Yervoy OK’d for MSI-H/dMMR mCRC patients

July 13, 2018—The FDA granted accelerated approval to ipilimumab (Yervoy, Bristol-Myers Squibb) for use in combination with nivolumab (Opdivo, BMS) for the treatment of patients 12 years and older with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Approvals were based on data from the ongoing phase two CheckMate 142 study; the Opdivo plus Yervoy cohort of the trial enrolled MSI-H/dMMR mCRC patients who had received at least one prior line of therapy for metastatic disease, and efficacy was analyzed for patients who had received prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan (82 of the total 119 patients) and also for all enrolled patients.

“Metastatic colorectal cancers with dMMR or MSI-H biomarkers can be difficult to treat and some patients may need additional options,” Heinz-Josef Lenz, MD, L. Terrence Lanni chair in gastrointestinal cancer research, University of Southern California Keck School of Medicine, and principal investigator of the study at USC Norris Comprehensive Cancer Center, said in a BMS release. “The FDA’s approval of an I-O/I-O combination provides us with an encouraging approach to address this challenging disease in patients who have progressed following treatment with three standard chemotherapy options.”