NEWS RELEASE

Foundation Medicine and Its Collaborators Announce Acceptance of 21 Abstracts at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

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New studies demonstrate advancements in cancer monitoring, expanded liquid biopsy capabilities, and the validity and utility of complex genomic biomarker detection

Oral presentation on a landscape study of tumor mutational burden (TMB) in over 8,000 patients across 24 cancer types using FoundationOne ® CDx

Multiple abstracts defining the clinical application and demonstrating the value of FoundationOne ® Tracker for circulating tumor DNA monitoring

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- **Foundation Medicine, Inc**., today announced that the company and its collaborators will present 21 abstracts demonstrating the value of high-quality tumor profiling tests to inform cancer care at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting from June 2-6 in Chicago.

Informing outcomes through ctDNA monitoring

Circulating tumor DNA (ctDNA) has emerged as a promising tool to support oncologists in monitoring their advanced cancer patients' response to therapy. Two studies being presented at ASCO further define the clinical application of ctDNA monitoring and demonstrate the value of FoundationOne®Tracker to support and inform oncologists' treatment planning.

- Circulating tumor DNA (ctDNA) monitoring to inform maintenance outcomes in patients (pts) with advanced NSCLC treated with induction atezolizumab+carboplatin+nab-paclitaxel (**Abstract 9075**)
- Circulating tumor DNA (ctDNA) dynamics and survival outcomes in patients (pts) with advanced non-small cell lung cancer (aNSCLC) and high (>50%) programmed cell death-ligand 1 (PD-L1) expression, randomized to cemiplimab (cemi) vs chemotherapy (chemo) (**Abstract 9022**)

New Capabilities of Liquid Biopsy

Several studies to be presented by Foundation Medicine at ASCO demonstrate the unique capabilities of the company's FDA-approved liquid biopsy comprehensive genomic profiling (CGP) test, FoundationOne®Liquid CDx. Foundation Medicine is unique in its ability to report ctDNA tumor fraction in clinical reports for more confident clinical decision making, and along with its collaborators, is presenting two studies highlighting the clinical utility and differentiating factors of FoundationOne Liquid CDx's tumor fraction reporting. Foundation Medicine will also present new data describing FoundationOne Liquid CDx's robust ctDNA-based detection of rearrangements and fusions. It is the only company with companion diagnostics for fusions on both its tissue and blood-based CGP tests, and this research at ASCO continues to demonstrate the clinical utility of FoundationOne Liquid CDx's regulatory-grade fusion detection and bioinformatics.

- Utility of ctDNA tumor fraction to inform negative liquid biopsy (LBx) results and need for tissue reflex in advanced non-small cell lung cancer (aNSCLC) (**Abstract 9076**)
- The effect of ctDNA Tumor Fraction (TF) on overall survival and concordance between tissue genomics and ctDNA in Lung-MAP (**Abstract 9035**)
- Liquid-biopsy detection of FGFR2 and other actionable rearrangements in GI malignancies (**Abstract 4085**)
- Use of circulating tumor DNA (ctDNA) to complement tumor tissue homologous recombination repair (HRR) gene alteration testing in TALAPRO-2, a Phase 3 study of talazoparib (TALA) + enzalutamide (ENZA) versus placebo (PBO) + ENZA as first-line (1L) treatment in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) (**Abstract 5056**)1
- Mobocertinib efficacy in patients with NSCLC and EGFR exon 20 insertion mutations (ex20ins) identified by next-generation sequencing (NGS) of circulating tumor DNA (ctDNA) (**Abstract 9082**)

Driving innovation through development and validation of complex genomic biomarkers

Multiple lines of evidence, including what will be communicated in an oral presentation, demonstrate the validity and utility of Foundation Medicine's complex genomic biomarkers, including tumor mutational burden (TMB) and a signature for homologous recombination deficiency (HRDsig).

