Posters 795PD, 796PD and 892TiP

AVEO and Astellas Announce New Data Presented at ESMO 2012 Congress Demonstrating the Safety and Tolerability Profile of Tivozanib in Patients with Advanced Kidney Cancer

First Patient Enrolled in TAURUS Patient Preference Study

CAMBRIDGE, Mass. and TOKYO, Japan, October 1, 2012 - AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced new data from the Phase 3 TIVO-1 trial (TIvozanib Versus sOrafenib in 1st line advanced RCC) demonstrating the safety and tolerability profile of tivozanib versus sorafenib in the first line setting for patients with metastatic renal cell carcinoma (RCC). Results presented at the ESMO 2012 Congress (European Society for Medical Oncology) in Vienna, Austria show that patients treated with tivozanib experienced fewer Grade 3 and off-target adverse events (AEs), stayed on treatment longer, and required fewer dose reductions and interruptions compared with those treated with sorafenib.[1] Also presented were the first tivozanib biomarker data in RCC, and the design of the TAURUS (TivozAnib Use veRsUs Sunitinib in advanced renal cell carcinoma) patient preference study, in which the first patient has now been enrolled. AVEO recently submitted a New Drug Application to the U.S. Food and Drug Administration seeking approval for tivozanib.

"Minimizing toxicities associated with anti-VEGF therapy is a vital consideration in RCC. Adverse events have been shown to contribute to dose reductions, interruptions and discontinuations of anti-VEGF therapy," said Timothy Eisen, Ph.D., FRCP, study investigator, Cambridge University Health Partners. "The data from TIVO-1 show that treatment with tivozanib led to fewer side effects and lower rates of dose modifications than with sorafenib. This suggests that it is easier to maintain full dose therapy with tivozanib."

The TIVO-1 global, randomized Phase 3 clinical trial compared the safety and tolerability of tivozanib and sorafenib in 517 patients with advanced RCC. Results of the trial were presented at the ASCO Annual Meeting earlier this year and showed that tivozanib demonstrated a statistically significant improvement in progression-free survival (PFS) compared with sorafenib in the overall patient population (median PFS 11.9 months versus 9.1 months; p=0.042, HR=0.797). Further, in a pre-specified subset of RCC patients who were treatment-naïve, tivozanib demonstrated a statistically significant improvement in PFS with a median of 12.7 months compared with 9.1 months for sorafenib (p=0.037; HR=0.75), making tivozanib the first treatment to demonstrate a median PFS of greater than one year in this patient population.[2] Tivozanib is an investigational drug being evaluated for first-line treatment of advanced RCC.

Title: Detailed Comparison of the Safety of Tivozanib Versus Sorafenib in Patients with Advanced/Metastatic Renal Cell Carcinoma (mRCC) from a Phase 3 Trial
Date/Poster/Location: Oct. 1, 1:00-2:00pm CET / 7:00-8:00am ET; Poster #795PD; Hall F2

Investigators evaluated drug-related AEs versus sorafenib with the goal of better understanding the tivozanib safety profile. The results of the safety analysis showed:

- Investigator-reported adverse events for tivozanib showed lower rates of dose reductions, interruptions, and discontinuations compared to sorafenib: dose reductions (11.6% vs. 42.8%, $p<0.001$), interruptions (17.8% vs. 35.4%, $p<0.001$), and discontinuations (4.2% vs. 5.4%)[1]
- Drug-related AEs occurred in fewer patients on tivozanib than patients on sorafenib (67.6% vs. 83.3%)[1]
- Fewer patients in the tivozanib group had ≥Grade 3 drug-related AEs than patients in the sorafenib group (36.3% vs. 51.0%, respectively).[1] ≥Grade 3 hypertension, an established on-target effect of angiogenesis inhibitors, was more common in the tivozanib group (23.6% vs. 15.2%), and ≥Grade 3 hand-foot syndrome (1.9% vs. 16.7%), diarrhea (1.9% vs. 5.8%) and lipase elevation (0.8% vs. 5.8%) were more common in the sorafenib group.[1]

"Our tivozanib development program in RCC is comprehensive and ongoing. With positive safety and efficacy data from TIVO-1 in-hand, we continue to explore the role of biomarkers and patient preference with the ultimate goal of helping clinicians optimize RCC treatment," said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO. "Additional analyses from our ongoing biomarker program will be presented at future congresses and our TAURUS patient preference study vs. Sutent® (sunitinib) is now underway."

In addition to detailed safety results, pharmacokinetic/pharmacodynamic data from TIVO-1 were also presented.[3]

Title: Tivozanib Pharmacokinetic/Pharmacodynamic Analysis of Blood Pressure and Soluble Vascular Endothelial Growth Factor Receptor 2 (sVEGFR2) in Patients with Advanced Renal Cell Carcinoma
Date/Poster/Location: Oct. 1, 1:00-2:00pm CET / 7:00-8:00am ET; Poster #796PD; Hall F2

Analyses were conducted using pooled data from patients in AVEO's randomized placebo-controlled Phase 2 study of tivozanib in RCC and from the TIVO-1 study to explore the relationship between tivozanib exposure, blood pressure and sVEGFR2.[3]

Patients in the analysis showed a median increase in diastolic blood pressure of 5mm Hg compared with baseline, and also experienced a decrease in sVEGFR2 corresponding to tivozanib exposure.[3] Hypertension and sVEGFR are known to be on-target biomarkers of activity and clinical outcome.[4,5,6]

"One of our goals in becoming a global Category Leader in oncology is to develop precision medicines that revolutionize the methods used to treat patients with cancer," said Stephen Eck, M.D., Ph.D., Vice President of Medical Oncology, Astellas Pharma Global Development. "We believe the data showing the combination of tivozanib's statistically significant PFS and its tolerability profile represents a potentially important advancement in the treatment of this disease."

