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Transgenomic Demonstrates Very High Sensitivity Detection of Tumor-Associated KRAS Mutations in Matched Plasma Samples using COLD-PCR

OMAHA, Neb., February 8, 2010 -- Transgenomic, Inc. (OTC BB: TBIO.OB) announced today that it has completed a preliminary study with a leading pharmaceutical company that validates the use of its licensed COLD-PCR technology to detect colorectal tumor-associated KRAS mutations that determine efficacy of recently developed therapies. These were detected in plasma samples in which the mutation levels were too low for detection by standard DNA analysis methodologies such as Sanger sequencing.

The study, which was performed by Transgenomic's Pharmacogenomics Services Laboratory in Omaha, NE and the company's Molecular Biology research team in Gaithersburg, MD, consisted of testing DNA extracted from colorectal tumor-matched plasma samples. Screening with standard Sanger sequencing of the plasma samples resulted in only 70% concordance between matched plasma and tumor due to missing KRAS codon 12 and 13 mutations.

The samples were enriched by Transgenomic's COLD-PCR mutation enrichment technology before analysis with the SURVEYOR SCAN KRAS assay. COLD-PCR preferentially amplifies genomic DNA mutations in comparison to normal, wild-type sequences. This powerful enrichment and screening method can detect matched-tumor KRAS mutations in serum mutation levels at less than 0.1% of total wild-type DNA.

This resulted in the accurate detection of all KRAS codon 12 and KRAS codon 13 mutations with full discrimination against wild-type or normal samples tested concurrently. Due to the extent of the enrichment process, all of these KRAS containing plasma samples could subsequently be verified by DNA sequencing.

It was confirmed by the study's pharmaceutical partner that there was a 100% concordance between Transgenomic's mutation results and the matched tumor KRAS genotypes.

"We believe that the developments in COLD-PCR that we are pursuing at Transgenomic will open the way for detecting tumor mutations in surrogate tissues and body fluids such as serum, plasma and urine rather than by tumor biopsy," said Craig Tuttle, CEO of Transgenomic. "This study is a very promising start of the process of validating this technology in a clinically oriented setting. We intend to participate in further studies such as this with the aim of developing COLD-PCR serum assays for key gene mutations that are biomarkers for early tumor detection, tumor therapy efficacy, emergence of drug resistance biomarkers and relapse."

COLD-PCR was discovered in the laboratory of Dr. Mike Makrigiorgos at the Dana Farber Cancer Institute. It has been exclusively licensed by Transgenomic for all Sanger Sequencing and mitochondrial DNA applications. Furthermore, it can be coupled with Transgenomic's proprietary DNA mutation detection technologies to further improve its sensitivity.

Technical Information

When mutant and reference DNA samples from the same gene are mixed and re-annealed, variations between these sequences cause double-stranded DNA heteroduplexes to form. The WAVE System employs denaturing HPLC to separate these homo- and hetero-duplexes by ion-pairing reverse-phase HPLC. This technology has been in widespread use for genomic analysis

being cited in over 2000 peer-reviewed publications. As an alternative offering, Transgenomic's SURVEYOR Nuclease cleaves such heteroduplexes with high specificity at sites of base mismatch or small insertions/deletions. It has a proven track record as a robust and reliable tool in analyzing DNA variations, especially where the mutant alleles are at a very low concentration within the sample (less than 1% of the total wild type allele concentration). COLD-PCR protocols preferentially amplify heteroduplexes such that mutant alleles become enriched compared to normal alleles. The range of enrichment demonstrated to date varies from 3 to 100-fold, which will contribute to Transgenomic's target of achieving a 1/10,000 mutant to normal allele ratio detection in a routine, cost-effective and high throughput protocol. This level of detection will allow straightforward tumor analysis via surrogate tissues such as blood and urine.

About Transgenomic, Inc.

Transgenomic, Inc. (OTC BB: TBIO.OB, www.transgenomic.com) is a global biotechnology company specializing in high sensitivity genetic variation and mutation analysis, providing products and services in DNA mutation detection and discovery for clinical research, clinical molecular diagnostics and pharmacogenomics analyses. Its product offerings include the WAVE[®] Systems and associated consumables specifically designed for use in genetic variation detection and single- and double-strand DNA/RNA analysis and purification. With broad applicability to genetic research, over 1,450 systems have been shipped to customers in more than 30 countries. The SURVEYOR[®] Mutation Detection Kits and SURVEYOR Check-It Kit provide reagents and protocols for high sensitivity detection of mutations in DNA. In addition, HANABI automated chromosome harvesting systems improve laboratory productivity with consistent quality compared to manual methods for cytogenetic analyses. Service offerings include the Transgenomic Molecular Laboratory, which provides reference laboratory services specializing in molecular diagnostics including Mitochondrial Disorders, Oncology and Hematology, Molecular Pathology and Inherited Diseases. Transgenomic Pharmacogenomics Services is a CRO for pharmacogenomic, translational research and clinical trials.

Cautionary Statements

Certain statements in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, which involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Forward-looking statements include, but are not limited to, those with respect to management's current views and estimates of future economic circumstances, industry conditions, company performance and financial results, including the ability of the Company to grow its involvement in the diagnostic products and services markets. The known risks, uncertainties and other factors affecting these forward-looking statements are described from time to time in reports to the Securities and Exchange Commission. Any change in such factors, risks and uncertainties may cause the actual results, events and performance to differ materially from those referred to in such statements. Accordingly, the company claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 with respect to all statements contained in this press release.