- Tumor Mutational Burden (TMB) Measurement from an FDA-Approved Assay and Real-World Overall Survival (rwOS) on Single-Agent Immune Checkpoint Inhibitors (ICI) in over 8,000 Patients across 24 Cancer Types (**Abstract 2503**)

- Tumor Mutational Burden (TMB) in Real-world Patients with Pancreatic Ductal Adenocarcinoma (PDAC): Differences in Genomic Alterations (GA) and Predictive Value for Immune Checkpoint Inhibitor (ICI) Effectiveness (**Abstract 4146**)
- Metastatic Breast Cancer (MBC) with Ultra-high Tumor Mutational Burden (UHTMB): A Comprehensive Genomic Profiling (CGP) Study (**Abstract 1036**)
- HRD Signature and HRD Genomic Landscape of tumors from 896 Patients with Early-Stage Breast Cancer (BC) (**Abstract 539**)
- Effectiveness of PARP inhibitor maintenance therapy (mPARPi) in advanced ovarian cancer (OC) by BRCA1/2 and HRD signature in real-world practice (**Abstract 5583**)

Addressing inequities in next generation sequencing for patients with NSCLC

Additionally, in partnership with The West Cancer Center, OneOncology, Flatiron Health and Genentech, a member of the Roche Group, there will be an oral presentation of joint research examining inequities in next generation sequencing (NGS) testing for patients with advanced non-small cell lung cancer being treated in the community setting in the United States.

- Practice- and provider-level inequities in Next Generation Sequencing (NGS) by race/ethnicity for advanced non-small cell lung cancer (aNSCLC) patients (**Abstract 6508**)

“Our data at ASCO demonstrates the expanded and differentiated capabilities of our monitoring and liquid biopsy tests, reinforces our leadership in detection of complex genomic biomarkers, and supports increased confidence and ease in our tests’ use by doctors and researchers,” says Mia Levy, MD, PhD, chief medical officer at Foundation Medicine. “Much of this research was conducted in collaboration with our partners across the oncology ecosystem, underscoring our commitment to working together in order to make faster, more impactful progress for patients.”

The following is a list of abstracts that will be presented at the meeting. To access all abstracts being presented at ASCO, please visit **ASCO.org**.

Follow Foundation Medicine on **Twitter** and **LinkedIn** for more updates from #ASCO23 and visit us in person at Booth #19081.

Abstract #	Title	Collaborators	Product
Orals			
2503 Sunday, June 4 9:45 AM – 12:45 PM	**Tumor Mutational Burden (TMB) Measurement from an FDA-Approved Assay and Real-World Overall Survival (rwOS) on Single-Agent Immune Checkpoint Inhibitors (ICI) in over 8,000 Patients across 24 Cancer Types**	UC Davis Comprehensive Cancer Center, Flatiron Health and others	Foundation Medicine and Flatiron Health’s Joint Clinico-Genomic Database (CGDB)
6508 Tuesday, June 6 8:00 – 11:00 AM	**Practice- and provider-level inequities in Next Generation Sequencing (NGS) by race/ethnicity for advanced non-small cell lung cancer (aNSCLC) patients**	The West Cancer Center, OneOncology, Genentech Inc., Flatiron Health, Tennessee Oncology	Flatiron Health Database

