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Roche, Merck partner to develop a companion diagnostic test

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Roche collaborates with Merck to develop companion diagnostic for use with Keytruda (pembrolizumab), Merck's anti-PD-1 therapy, in advanced solid tumors with mismatch repair deficiency (dMMR)



Roche has announced that it entered into a collaboration with Merck (known as MSD outside the United States and Canada) to develop a companion diagnostic test to identify patients eligible for anti-PD-1 therapy based on the status of a biomarker in advanced solid tumors. The companies will collaborate on the development of a pan-cancer companion diagnostic to detect mismatch repair deficiency (dMMR) in solid tumors.

"We are excited to collaborate with Merck to develop a pan-cancer companion diagnostic test panel to detect mismatch repair deficiency," said Jill German, Head of Roche Tissue Diagnostics. "This new development could help change the way we identify patients best suited for immunotherapy treatment."

Cancer treatment has been predominantly determined by the location in the body where the tumor originated. The development of an MMR immunohistochemistry (IHC) assay potentially paves the way for treatment decisions to be made based on biomarker expression within solid tumors originating from various parts of the body.

"A key element of our strategy at Merck is focused on identifying those patients likely to benefit most from our medicines," said Dr. Eric Rubin, senior vice president, oncology clinical development, Merck Research Laboratories. "We look forward to working with Roche to develop a diagnostic test for mismatch repair deficiency."

In May 2017, Keytruda, Merck's anti-PD-1 therapy, became the first cancer treatment approved by the US Food and Drug Administration for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no other alternative treatment options, or colorectal cancer that has progressed following treatment with certain chemotherapy drugs.

Testing for MMR consists of the immunohistochemical detection of four MMR proteins (MLH1, MSH2, MSH6 and PMS2).[1,2] These assays, along with BRAF V600E, are currently used clinically to aid in the identification of a genetic predisposition for colorectal and other cancers called Lynch syndrome. This collaboration is expected to expand the utility of this panel to include selection of patients with solid tumors for immunotherapy.

The companion diagnostic currently under development is an IHC test for use on the Roche BenchMark ULTRA instrument, which, as the most widely installed IHC/ISH (in situ hybridization) staining platform globally, will provide broad testing access to patients.