**Patient preference for tivozanib hydrochloride or sunitinib in the treatment of metastatic renal cell carcinoma (mRCC): TAURUS study design**

Bernard Escudier,1 Lori Steelman,2 Dajana Cesic,2 Anna Berkenblit2

1 Institut Gustave Roussy, Villejuif, France; 2 AVEO Oncology, Cambridge, MA, USA

**Background**

- Vascular endothelial growth factor receptors (VEGFRs) play a critical role during tumor angiogenesis via the promotion of endothelial cell proliferation, migration, and survival.
- Most cases of renal cell carcinoma (RCC) are characterized by a loss of function of the von Hippel-Lindau tumor suppressor gene, which results in an increase in expression of vascular endothelial growth factor (VEGF) and a subsequent increase in tumor angiogenesis.
- Tivozanib hydrochloride (tivozanib) is a potent and selective inhibitor of VEGFRs 1, 2, and 3.
- Patients with controlled disease or progressive disease (PD) at the end of the first 12-week treatment period will remain blinded and will cross over to the second treatment for 12 weeks, following the washout period.
- Patients who withdraw early from either treatment period will have their disease status assessed immediately.

**Study Design**

- **Inclusion Criteria**
  - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
  - Patients with or without prior nephrectomy.
  - Histologically or cytologically confirmed RCC of any histology.

- **Exclusion Criteria**
  - Myocardial infarction or severe angina within 6 months prior to study entry.
  - Uncontrolled hypertension.
  - Patients with a significant clinical response may continue receiving the same treatment as during the first 12 weeks if the patient prefers it.
  - Patients who withdraw early from either treatment period will have their disease status assessed immediately.

- **Statistical Methods**
  - The proportion of patients who prefer tivozanib will be calculated and presented along with the 95% confidence interval based on the exact binomial distribution.
  - The receiving operating characteristic curve also will be reported for each arm.

- **Exploratory**
  - Analysis of safety data after the first 12 weeks will be exploratory.

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