



AVEO and Astellas Announce Submission of New Drug Application for Tivozanib for the Treatment of Advanced Renal Cell Carcinoma

CAMBRIDGE, Mass. and TOKYO, Japan, September 28, 2012 -- AVEO Oncology (NASDAQ: AVEO) and Astellas Pharma Inc. (TSE: 4503) today announced that AVEO has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for tivozanib in patients with advanced renal cell carcinoma (RCC). Tivozanib is designed to target the vascular endothelial growth factor (VEGF) pathway, a clinically validated target in RCC and other solid tumors.

The NDA submission is based on results of the global Phase 3 TIVO-1 (Tivozanib Versus Sorafenib in 1st line Advanced RCC) trial, a randomized superiority-designed pivotal trial evaluating the efficacy and safety of tivozanib compared to sorafenib in 517 patients with advanced RCC who had no prior treatment with a systemic therapy, as well as data from 17 clinical studies involving over 1,000 subjects who received tivozanib. In TIVO-1, tivozanib demonstrated a statistically significant improvement in progression-free survival (PFS) versus sorafenib, an approved targeted agent, and a favorable tolerability profile.

[Results from the study](#) were first presented in early June 2012 at the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting in Chicago, IL.

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 (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. Tivozanib is also under evaluation across a broad range of solid tumors, including metastatic colorectal cancer and metastatic breast cancer.

About Astellas

Astellas Pharma Inc., headquartered 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 Oncology, Urology, Immunology (including Transplantation) and Infectious Diseases, Neuroscience and DM Complications and Kidney Diseases. For more information on Astellas Pharma Inc., please visit the company's 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; AVEO's plans for advancing the registration process for tivozanib; 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 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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¹U.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.

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