FDA-approved cancer therapies

October 2018—The Food and Drug Administration approved moxetumomab pasudotox-tdfk (Lumoxity, AstraZeneca), a CD22-directed cytotoxin indicated for adult patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including treatment with a purine nucleoside analog. Approval was based on Study 1053 in patients with histologically confirmed HCL or HCL variant requiring treatment based on presence of cytopenias or splenomegaly and who had received prior treatment with at least two systemic therapies, including one PNA. A total of 80 patients were enrolled, 77 with classic HCL and three with HCL variant. Lumoxity was approved under FDA priority review.

The FDA in August approved an expanded label for Merck's Keytruda (pembrolizumab) in combination with pemetrexed and platinum chemotherapy as first-line treatment of patients with metastatic, nonsquamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations, based on results of the KEYNOTE-189 trial. In this phase three trial, Keytruda in combination with pemetrexed and platinum chemotherapy demonstrated a statistically significant and clinically meaningful improvement in overall survival, reducing the risk of death by half compared with chemotherapy alone. The study also showed a significant improvement in progression-free survival compared with chemotherapy alone.

The FDA granted accelerated approval to nivolumab (Opdivo, Bristol-Myers Squibb) for patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy. Approval was based on demonstration of a durable overall response rate in a subgroup of patients from CheckMate-032, a multicenter, open-label trial in patients with metastatic solid tumors. This subgroup comprised 109 patients with metastatic SCLC, with disease progression after platinum-based therapy, and at least one other prior line of therapy, regardless of tumor PD-L1 status.