

Pr NEWS WIRE, April 19, 2017

Ultra-sensitive cancer DNA test dramatically improves patient selection for chemotherapy

GREENSBORO, NC -- MultiGEN Diagnostics announces the publication of an extraordinarily sensitive companion diagnostic methodology called Allele Specific Multiplex Sequencing (ASMS) for the detection of cancer mutations. The study involving the Braf p.V600E mutation was published April 12th in a peer-reviewed international journal (<u>Journal of Solid Tumors, Vol. 7, No. 2, 2017</u>). The ASMS test identified and confirmed the Braf p.V600E mutation with a 1,000-fold increase in sensitivity compared to presently used methods. This dramatic increase in sensitivity enabled the detection of the target mutation in picogram concentrations (i.e. trillionths of a gram) in more than 50 per cent of various tumors that had previously been reported negative by two of the most commonly employed tests.

"This scientific report is a generic demonstration of the ability of ASMS to identify unprecedented low concentrations of relevant drug targets so matching chemotherapeutic drugs can be prescribed," says Dr. Thurai Moorthy, Founder and Chief Scientific Officer. He noted, "use of ASMS could immediately translate into many more patients qualifying for potentially curative treatment with drugs that selectively target cancer cells with the Braf p.V600E mutation — rather than normal cells."

Testing for Braf pV600E is now an expected best-practice prior to starting drug therapy for melanomas (incidence 68,000/yr, US), papillary thyroid cancer (incidence 62,000/yr, US) and other common cancers. The presence of this mutation predicts for much better treatment success with Braf kinase inhibitors such as Zelboraf.

"This elegant yet immensely practical new application of our patented MultiGEN platforms finally allows the commercialization of the accepted 'Gold Standard' of Sanger sequencing for personalized diagnostic medicine," says Dr. Roger Hodkinson, MultiGEN's Director of Medical Affairs. He added, "MultiGEN plans to use this best-in-class technology to test much more effectively for the presence or absence of other common tumor mutations such as EGFR, KRAS and KIT that predict for better treatment outcomes with Tarceva, Iressa, Erbitux, Gleevec and similar drugs."

Use of ASMS could also re-evaluate the currently accepted prevalence of cancer markers in various tumors, leading to a better understanding of the interplay of those key mutations in predicting treatment outcomes. As new cancer-specific markers are discovered, the ASMS platform will also function as a more sensitive companion diagnostic for the selection of appropriate patients for clinical trials.

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