FDA Approves Fotivda for Advanced Kidney Cancer

The kinase inhibitor delayed disease progression by 27% for people who had tried at least two prior therapies.

March 25, 2021 By Liz Highleyman

On March 10, the Food and Drug Administration (FDA) approved Fotivda (tivozanib) for people with relapsed or refractory (nonresponsive) renal cell carcinoma, the most common type of kidney cancer.

"Today's approval of Fotivda provides a new tool for treating patients with kidney cancer who have relapsed or become refractory to two or more prior systemic therapies," Brian Rini, MD, of Vanderbilt Ingram Cancer Center, said in an AVEO Oncology press release. "With advances in renal cell carcinoma treatment, patients are living longer, increasing the need for proven, well-tolerated treatment options in the relapsed or refractory setting.... I believe Fotivda represents an attractive intervention, and expect it to play a meaningful role in the evolving RCC treatment landscape."

Nearly 76,000 people will be diagnosed with kidney cancer this year, according to the American Cancer Society. Renal cell carcinoma (RCC) accounts for more than 90% of cases. Kidney cancer often has few symptoms during its early stages, and many patients already have metastatic disease by the time they are diagnosed. Standard treatment may involve surgery, radiation, targeted therapy or immunotherapy.

The approval is supported by findings from the Phase III TIVO-3 trial (ClinicalTrials.gov NCT02627963), which compared Fotivda versus Nexavar (sorafenib) in adults with relapsed or refractory advanced RCC who had received two or more prior systemic therapies.

Fotivda and Nexavar are both kinase inhibitors that block the action of VEGFR and other enzymes that play a role in cell growth and angiogenesis, the development of blood vessels that feed tumors.

Rini and his colleagues enrolled 350 participants in 12 countries. They were randomly assigned to receive Fotivda taken orally once daily for 21 days followed by a week off or Nexavar taken orally twice daily on a continuous basis until they experienced disease progression or unacceptable side effects.

As previously reported in Lancet Oncology, the overall response rate, meaning complete or partial tumor regression, was 18% in the Fotivda group compared with 8% in the Nexavar group.

The median progression-free survival time, meaning patients were still alive without worsening of their disease, was 5.6 months in the Fotivda group versus 3.9 months in the Nexavar group, a small but statistically significant difference. The median overall survival time was a bit longer in the Nexavar group (19.2 months) compared with the Fotivda group (16.4 months), but this difference was not significant, meaning it could have been due to chance.

Rini noted that TIVO-3 is the first positive Phase III study in RCC patients who had received two or more prior systemic therapies and also the first such study to include a defined population of patients who had received prior checkpoint inhibitor immunotherapy.

Treatment was generally safe, but side effects are common. In the trial, people taking Fotivda reduced their doses or interrupted treatment less often than those taking Nexavar (48% versus 63%); 8% and 15%, respectively, permanently discontinued treatment.

The most common adverse reactions associated with Fotivda are fatigue, high blood pressure, diarrhea, decreased appetite, nausea, difficulty speaking, hypothyroidism, cough and mouth sores. The Fotivda label lists warnings about less common but more serious side effects, including severe hypertension, heart problems, blood clots, severe bleeding, protein in the urine and impaired wound healing.

AVEO indicated that Fotivda would be available in the United States by the end of March.

“Relapsed or refractory RCC is a devastating disease for which patient outcomes can be limited due to the trade-off between tolerability and efficacy,” said KCCure president Dena Battle. “The FDA approval of Fotivda represents an exciting, meaningful advancement by providing a new treatment option for this patient population.”

Click here for full prescribing information for Fotivda.

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