Durvalumab Receives FDA Approval for Muscle Invasive Bladder Cancer

- Durvalumab, combined with gemcitabine and cisplatin, is approved for neoadjuvant treatment in MIBC, followed by adjuvant durvalumab post-cystectomy.
- The NIAGRA trial showed significant improvements in EFS and OS for patients receiving durvalumab, with a 67.8% EFS at 24 months.
- Treatment-related adverse events were similar between the durvalumab and control groups, with grade 3 or 4 events occurring in about 40% of patients.

Approval of durvalumab is in combination with gemcitabine and cisplatin as neoadjuvant treatment for adults with muscle invasive bladder cancer.

The FDA has approved durvalumab (Imfinzi; AstraZeneca) with gemcitabine and cisplatin as neoadjuvant treatment, followed by single-agent durvalumab as adjuvant treatment following radical cystectomy, for adults with muscle invasive bladder cancer (MIBC), according to a news release from the FDA.1

Durvalumab has indications in certain types of cancers either as a monotherapy or a combination therapy, including non-small cell lung cancer, small cell lung cancer, biliary tract cancer, unresectable hepatocellular carcinoma, and certain kinds of endometrial cancer.2

Typically, neoadjuvant chemotherapy followed by radical cystectomy is the standard when treating cisplatin-eligible patients with MIBC. By adding perioperative immunotherapy, patients may experience improved outcomes. NIAGRA (NCT03732677), a randomized, open-label, multicenter, phase 3 clinical trial, evaluated the efficacy and safety of durvalumab in this patient population. This trial enrolled 1063 patients who were candidates for radical cystectomy and had not received prior systemic therapy for bladder cancer.1,3,4

Patients were randomly assigned to receive either neoadjuvant durvalumab with chemotherapy followed by adjuvant durvalumab after surgery (n = 533), or neoadjuvant chemotherapy followed by surgery alone (n = 530). The primary end points were event-free survival (EFS), which was assessed up to 48 months, and pathologic complete response (pCR) rates, which were assessed up to 6 months. The key secondary end point was overall survival, with safety and tolerability end points also assessed.3,4

The estimated EFS, according to findings published in The New England Journal of Medicine, the estimated EFS at 24 months was about 67.8% (95% CI, 63.6 to 71.7) in the durvalumab group and 59.8% (95% CI, 55.4 to 64.0) in the comparison group (HR, 0.68; 95% CI, 0.56 to 0.82; P < .001 by stratified log-rank test). Additionally, the estimated OS at 24 months was 82.2% (95% CI, 78.7 to 85.2) in the durvalumab group and 75.2% (95% CI, 71.3 to 78.8) in the comparison group (HR, 0.75; 95% CI, 0.59 to 0.93; P = .01 by stratified log-rank test).3

Further, at a pre-specified interim analysis, NIAGRA demonstrated a statistically significant improvement in EFS and OS. Median EFS was not reached (NR; 95% CI, NR, NR) in the durvalumab with chemotherapy arm, but was 46.1 months (95% CI, 32.2, NR) in the chemotherapy arm (HR, 0.68 [95% CI: 0.56, 0.82]; 2-sided p < .0001). Median OS was not reached in either arm (HR, 0.75 [95% CI: 0.59, 0.93]; 2-sided p = .0106).1

Treatment-related adverse events (AEs) of grade 3 or 4 in severity occurred in about 40.6% of the patients in the durvalumab group and in 40.9% of those in the comparison group. Treatment-related AEs that lead to death occurred in 0.6% in each group. Radical cystectomy was performed in approximately 88.0% of patients in the durvalumab group and 83.2% in the comparison group.3 Additionally, AEs were found to be consistent with prior experience with durvalumab with platinum-based chemotherapy, according to the FDA news release.1

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