CIRCULOGENE

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CIRCULOGENE to Launch Comprehensive, 20-Fusion NTRK Biomarker Testing in Early 2019

Proprietary, cfRNA-enriched, real-time PCR testing rapidly identifies all patients with NTRK fusion-positive cancers potentially eligible for new TRK inhibitor targeted therapy

BIRMINGHAM, Ala. – CIRCULOGENE, advancing precision medicine through personalized molecular genetics testing, announced today it will introduce neurotrophic receptor tyrosine kinase (NTRK) gene fusion testing in early 2019. Upon completion of final validation testing, CIRCULOGENE's expanding proprietary technology platform will enable oncologists and pathologists to rapidly and thoroughly identify NTRK fusion-positive patients.

Unlike other NTRK tests that can miss qualified patients by targeting only three to six fusions, CIRCULOGENE's cfRNA-enriched, real-time PCR testing covers 20 NTRK fusions – the most comprehensive NTRK test in the industry. This is particularly important for cancers with a less than one percent NTRK-positive rate.

"This marks another major advance in precision medicine and an opportunity for our highly accurate, automated and scalable, cell-free DNA and RNA technology to help fight these previously untreatable cancers," said CIRCULOGENE CEO Mike Mullen. "With our industry-leading turnaround time, complete testing results will be available to physicians and their patients within one week, and all from a single 4 mL tube of blood, no matter which test or how many tests they order. Reducing the time from testing to targeted therapy while maintaining a high degree of sensitivity, especially in virulent cancers, may help reduce morbidity."

TRK inhibitor Vitrakvi® (larotrectinib) is a new FDA-approved therapy for the treatment of adult and pediatric patients with TRK fusion solid tumors whose cancer has spread after treatment, who have no satisfactory alternative treatments or who would experience severe complications by undergoing surgery.

"This is precision oncology, where a cancer treatment is approved based on a common biomarker rather than where in the body the cancer is located – a tumor-agnostic approach," said CIRCULOGENE Chief Scientific Officer Chen-Hsiung Yeh, Ph.D. "Genomic profiling on a cancer patient is then conducted to identify that biomarker, providing actionable information for evidence-based treatment options. That's where our rapid, precise and comprehensive test comes in, allowing physicians to identify cancer patients who have the NTRK biomarker."

NTRK testing is for patients with advanced solid tumors for the purpose of identifying any NTRK1, NTRK2 or NTRK3 gene fusion – a hybrid of two genes that can promote uncontrolled cell growth across multiple cancers.

Although TRK fusion cancers are rare, NTRK fusions occur in more than 90 percent of patients with infantile fibrosarcoma, according to the most recent data. Thyroid cancer has the second

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largest incidence of NTRK fusions, with two to 12 percent of patients exhibiting them, followed by 10 percent of high-grade gliomas among children, according to the data.

The FDA's accelerated approval of larotrectinib represents the first-ever approval of a cancer therapy based solely on a specific genetic mutation and just the second FDA approval of a tumor-agnostic therapy. PD-L1 checkpoint inhibitor Keytruda® (pembrolizumab), first approved to treat specific non-small-cell lung cancers, was approved in 2017 to treat patients with MSI-H and dMMR biomarkers across multiple cancer types. CIRCULOGENE announced genomic profiling for MSI-H and dMMR cancers shortly thereafter.

CIRCULOGENE molecular diagnostics capabilities include DNA, RNA, somatic and hereditary testing, as well as a complete package of immunotherapy testing, including PD-L1 and MSI, plus NTRK gene fusion testing. CIRCULOGENE is the only company that provides circulating DNA, RNA and MSI cancer immunotherapy testing from a single tube of blood.

CIRCULOGENE is Clinical Laboratory Improvement Amendments (CLIA) certified and provides biomarker testing for a broad range of cancers, allowing physicians to match results to specific drugs and clinical trials. For more information visit our website, connect with us on LinkedIn, Facebook and Twitter, email us at info@circulogene.com or call 855-614-7083. Clinicians interested in ordering tests may visit the Contact page on CIRCULOGENE's website.

About CIRCULOGENE

Headquartered in Birmingham, Ala., CIRCULOGENE is an innovative molecular diagnostics company founded and operated by a team of experienced industry executives and skilled molecular diagnostics scientists. Applying its proprietary laboratory developed test for cfDNA, cfRNA and MSI liquid biopsies, CIRCULOGENE has developed a next-generation sequencing (NGS) method to provide full genomic load analysis from one standard tube of blood in one week, enabling more accurate data to help clinicians and their patients choose targeted therapies, monitor efficacy and monitor for recurrence. One tube, one week, complete results. Somatic + Germline; Blood + Tissue + Buccal; DNA + RNA + MSI + PD-L1. For more information, visit www.circulogene.com or call 855-614-7083.

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