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Addendum: Nivolumab *(Opdivo)* for Metastatic Melanoma and Metastatic NSCLC

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]

NONSQUAMOUS 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] ■

1. Nivolumab (Opdivo) for metastatic melanoma and metastatic NSCLC. Med Lett Drugs Ther 2015; 57:85.
2. J Larkin et al. Combined nivolumab and ipilimumab or monotherapy in untreated melanoma. N Engl J Med 2015 May 31 (epub).
3. L Paz-Ares et al. Phase III, randomized trial (CheckMate 057) of nivolumab (NIVO) versus docetaxel (DOC) in advanced non-squamous cell (non-SQ) non-small cell lung cancer (NSCLC). J Clin Oncol 2015; 33 (suppl; abstr LBA109). Available at: abstracts.asco.org/156/AbstView_156_154634.html. Accessed June 11, 2015.

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