Fotivda® (tivozanib) – New drug approval

- On March 10, 2021, AVEO Oncology announced the FDA approval of Fotivda (tivozanib), for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

- Fotivda is a vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI).

- The efficacy of Fotivda was established in TIVO-3, a randomized, open-label study comparing Fotivda vs. Nexavar® (sorafenib) in patients with relapsed or refractory advanced RCC who received 2 or 3 prior systemic treatments including at least one VEGFR kinase inhibitor other than Nexavar or Fotivda. Patients received Fotivda or Nexavar until disease progression or unacceptable toxicity. The primary endpoint was progression-free survival (PFS). Other efficacy endpoints were objective response rate (ORR) and overall survival (OS).

    - Median PFS was 5.6 months for Fotivda vs. 3.9 months for Nexavar (hazard ratio [HR] 0.73, 95% CI: 0.56, 0.95; p = 0.016).
    - Median OS was 16.4 months for Fotivda vs. 19.2 months for Nexavar (HR 0.97, 95% CI: 0.75, 1.24).
    - The ORR was 18% (95% CI: 12, 24) for Fotivda vs. 8% (95% CI: 4, 13) for Nexavar.

- Warnings and precautions for Fotivda include hypertension and hypertensive crisis; cardiac failure; cardiac ischemia and arterial thromboembolic events; venous thromboembolic events; hemorrhagic events; proteinuria; thyroid dysfunction; risk of impaired wound healing; reversible posterior leukoencephalopathy syndrome; embryo-fetal toxicity; and allergic reactions to tartrazine (FD&C Yellow No.5).

- The most common adverse reactions (≥ 20%) with Fotivda use were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common grade 3 or 4 laboratory abnormalities (≥ 5%) were decreased sodium, increased lipase, and decreased phosphate.

- The recommended dosage of Fotivda is 1.34 mg taken orally once daily for 21 days on treatment followed by 7 days off treatment for a 28-day cycle. Treatment should be continued until disease progression or until unacceptable toxicity occurs.

- AVEO Oncology plans to launch Fotivda by March 31, 2021. Fotivda will be available as 1.34 and 0.89 mg capsules.