



AVEO and Astellas Announce Presentations of Tivozanib Clinical Data at 2013 ASCO Genitourinary Cancers Symposium

January 29, 2013

CAMBRIDGE, Mass. & TOKYO--(BUSINESS WIRE)--Jan. 29, 2013-- AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced that new clinical data on tivozanib, an investigational agent for the treatment of metastatic renal cell carcinoma (mRCC), will be presented at the 2013 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), taking place February 14-16 in Orlando, Florida.

The schedule for tivozanib poster presentations at ASCO GU is as follows:

Date & Time: Saturday, February 16, 2013; 6:45-7:55am and 11:50am-1:05pm EST

Session: General Poster Session: C: Renal Cell Cancer (B3)

(Abstract #350) Title: Overall Survival Results from a Phase 3 Study of Tivozanib Hydrochloride vs Sorafenib in Patients with Renal Cell Carcinoma

Presenter: Robert Motzer, M.D.

Date & Time: Saturday, February 16, 2013; 6:45-7:55am and 11:50am-1:05pm EST

Session: General Poster Session: C: Renal Cell Cancer (B7)

(Abstract #354) Title: Subgroup Analyses of a Phase 3 Trial Comparing Tivozanib Hydrochloride vs Sorafenib as Initial Targeted Therapy for Patients with Metastatic Renal Cell Carcinoma (mRCC)

Presenter: Thomas Hutson, D.O., Pharm.D.

Date & Time: Saturday, February 16, 2013; 6:45-7:55am and 11:50am-1:05pm EST

Session: General Poster Session: C: Renal Cell Cancer (B8)

(Abstract #355) Title: Treatment Benefit of Tivozanib Hydrochloride versus Sorafenib on Health-Related Quality of Life among Patients with Advanced/Metastatic Renal Cell Carcinoma (mRCC): TIVO-1 Study Results

Presenter: David Cella, Ph.D.

Date & Time: Saturday, February 16, 2013; 6:45-7:55am and 11:50am-1:05pm EST

Session: General Poster Session: C: Renal Cell Cancer (C1)

(Abstract #364) Title: Efficacy and Safety Data from Patients with Advanced Renal Cell Cancer Treated with Tivozanib Hydrochloride After Progression on Sorafenib

Presenter: Robert Motzer, M.D.

Date & Time: Saturday, February 16, 2013; 6:45-7:55am and 11:50am-1:05pm EST

Session: General Poster Session: C: Renal Cell Cancer (B14)

(Abstract #361) Title: Relationship of Hypoxia Signature with Variant Subgroup of Clear Cell Renal Cell Carcinoma (ccRCC) and its Association with Clinical Activity on Tivozanib Hydrochloride

Presenter: Murray Robinson, Ph.D.

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 progression-free survival (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 (potentially compromising efficacy), 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. Tivozanib, AVEO's lead investigational drug, is a potent, selective, long half-life inhibitor of all three 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.

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; AVEO's ability to deliver tivozanib to cancer patients 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 AVEO's Phase 3 TIVO-1 trial (Tivozanib Versus sQrafenib in 1st line advanced RCC) are sufficient to obtain marketing approval for tivozanib, which turns on the ability of AVEO to demonstrate to the satisfaction of the U.S. Food and Drug Administration (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' 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

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