FDA approves Roche MMR test as a companion diagnostic

April 23, 2021—Roche announced FDA approval of the Ventana MMR RxDx Panel for advanced or recurrent endometrial cancer patients. Testing can identify patients eligible for treatment with JEMPERLI (dostarlimab-gxly) monotherapy, an anti-PD1 immunotherapy from GlaxoSmithKline that was FDA approved on April 22.

The Ventana MMR RxDx Panel is a qualitative immunohistochemistry test intended for use in the assessment of mismatch repair proteins MLH1, PMS2, MSH2, and MSH6 in formalin-fixed, paraffin-embedded endometrial carcinoma tissue by light microscopy. The OptiView DAB IHC detection kit is used for MLH1, MSH2, and MSH6, and the OptiView DAB IHC detection kit with the OptiView amplification kit is used for PMS2 on a Ventana BenchMark Ultra instrument.

“We are excited to launch this companion diagnostic test with GSK to help recurrent or advanced endometrial cancer patients with limited treatment options,” Thomas Schinecker, CEO of Roche Diagnostics, said in a press release. “This test provides clinicians with an effective tool to identify patients best suited for treatment with GSK’s JEMPERLI, providing a new therapeutic option for women with MMR-deficient endometrial cancer whose disease progresses on or following initial chemotherapy treatment.”

The Ventana MMR RxDx Panel is a label expansion of Roche’s Ventana MMR IHC Panel.