FDA approves Therascreen FGFR kit + erdafitinib

April 17, 2019—Qiagen announced the U.S. launch of its Therascreen FGFR RGQ RT-PCR Kit as a companion diagnostic to help guide the use of the FGFR kinase inhibitor Balversa (erdafitinib; Janssen Biotech). The test will aid in identifying patients with urothelial cancer whose tumors have certain alterations in the fibroblast growth factor receptor 3 gene. The FDA co-approved the test with Balversa.

“We are very excited about the launch of the new Therascreen FGFR kit, the first companion diagnostic test to obtain FDA approval for detection of FGFR gene alterations to guide therapy in any cancer indication. Using our test to help guide treatment decisions in urothelial cancer will address a high unmet medical need among patients,” Thierry Bernard, senior vice president and head of molecular diagnostics, Qiagen, said in a press release. “The new Therascreen FGFR kit and significant testing capacities at leading laboratories will be available through Qiagen’s Day-One Lab Readiness program to accelerate the availability of innovations in precision medicine.”

The Therascreen FGFR kit will run on Qiagen’s Rotor-Gene Q MDx.