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Liquid Biopsy Monitoring of Circulating Cell-Free Tumor DNA and Identification of Cancer Gene Variations for Precision Diagnostics

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Current clinically available molecular tests for detection of nucleic acid variations especially those performed on circulating cell-free nucleic acids present in biological fluids such as patient's blood plasma have limited sensitivity. In order to achieve high sensitivity for the detection of only a few target molecules (mutant alleles) present in a vast excess of non-target molecules (wild-type alleles) sophisticated methodologies that require expensive instrumentation, highly skilled operators and in some cases intensive computational bioinformatics methods such as digital-droplet PCR (ddPCR), BEAMing PCR and next generation deep sequencing (NGS) are being employed in large clinical research centers. The limited availability, high cost and long analysis times of these methods prompted us to develop a new technology that can be performed globally by existing pathology personnel with instrumentation that is already present in every hospital pathology laboratory. At the heart of this innovative technology are new molecular nucleic acid analogs: xenonucleic acids (XNA) that possess all the natural bases that occur in DNA appended to a novel chemical backbone that imbibes these oligomeric nucleic acid binding molecules with exquisite specificity and extremely avid binding affinity for complementary target sequences. Any variation in the sequence that the XNA binds to creates a differential thermodynamic free energy of binding anomaly that-has been exploited to develop target amplification based real-time qPCR and extremely high sensitivity NGS and bead-based hybridization capture assays that can detect as little as 2 copies of variant templates in a large excess of wild-type templates in DNA obtained from tissue biopsies or plasma circulating cell free DNA (cfDNA). Commercial CE/IVD Certified Products that have been developed and validated include QClamp™ gene specific real-time qPCR based tests, a new colorectal cancer detection test called ColoScape™ a high sensitivity amplicon based target NGS platform called OptiSeq™ and a multiplex target amplicon hybridization capture technology for monitoring drug sensitizing and resistance mutations in cancer patients. This presentation will discuss this new ground-breaking technology and the precision diagnostics and targeted therapy opportunities that it affords.

Biography:

Mike is currently Chief Scientific Officer at DiaCarta, Inc. where he manages the company's scientific and strategic direction in molecular diagnostics for oncology and infectious disease personalized diagnostics markets, most notably the development of branched DNA (bDNA) signal amplification and a novel somatic gene mutation Real-Time PCR based assay technology called QClamp™ for applications in the diagnosis of cancer and infectious diseases and the rapid detection of cancer 'driver' and drug resistance genetic variations. Mike was previously a Founder of Odyssey Thera Inc., a privately held company that commercialized a proprietary fluorescent live cell-based assay and diagnostic imaging technology for the application in target validation and drug discovery. Mike was the Director of New Technology at Roche Diagnostics (Roche acquired Boehringer Mannheim Corporation in May, 1997 for $11B). Prior to the acquisition by Roche he was Director of New Technology at Boehringer Mannheim. He was also the Director of New Technology at Microgenics Corporation, in Concord, California. He was pioneer and lead scientist and inventor of the electrochemiluminescence (ECL) assay technology and also developed catalytic antibodies at IGEN, Inc. The ECL technology is the basis of Roche Diagnostics automated 'in-vitro' diagnostics immunoassay platform: 'ElecSys'. Mike has held several other R & D senior management positions at Integrated Genetics Inc., Medisense and Celltech PLC, in the UK. Mike has published many research papers in leading scientific journals and holds over 30 patents and patent-pending applications. He received his Ph.D. in medicinal organic chemistry from Loughborough University, Loughborough, UK and Ph.D. from University of Nottingham, Nottingham, UK.