Supplemental Approvals

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
February 28, 2018	
Durvalumab	FDA expanded the approval of durvalumab for the treatment of patients with Stage III non–small cell lung cancer (NSCLC) whose tumors cannot be surgically removed (unresectable) and whose cancer has not progressed after treatment with chemotherapy and radiation. The agent was previously granted accelerated approval in 2017 for the treatment of certain patients with locally advanced or metastatic bladder cancer. Durvalumab targets the PD-1/PD-L1 pathway. By blocking these interactions, the agent may help the body's immune system attack cancer cells. Approval of durvalumab for the treatment of stage III, unresectable NSCLC was based on a randomized trial of 713 patients whose cancer had not progressed after completing chemotherapy and radiation. The median progression-free survival for patients taking durvalumab was 16.8 months compared with 5.6 months for patients receiving a placebo. In addition, the sponsor has agreed to a postmarketing commitment to provide additional information from their study to FDA about how long patients lived following treatment with durvalumab after chemotherapy and radiation (overall survival). Common adverse effects of durvalumab in patients with stage III unresectable NSCLC include cough, fatigue, inflammation in the lungs (pneumonitis/radiation pneumonitis), upper respiratory tract infections, difficulty breathing, and rash. Serious immune-mediated adverse effects include pneumonitis, hepatitis, colitis, endocrinopathies, and nephritis. Other serious adverse effects include infection and infusion-related reactions. Because the agent can cause harm to a developing fetus, women should be advised of the potential risk to

(Imfinzi—AstraZeneca)

FDA expands approval to reduce the risk of NSCLC progressing

the fetus and to use effective contraception.

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