Put It on the Board

FDA approves Ventana FOLR1 (FOLR1-2.1) RxDx as companion diagnostic

December 2022—The Food and Drug Administration has approved the Ventana FOLR1 (FOLR1-2.1) RxDx Assay, the first immunohistochemistry companion diagnostic test to aid in identifying epithelial ovarian cancer patients who are eligible for targeted treatment with Elahere (mirvetuximab soravtansine-gynx). Elahere is a first-in-class antibody-drug conjugate therapy developed by ImmunoGen and approved under the FDA's accelerated approval program for the treatment of FRα-positive platinum-resistant ovarian cancer.

Folate receptor 1 protein (FOLR1), also known as folate receptor alpha (FRα), is expressed at some level in about 90 percent of ovarian carcinomas and serves as a predictive biomarker for FOLR1-targeted therapy for epithelial ovarian cancer patients. The new test informs clinicians about the likelihood of potential patient benefit from FOLR1 therapy, Roche said in its Nov. 14 news release. "We're proud to expand our women's health and oncology portfolios through the addition of the first companion diagnostic IHC test for ovarian cancer," Jill German, head of pathology lab, Roche Diagnostics, said in the release.

The approval is based on the results of the SORAYA clinical study, in which about 35 percent of ovarian cancer patients expressed high levels of FRα (defined as ≥ 75 percent tumor cells staining with 2+/3+ intensity) and were considered FRα positive by the Ventana FOLR1 (FOLR1-2.1) RxDx Assay. Of the FRα-positive patients, about 32 percent demonstrated a partial or complete response to Elahere therapy.

The Ventana FOLR1 (FOLR-2.1) RxDx Assay is a qualitative IHC assay using mouse monoclonal anti-FOLR1 clone FOLR1-2.1 intended for use in assessing FRα in formalin-fixed, paraffin-embedded epithelial ovarian cancer (including primary peritoneal cancer and primary fallopian tube cancer) tissue specimens by light microscopy. The OptiView DAB IHC detection kit is used for staining on a BenchMark Ultra instrument.

Werfen to acquire Immucor

Werfen has agreed to acquire Immucor, a privately held corporation with a global presence in transfusion and transplant in vitro diagnostics, headquartered in Norcross, Ga. Werfen says the acquisition will allow it to expand its portfolio of specialized diagnostics solutions for hospitals and clinical laboratories.

The purchase price is expected to be about $2 billion, with closing subject to customary regulatory approvals.

"As a global leader in the research, development, manufacturing, and distribution of innovative, specialized diagnostics solutions for hospitals and clinical laboratories, Immucor is a natural fit with our existing business model," Werfen president Marc Rubiralta said in a news release.

Werfen CEO Carlos Pascual called the acquisition a "major milestone" in Werfen's future and said, "Immucor's expertise and innovations in transfusion and transplant diagnostics enable us to enter new markets and will help achieve our vision to be the preferred choice of the most advanced laboratory and point-of-care customers, globally."

The transaction is expected to close during the first half of 2023.

Illumina introduces research panel for genitourinary pathogen ID

Illumina introduced a research test for genitourinary pathogen and antimicrobial resistance identification. The Illumina Urinary Pathogen Infectious Disease/Antimicrobial Resistance Panel (UPIP) applies precision metagenomics to detect and quantify pathogens, including those that are drug resistant.

In less than 48 hours, Illumina says, UPIP, a next-generation sequencing-based panel, detects and quantifies more than 170 organisms that can cause genitourinary infections and more than 3,700 antimicrobial resistance markers

associated with 18 different drug classes. Combined with the use of Explify, a fully automated data analysis platform, this workflow provides a comprehensive infection profile across bacterial, fungal, viral, and parasitic microbes.

“The growing threat of infections by common and uncommon microbes with growing antimicrobial drug resistance is alarming; public health and private laboratories require new tools to fight emerging threats,” Phil Febbo, MD, chief medical officer of Illumina, said in a news release. The UPIP test, he said, is “a unique opportunity for microbiologists and clinical researchers to rapidly identify pathogens and potential drug resistance for complicated or recurrent urinary infections.”

Biocare Medical acquires Empire Genomics

Biocare Medical announced its acquisition of Empire Genomics, a designer, manufacturer, and distributor of a comprehensive menu of clinical and custom-labeled molecular probes.

“This acquisition complements our broad portfolio of IHC antibodies, robust molecular menu, and advanced automation platforms,” Biocare Medical CEO Luis de Luzuriaga said in a news release.