Poster Discussions			
9022 Sunday, June 4 4:30 – 6:00 PM	**Circulating tumor DNA (ctDNA) dynamics and survival outcomes in patients (pts) with advanced non-small cell lung cancer (aNSCLC) and high (>50%) programmed cell death-ligand 1 (PD-L1) expression, randomized to cemiplimab (cemi) vs chemotherapy (chemo)**	Third-party poster generated by Regeneron Pharmaceuticals, Inc., MD Anderson Cancer Center and others featuring results obtained through collaboration with Foundation Medicine, Natera Inc., and others	FoundationOne®Tracker
Posters			
5056 Saturday, June 3 8:00 – 11:00 AM	**Use of circulating tumor DNA (ctDNA) to complement tumor tissue homologous recombination repair (HRR) gene alteration testing in TALAPRO-2, a Phase 3 study of talazoparib (TALA) + enzalutamide (ENZA) versus placebo (PBO) + ENZA as first-line (1L) treatment in patients (pts) with metastatic castration-resistant prostate cancer)**	Peter MacCallum Cancer Centre, Institute Gustave Roussy, Pfizer and others	FoundationOne®CDx FoundationOne®Liquid CDx
11541 Saturday, June 3 1:15 – 4:15 PM	**Clinical Utility of Liquid-based Comprehensive Genomic Profiling (CGP) in Gastrointestinal Stromal Tumors (GIST)**	Boston University Medical Campus, OHSU Knight Cancer Institute, Boston Medical Center	FoundationOne®CDx FoundationOne®Liquid CDx
TPS3166 Saturday, June 3 8:00 – 11:00 AM	**SPARK, Studying Pathways of Resistance in KRAS-driven Cancers: A remote plasma ctDNA participation study to identify mechanisms of resistance to KRAS inhibitors**	Dana-Farber Cancer Institute, Lowe Center for Thoracic Oncology, KRAS Kickers, GO2 Foundation for Lung Cancer, Addario Lung Cancer Medical Institute, Bonnie J Addario Lung Cancer Foundation, Addario Lung Cancer Medical Institute (ALCMI)	FoundationOne®Liquid CDx
9587 Saturday, June 3 1:15 – 4:15 PM	**Comprehensive Genomic Profiling (CGP) of Clinically Advanced and Metastatic Cutaneous Adnexal Carcinomas (CAs; MCADCA): A Genomic Landscape Study**	SUNY Upstate Medical University, Upstate University Hospital	FoundationOne®CDx
5044 Saturday, June 3 8:00 – 11:00 AM	**Penile Squamous Cell Carcinoma (PSCC) with Elevated Tumor Mutational Burden (TMB): A Genomic Landscape Study**	SUNY Upstate Medical University, H. Lee Moffitt Cancer Center and Research Institute, University of Washington; Fred Hutchinson Cancer Center, The University of Texas MD Anderson Cancer Center, Vita-Salute San Raffaele University	FoundationOne®CDx
4587 Saturday, June 3 8:00 – 11:00 AM	**CDH1-Mutated Clinically Advanced Urothelial Bladder Cancer (UBC): A Genomic Landscape and Real-World Clinical Outcome Study (RWCOS)**	Moffitt Cancer Center and Research Institute, Vita-Salute San Raffaele University, Saint Louis University Hospital, University of Washington; Fred Hutchinson Cancer Center, SUNY Upstate Medical University	FoundationOne®CDx CGDB
9075 Sunday, June 4 8:00 – 11:00 AM	**Circulating Tumor DNA (ctDNA) Monitoring to inform maintenance outcomes in patients (pts) with advanced NSCLC treated with induction atezolizumab+carboplatin+nab-paclitaxel**	H. Lee Moffitt Cancer Center and Research Institute, Natera, Inc., Genentech Inc., AdventHealth Cancer Institute	FoundationOne®Tracker
9076 Sunday, June 4 8:00 – 11:00 AM	**Utility of ctDNA tumor fraction to inform negative liquid biopsy (LBx) results and need for tissue reflex in advanced non-small cell lung cancer (aNSCLC)**	Icahn School of Medicine at Mount Sinai, UC San Diego Moores Cancer Center	FoundationOne®CDx FoundationOne®Liquid CDx CGDB
9082 Sunday, June 4 8:00 – 11:00 AM	**Mobocertinib efficacy in patients with NSCLC and EGFR exon 20 insertion mutations (ex20ins) identified by next-generation sequencing (NGS) of circulating tumor DNA (ctDNA)**	Third-party poster generated by Takeda Pharmaceuticals USA and others featuring FoundationOne®Liquid CDx results obtained through collaboration with Foundation Medicine	FoundationOne®Liquid CDx
9035 Sunday, June 4 8:00 – 11:00 AM	**The effect of ctDNA Tumor Fraction (TF) on overall survival and concordance between tissue genomics and ctDNA in Lung-MAP**	Mount Sinai Health System and others	FoundationOne®CDx FoundationOne®Liquid CDx
9094 Sunday, June 4 8:00 – 11:00 AM	**Characterization of diverse targetable alterations in ERBB2 and ERBB3 in 93,465 non-small cell lung cancers (NSCLC)**	Memorial Sloan Kettering Cancer Center, University of California San Diego, Moores Cancer Center	FoundationOne®CDx FoundationOne®Liquid CDx
539 Sunday, June 4 8:00 – 11:00 AM	**HRD Signature and HRD Genomic Landscape of tumors from 896 Patients with Early-Stage Breast Cancer (BC)**	Yale School of Medicine, Yale Cancer Center	CGDB
1036	**Metastatic Breast Cancer (MBC) with Ultra-high Tumor**	Lifespan Health System, Ohio State	FoundationOne®CDx

