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After our article on nivolumab (Opdivo – BMS) for treatment of metastatic melanoma and metastatic squamous non-small cell lung cancer (NSCLC) was published in the most recent issue of The Medical Letter (June 8, 2015),1 some new data became available supporting the efficacy of the drug in previously untreated melanoma and previously treated nonsquamous NSCLC.

MELANOMA – In a double-blind trial, 945 patients with previously untreated, unresectable stage III or IV melanoma were randomized to receive ipilimumab, nivolumab, or combination therapy with ipilimumab and nivolumab. Progression-free survival, a primary endpoint, improved by 43% with nivolumab (median 6.9 months) and by 58% with combination therapy (median 11.5 months), compared to ipilimumab (median 2.9 months). In patients with tumors that expressed the programmed death ligand 1 (PD-L1) on ≥5% of cells, median progression-free survival was similar in the nivolumab and combination groups (both 14.0 months); in those with tumors that expressed PD-L1 on <5% of cells, it was 5.3 months with nivolumab alone and 11.2 months with both drugs. Rates of complete or partial response were 19.0% with ipilimumab, 43.7% with nivolumab, and 57.6% with combination therapy. At least one severe (grade 3-4) drug-related adverse effect occurred in 27.3% of patients receiving ipilimumab, 16.3% of those receiving nivolumab, and 55.0% of those receiving both drugs.2

NON-SQUAMOUS NSCLC – In an open-label trial (available only as an abstract), 582 patients with advanced nonsquamous NSCLC that had progressed during or after treatment with a platinum doublet-based regimen (and, if appropriate, a kinase inhibitor) were randomized to receive nivolumab or docetaxel until disease progression or unacceptable toxicity occurred. Nivolumab significantly improved overall survival, the primary endpoint, by 27% compared to docetaxel (median 12.2 vs 9.4 months). Survival rates in the two groups were similar in patients with tumors expressing PD-L1 on <1% of cells, but in patients with tumors expressing PD-L1 on ≥1%, ≥5%, and ≥10% of cells, nivolumab improved overall survival by 41%, 57%, and 60%, respectively, compared to docetaxel. Patients receiving nivolumab were significantly more likely to have an objective response (19.2% vs 12.4%). Severe (grade 3+) drug-related adverse effects occurred in 10.5% of patients receiving nivolumab and in 53.7% of those receiving docetaxel.3