KIDNEY CANCER NEWS

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Cancer Vaccine Fails to Improve Survival in Metastatic Renal Cell Carcinoma

The addition of the IMA901 multipeptide cancer vaccine to sunitinib (Sutent, Pfizer) did not improve overall survival (OS) vs sunitinib alone as first-line treatment for metastatic renal cell carcinoma (RCC), according to results from IMPRINT, an international phase 3 trial.

For the trial, which appeared in the November issue of the *Lancet Oncology*, Dr Brian Rini and colleagues randomly assigned 339 patients with *HLA-A*02*–positive metastatic or locally advanced clear cell RCC to receive up to 10 doses of IMA901 plus sunitinib (204 patients) or sunitinib alone (135 patients). Patients who received IMA901 also received granulocyte-macrophage colony-stimulating factor with each injection and a dose of cyclophosphamide before the first vaccination.

After a median follow-up of 33.27 months, median OS did not differ significantly between the vaccine group (33.17 months; 95% CI, 27.81-41.36) and the sunitinib-alone group (not reached; 95% CI, 33.67 months-not reached). Median progression-free survival also did not differ significantly between the vaccine group (15.22 months; 95% CI, 12.46-18.08) and the sunitinib-alone group (15.12 months; 95% CI, 10.19-18.58). Grade 3 or higher adverse events, which included hypertension, neutropenia, and anemia, occurred in 57% of patients in the vaccine group and 47% of patients in the sunitinib-alone group.

In a commentary that appeared in the same issue, Dr Sumanta Pal and colleagues wrote that "these long-awaited results strike yet another blow to the concept of vaccine therapy in metastatic renal cell carcinoma." They recommended that investigators continue to pursue vaccines that produce robust preliminary data, as well as combinations of vaccines and checkpoint inhibitors.

Girentuximab Does Not Improve Outcomes After Nephrectomy for High-Risk RCC

Adjuvant therapy with girentuximab does not improve survival in patients with high-risk clear cell RCC, a new study finds. Girentuximab is a monoclonal antibody that binds carbonic anhydrase IX.

The phase 3 study, called ARISER, was published online October 27 in *JAMA Oncology*. It included 864 patients who had undergone partial or radical nephrectomy for high-risk clear cell RCC (high risk was defined as pT3/pT4Nx/N0M0, pTanyN+M0, or pT1b/pT2Nx/N0M0 with a nuclear grade of 3 or higher). Dr Karim Chamie and colleagues randomly assigned participants to receive a single loading dose of girentuximab followed by weekly intravenous infusions (433 patients) or placebo (431 patients).

After a median follow-up of 54 months, there was no difference in disease-free survival (DFS) between the groups, with a median DFS of 71.4 months for the girentuximab group vs not reached for the placebo group. There also was no difference between the groups in median OS, which was not reached in either of the groups. Drug-related and serious adverse events were similar in the 2 groups.

In an editorial that accompanied the article, Drs Martin Voss and Robert Motzer said that although ARISER "is an impressive international effort to address a critical clinical need in this disease," it may have been underpowered to show a significant treatment effect because the study population was at lower risk than anticipated.

Sunitinib After Nephrectomy for RCC Increases Disease-Free Survival But Also Toxicity

Sunitinib significantly increases DFS compared with placebo in patients with RCC who are at high risk for tumor recurrence after nephrectomy, according to a new phase 3 trial.

For the S-TRAC trial, which was published online October 10 in the *New England Journal of Medicine*, Dr Alain Ravaud and colleagues randomly assigned 615 patients with resected locoregional, high-risk clear cell RCC to receive either sunitinib or placebo for 1 year or until disease recurrence or unacceptable toxicity.

After a median follow-up of 5.4 years, median DFS was significantly longer in the sunitinib group than in the placebo group: 6.8 years (95% CI, 5.8-not reached) vs 5.6 years (95% CI, 3.8-6.6). Grade 3 or 4 adverse events were more frequent with sunitinib than with placebo, at 60.5% vs 19.4%.

The authors concluded that although sunitinib increased DFS in patients with locoregional RCC, it led to "moderate declines in quality of life" while patients received active treatment.