HER2- advanced breast cancer with a PIK3CA mutation," said Marcia Eisenberg, PhD, chief scientific officer, LabCorp Diagnostics. "Through our collaboration with QIAGEN and participation in their Day-One Lab Readiness Program, LabCorp is able to quickly make new companion diagnostics available to help identify patients who are eligible for the most innovative treatments, individualized to their disease. Enabling patients to gain access to new treatments faster, furthering LabCorp's mission to improve health and improve lives."

The American Cancer Society estimates that in 2019, there will be 268,600 new cases of breast cancer and approximately 70% will be HR+/HER2-. For patients with HR+/HER2-advanced breast cancer, approximately 40% have the PIK3CA mutation, which is associated with tumor growth, resistance to endocrine treatment and a poor overall prognosis.

The availability of this new companion diagnostic demonstrates LabCorp's continued leadership in companion diagnostics and precision medicine, with the industry's leading portfolio of tests that identify personalized characteristics for each patient, and help guide more specific treatment choices. For more than 20 years, long before they joined forces, LabCorp Diagnostics and Covance Drug Development have been involved in the development, commercialization and launch of companion and complementary diagnostics, and together they have supported more FDA-approved companion diagnostics than any other company. Since 2018, the Company has collaborated with more than 75 clients on over 150 projects targeted at the development of new companion diagnostics.

LabCorp joined QIAGEN's Day-One Lab Readiness program in early 2019. In addition to the *therascreen* PIK3CA PCR mutation analysis assay announced, LabCorp also recently launched the *therascreen* FGFR mutation assay by RGQ RT-PCR for bladder cancer through the Day-One program. Multiple other assays, including novel companion diagnostics for lung, colorectal, bladder and other cancers, and eventually pan-tumor disease areas, are currently in LabCorp's Day-One Lab Readiness pipeline.

"The promise of precision medicine is delivering the right drug to the right patient at the right time, and it can be an absolute game-changer for cancer patients," said Dr. Dot Adcock, chief medical officer, LabCorp Diagnostics. "LabCorp's close relationships with numerous hospitals, health systems, cancer clinics and oncologists across the U.S. enables us to provide genetic testing for an increasing number of patients, helping them to more quickly access the targeted therapy that is right for them. We're seeing extraordinary breakthroughs in precision medicine in oncology patients, and it's exciting to be a part of these advances in patient care."