Biodesix Announces Expanded Bio-Rad Laboratories Partnership Agreement to Develop Droplet Digital™ PCR High Complexity Assays

October 22, 2025

Biodesix will perform the clinical validation of ddPLEX ESR1 Mutation Detection Assay for advanced breast cancer testing

LOUISVILLE, Colo., Oct. 22, 2025 (GLOBE NEWSWIRE) -- Biodesix, Inc. (NYSE: BDSX), a leading diagnostics solutions company, today announced the signing of an expanded partnership agreement under which Biodesix will conduct the development, clinical validation, and regulatory submissions of *in vitro* diagnostic (IVD) assays to enable highly sensitive detection of multiple genomic markers focused on oncology applications, utilizing Bio-Rad's Droplet Digital™ PCR (ddPCR™) technology on Bio-Rad's QX600 platform. Following regulatory clearance, Biodesix will manufacture and distribute dedicated specimen collection kits for the developed assays.

The first assays to be validated under the agreement include Bio-Rad's ddPLEX ESR1 Mutation Detection Assay. ESR1 testing is becoming critical in HR+/HER2- advanced breast cancer due to the clinically demonstrated survival benefits from a new generation of therapy called oral selective estrogen receptor degraders (SERDs). The ddPLEX ESR1 Mutation assay will enable highly sensitive detection and absolute quantification of multiple ESR1 mutations from ctDNA samples.

Once validated, the ESR1 assay will be offered as a test service at Biodesix' accredited CLIA-CAP laboratory for biopharma customers to support the development of targeted therapeutics, as well as for clinical customers to support cancer treatment monitoring. Biodesix will also seek reimbursement for this assay through Centers for Medicare & Medicaid Services (CMS).

"The emergence of ESR1 mutations as biomarkers for breast cancer has had a significant impact on the oncology market, leading to an increased global demand for rapid, sensitive assays," **said Scott Hutton, CEO, Biodesix.** "We are proud to expand our partnership with Bio-Rad through this new agreement, demonstrating how our combined capabilities in mutation detection can address clinical needs with speed and precision, and opening doors to personalized, data-driven medicine."

"Through our long-standing relationship with Biodesix we have effectively delivered both clinical and research-based applications of our ddPCR technology for non-small cell lung cancer, as part of its Lung Diagnostics portfolio," **commented Steve Kulisch, VP Product Management, Life Science Group, Bio-Rad Laboratories.** "Validation of our ddPLEX ESR1 kits will further expand our combined capabilities in clinical diagnostics, increasing access to sensitive biomarker detection for advanced breast cancer."

At the upcoming AMP conference, Nov 11-15, Boston, MA, both companies will be providing more detail on their R&D visions, partnerships, and commercial roadmaps:

- Bio-Rad Laboratories Corporate Workshop, Nov 12, at 8:00 am ET
- Biodesix Corporate Workshop, Nov 12, at 4:00 pm ET

About Biodesix:

Biodesix is a leading diagnostic solutions company, driven to improve clinical care and outcomes for patients. **Biodesix Diagnostic Tests**, marketed as Nodify Lung® Nodule Risk Assessment and IQLung® Cancer Treatment Guidance, support clinical decisions to expedite personalized care and improve outcomes for patients with lung disease. **Biodesix Development Services** enable the world's leading biopharmaceutical, life sciences, and research institutions with scientific, technological, and operational capabilities that fuel the development of diagnostic tests, tools, and therapeutics. For more information, visit biodesix.com.

Biodesix Contacts:
Media:
Natalie St. Denis, Director Corporate Communications, Biodesix
natalie.stdenis@biodesix.com
(720) 925-9285

Investors:
Chris Brinzey, Partner, ICR
chris.brinzey@icrhealthcare.com
(339) 970-2843