



AVEO and Astellas Report Final Overall Survival Results from TIVO-1

February 12, 2013

Median Overall Survival of 28.8 Months Reported for Tivozanib in Patients with Advanced Kidney Cancer

CAMBRIDGE, Mass. & TOKYO--(BUSINESS WIRE)--Feb. 12, 2013-- AVEO Oncology (NASDAQ:AVEO) and Astellas Pharma Inc. (TSE:4503) today announced overall survival (OS) for tivozanib, an investigational agent, from the Phase 3 TIVO-1 (Tivozanib Versus Sorafenib in 1st line advanced RCC) study in patients with advanced renal cell carcinoma (RCC). The final OS analysis, as specified by the protocol, shows a median OS of 28.8 months (95% confidence interval [CI]: 22.5–NA) for tivozanib versus a median OS of 29.3 months (95% CI: 29.3–NA) for the comparator arm, sorafenib. No statistical difference between the two arms (HR=1.245, p=0.105) was observed. The OS data are included in the tivozanib New Drug Application (NDA) filing and will be presented on February 16 at the 2013 American Society for Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), abstract #350.

Overall survival is a secondary endpoint of the TIVO-1 study. A one-sided crossover for patients randomized to the sorafenib (comparator) arm was offered pursuant to a separate, long-term treatment protocol to allow trial participants to receive tivozanib upon disease progression. This resulted in a substantial difference in the use of subsequent therapies. Of the patients who discontinued their initial therapy, 10% originally on the tivozanib arm received subsequent anti-VEGF therapy (36% received any subsequent therapy) while 70% of patients originally on the comparator arm received subsequent anti-VEGF therapy (74% received any subsequent therapy).

"It's encouraging to see that patients in the study who received tivozanib had a median overall survival of 28.8 months, particularly given that these patients received minimal subsequent therapy," said principal investigator Robert J. Motzer, M.D., attending physician, genitourinary oncology service, Memorial Sloan-Kettering Cancer Center, and professor of medicine, Weill Medical College, Cornell University, New York. "The safety and efficacy results from TIVO-1 and other clinical trials of tivozanib in advanced RCC suggest it may provide an important new first line treatment option for patients with this aggressive disease."

In TIVO-1, tivozanib demonstrated a statistically significant improvement in progression-free survival (PFS), the primary endpoint of the study, when compared with sorafenib. The FDA has accepted the tivozanib NDA for filing, and according to the timelines established by the Prescription Drug User Fee Act (PDUFA), the review of the NDA is expected to be complete by July 28, 2013.

Other data being presented at ASCO GU show the anti-tumor activity of tivozanib following treatment with sorafenib resulted in a median PFS of 8.4 months and response rate of 13%. These data have matured and have been updated from the initial ASCO GU abstract submission (abstract #364), and will be included in the poster. Additional TIVO-1 data relating to subset analyses (abstracts #354 and #361) and Quality of Life (abstract #355) will also be included in posters presented at ASCO GU.

"We believe that these data being presented at ASCO GU reinforce the positive efficacy results and safety profile of tivozanib in patients with advanced RCC," said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO.

"We are excited to be working with AVEO in our efforts to bring tivozanib to patients who are in need of new therapeutic options," added Stephen Eck, M.D., Ph.D., vice president of medical oncology, Astellas Pharma Global Development.

AVEO Conference Call and Webcast

These data will be reviewed in more detail by AVEO management during the company's conference call and webcast tomorrow at 10:00 a.m. (ET). The call can be accessed by dialing 1-866-831-6243 (domestic) or 1-617-213-8855 (international) five minutes prior to the start of the call and providing the passcode 81400823. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing 1-888-286-8010 (domestic) or 1-617-801-6888 (international), providing the passcode 61126312. The replay will be available for two weeks from the date of the call.

A webcast of the conference call can also be accessed by visiting the investors section of the AVEO website at investor.aveooncology.com. A replay of the webcast will be archived on the company's website for two weeks following the call.

About TIVO-1

TIVO-1 is a global, randomized Phase 3 superiority-designed 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 in which an investigational agent (tivozanib) has demonstrated statistically significant and clinically meaningful PFS superiority versus an approved targeted agent (sorafenib).

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 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 naive patients and are associated with significant toxicities.⁴ These toxicities not only lead to high rates of dose reductions and interruptions, but also can impact a patient's quality of daily living.⁵

About Tivozanib

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. Tivozanib is an oral, once-daily, investigational tyrosine kinase inhibitor for which positive results from a Phase 3 clinical study in advanced RCC have been reported, and is being evaluated in other tumors.

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. 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 within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. 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 planned launch and commercialization of tivozanib; the potential approval by the FDA of tivozanib in advanced RCC; the targeted date for the completion of the FDA's review of the NDA; tivozanib's safety and efficacy profile and its potential in treating patients with kidney cancer; 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 AVEO's Phase 3 TIVO-1 trial 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, overall survival 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 the 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's 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 current report on Form 8-K filed with the SEC on January 16, 2013 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.

1U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2009 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; 2013. Available at: www.cdc.gov/uscs

2Cancer 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

3American Cancer Society. Available at: <http://www.cancer.org/Cancer/KidneyCancer/OverviewGuide/kidney-cancer--adult--renal-cell-carcinoma-overview-what-is-kidney-cancer>

4Bhargava, P., Robinson, M. *Curr Oncol Rep* (2011) 13:103–111

5Ravaud, A. *Annals of Oncology* 20 (Supplement 1): i7–i12, 2009

Source: AVEO Oncology

Investor Contact:

AVEO Oncology

Monique Allaire, 617-299-5810

or

Media Contacts:

AVEO Oncology

Rob Kloppenburg, 617-930-5595

or

Astellas US LLC

Jenny Kite, 224-205-5405