Title: Patient Preference for Tivozanib Hydrochloride or Sunitinib in the Treatment of Metastatic Renal Cell Carcinoma (mRCC): TAURUS study
Date/Poster/Location: Sep. 29, 1:00-2:00pm CET / 7:00-8:00am ET; Poster #892TiP; Hall XL

A review of the clinical study design of TAURUS, 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 was presented at the meeting. The primary objective of the study is to compare patient preference for tivozanib or sunitinib.

The first patient has been enrolled in TAURUS, and the study will continue to enroll patients at sites throughout the United States and Western Europe.

About Kidney Cancer
Advanced RCC, or kidney cancer, is the ninth most commonly diagnosed cancer in men and women in the U.S.[8] Worldwide it is estimated that more than 250,000 people are diagnosed and more than 100,000 people die from the disease each year.[9] RCC accounts for more than 90 percent of all kidney cancers.[10] Currently available therapies provide less than one year of median PFS in treatment naïve patients and are associated with significant toxicities.[11] 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.[12]

About Tivozanib
Tivozanib is the first investigational compound to demonstrate a combination of statistically significant PFS and tolerability in a pivotal study for advanced RCC versus an approved targeted agent, sorafenib. Tivozanib is a potent, selective and 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, potentially resulting in improved efficacy and minimal dose modifications. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor (TKI) for which positive results from a Phase 3 clinical study in advanced RCC 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 first-line 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.[1]

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 the AVEO/Astellas Collaboration
In February 2011, AVEO and Astellas entered into a worldwide agreement to develop and commercialize tivozanib outside of Asia 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).

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 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, including the potential that tivozanib may offer an important advancement in the treatment of RCC; the potential that few side effects and lower rates of dose modifications may lead to more optimal dosing of tivozanib; using biomarkers to help clinicians optimize treatment of kidney cancer; developing medicines that revolutionize the methods used to treat patients with cancer; plans by AVEO and Astellas to commercialize tivozanib in North America and the EU, respectively; AVEO's plans to present additional data from its biomarker program and clinical trials in the future; and AVEO's plans to leverage its Human Response Platform™. 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 or the TAURUS clinical study 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 ability 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 ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; unplanned operating expenses; AVEO's ability 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 Quarterly Report on Form 10-Q 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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References

[1] Eisen T, Sternberg CN et al. Detailed comparison of the safety of tivozanib hydrochloride versus sorafenib in patients with advanced/metastatic renal cell carcinoma (mRCC) from a Phase III trial. ESMO 2012 Congress (Poster 795PD)
[2] Motzer RJ, Eisen T, et al. Tivozanib versus sorafenib as initial targeted therapy for patients with advanced renal cell carcinoma: Results from a phase III randomized, open label, multicenter trial. *J Clin Oncol* 2012;30 (suppl; abstr 4501)
[3] Nosov DA, Motzer RJ, et al. Tivozanib pharmacokinetic/pharmacodynamic analysis of blood pressure and soluble vascular endothelial growth factor receptor 2 (sVEGFR2) in patients with advanced renal cell carcinoma. ESMO 2012 Congress (Poster 796PD)
[4] De Primo SE, Bello CL, Smeraglia J et al. Circulating protein biomarkers of pharmacodynamic activity of sunitinib in patients with metastatic renal cell carcinoma: modulation of VEGF and VEGF related proteins. *J Transl Med* 2007;5:32.
[5] Hutson T, Davis ID, Macheils JH et al. Biomarker analysis and final efficacy and safety results of a phase II renal cell carcinoma trial with pazopanib (GW786034), a multi-kinase angiogenesis inhibitor. *J Clin Oncol* 2008;26:Abstract 5046.
[6] Rini BI, Michaelson D, Rosenberg JE et al. Antitumor activity and biomarker analysis of sunitinib in patients with bevacizumab-refracory metastatic renal cell carcinoma. *J Clin Oncol* 2008;26:3743–3748.
[7] Escudier B, Steelman L et al. Patient preference for tivozanib hydrochloride or sunitinib in the treatment of metastatic renal cell carcinoma (mRCC): TAURUS study. ESMO 2012 Congress (Poster 892TiP)
[8] U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2007 Incidence and Mortality Web-based Report. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; 2010. Available at: www.cdc.gov/uscs.
[9] Cancer Research UK. Available at: http://info.cancerresearchuk.org/cancerstats/world/the-global-picture/#Common; http://publications.cancerresearchuk.org/downloads/Product/cs_pdf_worldwide_2011.pdf
[10] American Cancer Society. Available at: http://www.cancer.org/Cancer/KidneyCancer/OverviewGuide/kidney-cancer--adult--renal-cell-carcinoma-overview-what-is-kidney-cancer.
[11] Bhargava, P., Robinson, M. Curr Oncol Rep (2011) 13:103–111
[12] Ravaud, A. Annals of Oncology 20 (Supplement 1): i7–i12, 2009