

Adjuvant nivolumab + ipilimumab lacks efficacy for localized renal cell carcinoma

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Disease-free survival (DFS) does not differ with adjuvant nivolumab

plus ipilimumab (NIVO+IPI) compared with placebo in patients with localized renal cell carcinoma (RCC) at high risk for postnephrectomy relapse, according to a study presented at the annual meeting of the European Society for Medical Oncology, held from Sept. 9 to 13 in Paris.

Robert J. Motzer, M.D., from the Memorial Sloan Kettering Cancer Center in New York City, and colleagues conducted a phase 3, randomized trial evaluating NIVO+IPI versus placebo (part A) or NIVO monotherapy versus NIVO+IPI versus placebo (part B) in patients with localized RCC at high risk for postnephrectomy relapse. Results were reported for part A of the trial.

Overall, 816 patients were randomly assigned to NIVO+IPI and placebo (405 and 411 patients, respectively). The researchers found that the primary efficacy end point of DFS was not met. The median DFS was not reached and was 50.7 months for NIVO+IPI and placebo, respectively; at 24 months, the probabilities of DFS were 76.4 and 74.0 percent, respectively. The median duration of treatment was 5.1 months in both groups. In 88.9 and 56.8 percent of patients receiving NIVO+IPI and placebo, respectively, any-grade treatment-related adverse events were reported; grade ≥ 3 treatment-related adverse events were reported in 28.5 and 2.0 percent, respectively.

"It is important to share these results with the [scientific community](#) to provide valuable insight for the advancement of medicines that may help patients achieve better outcomes," Motzer said in a statement. "We must remain focused on bringing innovative treatment options to [patients](#) with challenging-to-treat diseases like RCC."

Several authors disclosed financial ties to biopharmaceutical companies, including Bristol Myers Squibb, which manufactures nivolumab and ipilimumab and funded the study.

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