FOR IMMEDIATE RELEASE

AVEO and Astellas Announce TAURUS Patient Preference Clinical Study Comparing Tivozanib with Sunitinib in First-Line Kidney Cancer

Study designed to build upon safety profile demonstrated in TIVO-1 study

CAMBRIDGE, Mass. and TOKYO, Japan, June 4, 2012 – AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced plans to initiate a new clinical study, TAURUS (TivozAnib Use veRsUs Sutent in advanced renal cell carcinoma (RCC): Patient Preference), to establish additional data regarding the investigational drug tivozanib when used as first-line therapy in patients with advanced RCC. The TAURUS study will enroll patients at sites throughout the United States and Western Europe.

"With more treatment options available for patients living with cancer, it's becoming increasingly critical to understand how patient preference is influenced by side effects and other related issues," said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO. "Following the positive findings from the Phase 3 TIVO-1 trial, the TAURUS study will allow us to further define the tolerability profile of tivozanib and understand the role that tivozanib could play in the treatment of first line advanced kidney cancer compared to a standard of care drug."

"Patients and their healthcare providers are looking for anti-cancer agents that are more effective and better tolerated than existing therapeutic options," said Bernard Escudier, M.D., principal investigator for TAURUS, Institut Gustave Roussy, "The TAURUS study will help us better understand how the side effect profiles of drugs affect patients' treatment choices. The typical patient being treated for metastatic kidney cancer is middle-aged, active and is still in the work force and therefore the impact of side effects may be more important to them."

"The TAURUS trial will help us better understand patient preference in selecting kidney cancer treatment options," stated Steven Ryder, M.D., president, Astellas Pharma Global Development. "The study supports Astellas' goal of leadership in oncology and our commitment to improving patient care."

TAURUS is a randomized (1:1), double-blind, crossover controlled, multi-center Phase 2 study comparing tivozanib versus sunitinib in approximately 160 patients with advanced RCC who have received no prior systemic therapy. The primary objective of the study is to compare patient preference after receiving both tivozanib and sunitinib in sequence. Secondary objectives are to

evaluate the incidence of treatment-emergent Grade 3/4 adverse events (AEs) and serious adverse events (SAEs); frequency of dose modifications; and quality of life in patients treated with tivozanib versus sunitinib.

Tivozanib is an investigational drug that successfully completed a pivotal Phase 3 trial called TIVO-1 in which tivozanib demonstrated superiority in progression-free survival and favorable tolerability versus sorafenib in first-line advanced RCC.

About Kidney Cancer
Advanced RCC, or kidney cancer, is the ninth most commonly diagnosed cancer in men and women in the U.S.[1] Worldwide it is estimated that more than 250,000 people are diagnosed and more than 100,000 people die from the disease each year.[2] RCC accounts for more than 90 percent of all kidney cancers.[3] Currently available therapies provide less than one year of median PFS in treatment naïve patients and are associated with significant toxicities.[4] These toxicities not only lead to high rates of dose reductions and interruptions (potentially compromising efficacy), but also can impact a patient's quality of daily living.[5]

About Tivozanib
Tivozanib is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor for which positive results from a Phase 3 clinical study in advanced renal cell carcinoma have been reported, and is being evaluated in other tumors.

About TIVO-1
TIVO-1 is a global, randomized Phase 3 superiority clinical trial evaluating the efficacy and safety of investigational drug tivozanib compared to sorafenib in 517 patients with advanced RCC. TIVO-1 is the first superiority pivotal study in advanced RCC that has demonstrated statistically significant progression-free survival (PFS) superiority versus an approved targeted agent (sorafenib) in advanced RCC.

