Labcorp Presents New Research Demonstrating Clinical Impact of Precision Diagnostics in Guiding Biomarker-targeted Therapies for Patients with Epithelial Ovarian Cancer

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Outcomes point to value of biomarker testing in addressing testing gaps in clinical practice

BURLINGTON, N.C., March 16, 2024 /PRNewswire/ -- Labcorp (NYSE: LH), a global leader of innovative and comprehensive laboratory services, today presented the results from two studies at the 2024 SGO Annual Meeting on Women's Cancer. The studies demonstrate the value of biomarker testing in closing testing gaps and guiding targeted therapies for patients with epithelial ovarian cancer (EOC).

With the rapid rate at which cancer biomarkers are being identified and new targeted therapies become available, comprehensive testing approaches are becoming even more critical as corresponding treatment guidelines evolve. Labcorp researchers conducted two studies to generate further evidence of the value of comprehensive genomic profiling to drive guideline-compliant testing that enables increased patient access to targeted therapies for improved outcomes.

Combination of *BRCA* testing with HRD Testing Needed to Inform Benefit of PARP Inhibitor Therapy
In one such study, conducted in partnership with Illumina, a leader in next-generation sequencing technologies, 1,093 patients diagnosed with EOC were evaluated to assess real-world clinical practice patterns for ordering *BRCA* and Homologous Recombination Deficiency (HRD) testing. When combined, the results of *BRCA* and HRD testing can determine which patients are most likely to benefit from treatment with poly-ADP ribose polymerase (PARP) inhibitors. For patients who test negative for *BRCA1* and *BRCA2*, testing for HRD can help determine the degree of benefit from a PARP inhibitor.[1]

PARP inhibitors have transformed the standard of care, especially for women with germline or deleterious somatic mutations in *BRCA1* or *BRCA2*.[2] However, at least 40% of patients do not respond to PARP inhibitors, and if treated with PARP inhibitors, may experience longer treatment durations and potentially serious side effects,[3] as well as increased overall costs. Treatment guidelines for PARP inhibitors emphasize the importance of diagnostic testing and individualized patient assessments.[1]

Within the study population, 84% of patients underwent evaluation for *BRCA* mutations or HRD testing; however, less than 50% of patients underwent HRD testing. Researchers then evaluated PARP inhibitor utilization and evaluated the time to treatment discontinuation (TTD) among patients with germline/somatic *BRCA* mutations, tumors with HRD, and those that were homologous recombination proficient (HRP). Patients with *BRCA* mutations[4] or HRD[5] tend to do well on PARP inhibitors, so testing for each can help identify patients who may be most appropriate for PARP inhibitor maintenance.

Consistent with prior prospective clinical trials, researchers reported that the median TTD of first-line PARP inhibitor maintenance therapy was the longest for patients with germline or somatic *BRCA* mutations or HRD tumors. Among the study groups, 77% of the patients with a germline *BRCA* mutation, 65.1% of patients with a somatic *BRCA* mutation, and 42.7% of those with HRD and *BRCA* wild-type continued PARP inhibitor therapy at 18 months, compared to 29% of patients in the HRP/*BRCA* wild-type group.

"This research emphasizes the power of comprehensive biomarker testing in advancing the treatment of ovarian cancer. By closing critical diagnostic gaps through precision testing, we are not just improving patient care but also propelling science and healthcare forward," said Shakti Ramkissoon, M.D., Ph.D., vice president, head of oncology at Labcorp. "These findings affirm that access to advanced technology, in collaboration with partners with a shared commitment to the most current care models, is the cornerstone of developing innovative diagnostic tools. These new assays can offer more patients with access to effective, biomarker-guided therapies, ultimately leading to better prognoses and opening doors to new possibilities in gynecologic oncology."

The studies are among the growing body of evidence highlighting the value of biomarker testing for EOC, specifically in real-world settings. High-grade serous epithelial ovarian cancer (HGSOC) is the deadliest of all gynecological cancers, with 70% of patients having a cancer recurrence within two to three years and almost 50% dying from the disease after five years of diagnosis.

"This research highlights the need for additional healthcare provider education on comprehensive genomic approaches and the clinical utility of guideline-driven testing to improve patient care in ovarian cancer," said Pratheesh Sathyan, head of oncology for Americas region in medical affairs at Illumina.

High Folate-receptor Alpha (FOLR1/FRα) Expression Seen in Primary EOC Tumors
In another study, Labcorp researchers evaluated real-world testing practice patterns for Folate-receptor Alpha (FRα) on primary tumors versus metastatic tumors to guide targeted therapy for patients with platinum-resistant EOC. FRα is an actionable biomarker in ovarian cancer and is overexpressed in up to 90% of EOC patients.[6] Patients with platinum-resistant EOC whose tumors highly express FRα may be eligible for treatment with Mirvetuximab soravtansine (MIRV), the only currently available targeted therapy that improves overall survival for patients with platinum-resistant EOC.

Researchers performed a retrospective analysis of tumor samples from 432 patients with EOC undergoing standard-of-care testing via the VENTANA FOLR1 (FOLR1-2.1) RxDx Assay (developed by Roche). Of the tumor samples analyzed, 291 were from metastatic tumors, and 133 were from

primary tumors. Researchers reported that 36.2% of patients had tumors that highly expressed FRα. In a critical study finding, tumor samples from primary sites were associated with higher rates of FRα positivity than those from metastatic sites.

"This study demonstrates not only the important role that FOLR1 testing can play in developing treatment strategies, but how it can help guide clinicians on the appropriate tumor sites to test to acquire the best information for that treatment guidance," said Ramkissoon.

About Labcorp
Labcorp (NYSE: LH) is a global leader of innovative and comprehensive laboratory services that helps doctors, hospitals, pharmaceutical companies, researchers and patients make clear and confident decisions. We provide insights and advance science to improve health and improve lives through our unparalleled diagnostics and drug development laboratory capabilities. The company's more than 67,000 employees serve clients in over 100 countries, worked on over 84% of the new drugs approved by the FDA in 2023 and performed more than 600 million tests for patients around the world. Learn more about us at www.labcorp.com.

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[1] Antitumor efficacy of PARP inhibitors in homologous recombination deficient carcinomas

[2] Poly(ADP-Ribose) Polymerase Inhibitors in the Management of Ovarian Cancer: ASCO Guideline Rapid Recommendation Update

[3] PARP Inhibitors: Clinical Limitations and Recent Attempts to Overcome Them

[4] Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer

[5] First-line PARP inhibition in ovarian cancer — standard of care for all?

[6] Final SORAYA Analysis Supports Mirvetuximab Soravtansine in Ovarian Cancer

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SOURCE Laboratory Corporation of America Holdings

Media, Kimbrel Arculeo, 336-436-8263, Media@Labcorp.com; Investors, Christin O'Donnell, 336-436-5076, Investor@Labcorp.com