FDA approves Ventana CDx to ID patients eligible for Elahere

Nov. 17, 2022—Roche announced FDA approval of 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 folate receptor alpha–positive platinum-resistant ovarian cancer.

The Ventana FOLR1 RxDx assay is a qualitative immunohistochemical assay using mouse monoclonal anti-FOLR1, clone FOLR1-2.1, intended for use in the assessment of folate receptor alpha protein in formalin-fixed, paraffin-embedded epithelial ovarian, fallopian tube, or primary peritoneal cancer tissue specimens by light microscopy. It is for use with an OptiView DAB IHC detection kit for staining on a BenchMark Ultra instrument.