AVEO and Astellas Announce Positive Findings from TIVO-1 Superiority Study of Tivozanib in First Line Advanced RCC

- Tivozanib is the First Agent to Demonstrate Greater than One Year PFS in Patients without Prior Systemic Treatment -

- First Pivotal Trial vs. Active Targeted Agent in First-Line Advanced RCC -

- Study Results Demonstrate Unique Combination of Superior PFS and Favorable Tolerability -

CAMBRIDGE, MASS. and TOKYO, JAPAN, MAY 16, 2012 -- AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced that detailed data from TIVO-1 (Tivozanib Versus Sorafenib in 1st line Advanced RCC), will be presented on June 2 in an oral session by the principal investigator, Robert J. Motzer, M.D., attending physician, genitourinary oncology service, Memorial Sloan-Kettering Cancer Center, professor of medicine, Weill Medical College, Cornell University, New York, at the 2012 Annual Meeting of the American Society of Clinical Oncology (ASCO).

TIVO-1 is the first superiority pivotal study in first-line advanced RCC in which an investigational agent (tivozanib) has demonstrated statistically significant and clinically meaningful PFS superiority versus an approved targeted agent (sorafenib) in advanced RCC.

"TIVO-1 is novel in that this Phase 3 clinical study used an approved targeted comparator drug to evaluate first-line RCC treatment," said Dr. Motzer. "Patients in the study who had no prior treatment for advanced kidney cancer and who were given tivozanib met the primary PFS endpoint and tolerated the drug well."

A total of 517 patients were randomized to tivozanib (N=260) or sorafenib (N=257). The performance status and other prognostic indicators of patients enrolled in this study were consistent with other pivotal trials in first line advanced RCC.

"Despite recent advances in the treatment of kidney cancer, patients are in need of new options which are effective and well-tolerated," said Daniel George, M.D., director, GU Medical Oncology and director, prostate clinic, Duke University. "The superior PFS and favorable tolerability demonstrated by tivozanib in TIVO-1 represents an important potential step forward for patients in the treatment of kidney cancer."

Key data from TIVO-1 to be highlighted include (Abstract # 4501):

- Based on independent radiological reviews, tivozanib demonstrated a statistically significant improvement in progression-free survival (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). This is the longest median PFS reported to date in treatment naïve advanced RCC patients in a pivotal study.
    - 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.
    - Study results demonstrated favorable tolerability as evidenced by a distinctively low rate of dose interruptions and reductions. 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 was 14% for tivozanib compared to 44% for sorafenib (p<0.001).

Overall survival (OS) data are not yet mature. In TIVO-1, 53% of patients randomized to the sorafenib arm of the trial went on to receive subsequent therapy, nearly all of whom received tivozanib after sorafenib. Based on an early, interim analysis, 81% of these patients achieved one year OS. In comparison, only 17% of patients randomized to tivozanib went on to receive a subsequent therapy, and 77% of these patients achieved one year OS. Mature data are expected to be presented in 2013.

“We believe that tivozanib may play a significant role in improving the treatment of patients with advanced kidney cancer,” stated Tuan Ha-Ngoc, president and CEO of AVEO Oncology. “Together with our partner Astellas, we look forward to the next steps in our registration process and are continuing our preparations for the planned commercialization of tivozanib.”

“Based on these data, we look forward to advancing tivozanib in kidney cancer with AVEO,” stated Steven Ryder, M.D., president, Astellas Pharma Global Development. “These data further support Astellas’ goal of leadership in oncology and our commitment to developing a world-class oncology platform based on innovative, research-driven solutions and dynamic partnerships.”

About Renal Cell Carcinoma
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 renal cell carcinoma (RCC). TIVO-1 is the first superiority pivotal study in advanced RCC that has demonstrated statistically significant and clinically meaningful PFS superiority versus an approved targeted agent (sorafenib) in advanced RCC. The TIVO-1 study has demonstrated that a potent, selective and long-half life inhibitor of all three VEGF receptors can result in superior efficacy and improved tolerability.

The global, randomized, TIVO-1 superiority study evaluated the efficacy and safety of tivozanib compared to sorafenib in > 500 patients with advanced RCC. Eighty-six centers participated in the TIVO-1 study, including centers in Europe and North America. The primary efficacy endpoint (PFS) was ascertained for each subject by a central panel of blinded independent radiologists. Patients randomized to the sorafenib arm of TIVO-1 were eligible to cross over to tivozanib therapy under a separate protocol after radiographic confirmation of disease progression. No crossover protocol was available for patients randomized to the tivozanib arm.

About AVEO Oncology
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.

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 16,800 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.

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: the potential efficacy, safety and tolerability of tivozanib, tivozanib's potential and role in treating patients with kidney cancer, 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.

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