All patients in TIVO-1 had clear cell RCC, had undergone a prior nephrectomy, and had not previously been treated with either a VEGF or mTOR therapy. Key findings from TIVO-1 include[6]:

- Based on independent radiological reviews, tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib in the overall (Intent To Treat) study population (HR=0.797, 95% CI 0.639–0.993; P=0.042). Objective response rate (ORR) for tivozanib was 33% compared to 23% for sorafenib (p=0.014). The efficacy advantage of tivozanib over sorafenib was consistent across subgroups in the study.
- In patients who were treatment naïve for advanced RCC (70% of total study population), tivozanib demonstrated a statistically significant improvement in PFS with a median PFS of 12.7 months compared to a median PFS of 9.1 months for sorafenib (HR 0.756, 95% CI 0.580–0.985; P=0.037).

    - In the subpopulation of patients who were pretreated with systemic therapy including cytokines (30% of total study population), tivozanib demonstrated an improvement in PFS with a median PFS of 11.9 months compared to a median PFS of 9.1 months for sorafenib.
- The most common adverse event (all grades/≥grade 3) for tivozanib was hypertension (T: 44%/25% vs S: 34%/17%) and for sorafenib was hand-foot syndrome (T: 13%/2% vs S: 54%/17%). Other adverse events included diarrhea (T: 22%/2% vs S: 32%/6%), fatigue (T: 18%/5% vs S: 16%/4%), and neutropenia (T: 10%/2% vs S: 9%/2%).
    - The rate of dose interruptions due to adverse events was 18% for tivozanib compared to 35% for sorafenib ($p<0.001$).
    - The rate of dose reductions due to adverse events was 12% for tivozanib compared to 43% for sorafenib ($p<0.001$).

About the AVEO/Astellas Collaboration
In February 2011, AVEO and Astellas entered into a worldwide agreement outside of Asia to develop and commercialize tivozanib for the treatment of a broad range of cancers. Tivozanib, AVEO's lead investigational drug, is a potent, selective, long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors that is designed to optimize VEGF blockade while minimizing off-target toxicities. Subject to regulatory approval, AVEO will lead commercialization of tivozanib in North America and Astellas will lead commercialization of tivozanib in the European Union (EU). AVEO and Astellas are evaluating tivozanib in clinical trials in multiple solid tumors; updates on the progress of those trials are expected to be available in the coming months.

About Astellas
Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals. Astellas has approximately 17,000 employees worldwide. The organization is committed to becoming a global category leader in Urology, Immunology (including Transplantation) and Infectious Diseases, Oncology, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company website at www.astellas.com/en.

About AVEO
AVEO Oncology (NASDAQ: AVEO) is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. AVEO's proprietary Human Response Platform™ provides the company unique insights into cancer biology and is being leveraged in the discovery and clinical development of its cancer therapeutics. For more information, please visit the company's website at www.aveooncology.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "could," "should," "seek," or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: tivozanib's potential and role in treating patients with kidney cancer, whether the Taurus clinical study will reveal new and/or beneficial information about tivozanib or other drugs; and AVEO's plans for advancing the registration process for tivozanib. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including risks relating to: whether the results of TIVO-1 are sufficient to obtain marketing approval for tivozanib, which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities the safety and efficacy of tivozanib based upon the findings of TIVO-1, including its data with respect to PFS, the rate of adverse events, OS and other information that the FDA may determine to be relevant to approvability; AVEO's inability to demonstrate in subsequent trials any safety and efficacy it demonstrated in earlier trials of tivozanib; ongoing regulatory requirements with respect to the approval of tivozanib, including the risk that FDA or any comparable foreign regulatory agency could require additional positive clinical trials as the basis for product approval; AVEO's inability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; unplanned operating expenses; AVEO's inability to raise the substantial additional funds required to achieve its goals; adverse general economic and industry conditions; competitive factors; AVEO's ability to maintain its collaboration with Astellas; AVEO's and Astellas' ability to successfully launch and commercialize tivozanib if and when it may be approved for commercialization; and those risks discussed in the section titled "Risk Factors" and elsewhere in AVEO's most recent Annual Report on Form 10-K and in its other filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent AVEO's views as of the date of this press release. AVEO anticipates that subsequent events and developments will cause its views to change. However, while AVEO may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing AVEO's views as of any date subsequent to the date of this press release. Sutent® is a registered trademark of Pfizer Inc.

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