Sunday, June 4 8:00 – 11:00 AM	**Mutational Burden (UHTMB): A Comprehensive Genomic Profiling (CGP) Study**	University Comprehensive Cancer Center, SUNY Upstate Medical University, Upstate University Hospital, Yale Cancer Center, Yale School of Medicine	
4085 Monday, June 5 8:00 – 11:00 AM	**Liquid-biopsy detection of FGFR2 and other actionable rearrangements in GI malignancies**	Weill Cornell Medicine, Englander Institute of Precision Medicine, New York Presbyterian Hospital, Vanderbilt University Medical Center, The University of Texas MD Anderson Cancer Center	FoundationOne®CDx FoundationOne®Liquid CDx
4146 Monday, June 5 8:00-11:00 AM	**Tumor Mutational Burden (TMB) in Real-world Patients with Pancreatic Ductal Adenocarcinoma (PDAC): Differences in Genomic Alterations (GA) and Predictive Value for Immune Checkpoint Inhibitor (ICI) Effectiveness**	University Hospital Seidman Cancer Center, Case Western Reserve University, Mayo Clinic	FoundationOne®CDx CGDB
5593 Monday, June 5 1:15 – 4:15 PM	**Gynecologic-Cancer Analysis of ARID1A Alterations Detected in Both Tissue and Liquid Biopsies**	National Cancer Institute	FoundationOne®CDx FoundationOne®Liquid CDx
5583 Monday, June 5 1:15 – 4:15 PM	**Effectiveness of PARP inhibitor maintenance therapy (mPARPi) in advanced ovarian cancer (OC) by BRCA1/2 and HRD signature in real-world practice**	Stephenson Cancer Center/University of Oklahoma Health Sciences Center and Sarah Cannon Research Institute, University of Oklahoma, Flatiron Health	FoundationOne®CDx CGDB
4088 Monday, June 5 8:00 – 11:00 AM ASCO Merit Award	**Characterizing KRAS Allele Variants Within Biliary Tract Cancers**	Princess Margaret Cancer Centre, MD Anderson Cancer Center University Health Network, University of Toronto, SUNY Upstate Medical University	FoundationOne®CDx

About Foundation Medicine: Your Essential Partner in Cancer Care

Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and research. We collaborate with a broad range of partners across the cancer community and strive to set the standard for quality, scientific excellence, and regulatory leadership. Our deep understanding of cancer biology helps physicians make informed treatment decisions for their patients and empowers researchers to develop new medicines. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care. For more information, please visit us on **www.FoundationMedicine.com** and follow us on **Twitter** and **LinkedIn**.

About FoundationOne CDx

FoundationOne CDx is a next-generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. FoundationOne CDx is for prescription use only and is intended as a companion diagnostic to identify patients who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For a full list of targeted therapies for which FoundationOne CDx is indicated as a companion diagnostic, please visit **www.F1CDxLabel.com**.

About FoundationOne Liquid CDx

FoundationOne Liquid CDx is a qualitative next generation sequencing based in vitro diagnostic test for prescription use only that uses targeted high throughput hybridization-based capture technology to analyze 324 genes utilizing circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of advanced cancer patients. The test is FDA-approved to report short variants in over 300 genes and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and complete risk information, please visit **www.F1LCDxLabel.com**.

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1 FoundationOne®Liquid CDx is not FDA-approved as a companion diagnostic for talazoparib.

Source: Foundation Medicine

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Source: Foundation Medicine, Inc.