

Biodesix Reaches Agreement to Deliver Next-Generation Sequencing Assay for Blood-Based Companion Diagnostic Solutions in Cancer

Initiative Aims to Develop Lung Cancer Diagnostic Testing with FDA Premarket Approval Classification Using Thermo Fisher Scientific's OncoPrint Assay

BOULDER, Colo., July 9, 2019 – Biodesix, Inc, the leader in blood-based lung cancer diagnostic solutions, today announced it has entered into an agreement with Thermo Fisher Scientific. The agreement is designed to bring a blood-based next-generation sequencing (NGS) assay to market with premarket approval (PMA) classification from the U.S. Food and Drug Administration (FDA). Biodesix will work to develop all required analytical and clinical data using Thermo Fisher's Ion Torrent™ OncoPrint™ Pan-Cancer Cell-Free Assay in an effort to obtain regulatory approval from the FDA. The program will focus on an NGS-based solution for patients with advanced non-small cell lung cancer (NSCLC).

Upon FDA approval Biodesix will have a single-site PMA (ssPMA) for an NGS liquid biopsy covering actionable markers in cancer. The designation will extend Biodesix collaborations with biopharmaceutical companies for NGS-based biomarker discovery, validation studies, and commercialization capabilities that include regulatory approval and reimbursement for companion diagnostics.

The Ion Torrent OncoPrint Pan-Cancer Cell-Free Assay enables reproducible detection and analysis of tumor DNA and RNA across all major classes of somatic mutations (SNVs, indels, CNVs and fusions) from a single vial of blood within two days. Targeting 52 genes across multiple cancer types, including lung, colorectal, breast, pancreatic, thyroid and others, the cell-free total nucleic acid (cfTNA) assay has broad application for liquid biopsy clinical research applications.

“We are dedicated to providing actionable answers that physicians and patients need by leveraging the best technology available,” said David Brunel, Biodesix CEO. “Building on our expertise in blood-based solutions, this assay will expand our lung cancer portfolio to provide physicians and biopharmaceutical companies with blood-based NGS assays that provide fast turn around and comprehensive answers. This agreement enables Biodesix to continue innovating much needed cancer diagnostic solutions that service clinical and biopharma partners from early discovery through global distribution.”

Biodesix operates [two world-class clinical laboratories](#) regulated by the Centers for Medicare & Medicaid Services (CMS) pursuant to the Clinical Laboratory Improvement Amendments (CLIA). In addition to holding a CLIA certificate of accreditation by the College of American Pathologists (CAP), the Biodesix quality management system maintains a certification with ISO 13485, a harmonized international standard for quality management systems. The company has received approval from the New York State Department of Health Clinical Laboratory Standards of Practice (NYS CLEP) in soluble and molecular tumor markers. Biodesix labs support the company's global products, clinical trials, and biopharmaceutical partnerships.

About Biodesix

Biodesix is a lung cancer diagnostic solutions company addressing the continuum of patient care from early diagnosis of lung nodules through late stage cancer. The company develops diagnostic tests addressing important clinical questions by combining simple blood draws and multi-omics with the power of artificial intelligence. Biodesix is the first company to offer three best-in class tests for patients with lung cancer, and multiple pipeline tests including one with the potential to identify patients who may benefit from immunotherapies. The Biodesix Lung Reflex[®] strategy integrates the GeneStrat[®] and VeriStrat[®] tests to support treatment decisions with results in 72 hours. The Nodify XL2[™] nodule test, which will be commercially available in the second half of 2019, evaluates the risk of malignancy, enabling physicians to triage patients to the most appropriate course of action. Biodesix also partners with the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges. For more information about Biodesix, please visit **www.biodesix.com**.

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