Opdivo + chemo approved as neoadjuvant treatment for NSCLC

March 9, 2022—The FDA has approved Bristol Myers Squibb's Opdivo (nivolumab) in combination with platinum-doublet chemotherapy for adult patients with resectable non-small cell lung cancer in the neoadjuvant setting. The treatment is approved regardless of PD-L1 status and is based on the CheckMate -816 trial, the first positive phase three trial of an immunotherapy-based combination used before surgery for resectable NSCLC.

The primary endpoints included event-free survival and pathologic complete response, which were evaluated using independent blinded review, and an additional efficacy outcome measure was overall survival. The study compared Opdivo plus platinum-doublet chemotherapy (n=179) to platinum-doublet chemotherapy alone (n=179). In the trial, Opdivo plus chemotherapy, when given before surgery, showed a statistically significant improvement in event-free survival with a 37 percent reduction in the risk of progression, recurrence, or death (hazard ratio=0.63; 95 percent confidence interval, 0.45–0.87; P=0.0052) compared with chemotherapy alone.

This application was approved under the FDA's real-time oncology review pilot program and was also conducted under the FDA's Project Orbis initiative, which enabled concurrent review by the health authorities in Australia, Canada, and the United Kingdom, where the application remains under review.