AVEDO Oncology Announces Results from Phase 2 Clinical Studies of Tivozanib in Patients with Advanced Colorectal and Kidney Cancers Presented at ESMO 2014 Congress

CAMBRIDGE, Mass. – Sep. 29, 2014 – AVEO Oncology (NASDAQ: AVEO) today announced poster presentations for two Phase 2 clinical studies of tivozanib, one in metastatic colorectal cancer (mCRC) and one in renal cell carcinoma (RCC), at the 2014 Congress of the European Society for Medical Oncology (ESMO), taking place September 25–30 in Madrid, Spain. Tivozanib is an oral, potent, selective inhibitor of vascular endothelial growth factor tyrosine kinase inhibitor (VEGF TKI) with a long half-life and activity against all three VEGF receptors.

“We remain encouraged by clinical outcomes from these Phase 2 studies, as they suggest potential avenues for the development of tivozanib,” said Tuan Ha-Ngoc, president and chief executive officer of AVEO. “We continue to believe that there is significant value in tivozanib, an oral, potent, and selective VEGF inhibitor. With rights to this product candidate recently regained, we look forward to exploring additional partnership opportunities to realize its full potential.”

Results in Detail

Title: BATON-CRC: a phase 2 randomized trial comparing tivozanib (tivo) + mFOLFOX6 with bevacizumab (bev) + mFOLFOX6 in stage IV metastatic colorectal cancer (mCRC)

Date/Poster/Location: Monday, September 29, 2014 at 12:45 p.m. (CEST); #533P; Poster Area

In this Phase 2, randomized, open-label trial (BATON-CRC), tivozanib plus mFOLFOX6 (Arm A, n=177) was compared to bevacizumab plus mFOLFOX6 (Arm B, n=88) in patients with previously untreated mCRC to demonstrate superiority over bevacizumab therapy. The primary endpoint was PFS by investigator radiologic assessment. Secondary endpoints included overall survival (OS), and objective response rate (ORR), among others.

At a preplanned interim analysis, which included 95 PFS events, median PFS was 9.4 month for Arm A vs. 10.7 months for Arm B (HR=1.091, p=0.706) and ORR was 45% for Arm A vs. 43% for Arm B (p=0.718). There were no statistically significant associations between serum and/or tumor biomarkers and outcomes, although patients with high LDH (LDH ≥ 1.5 ULN, n=74), a prespecified biomarker, showed an encouraging PFS trend (HR=0.58, p=0.116), with approximately half of events reported at the interim analysis. The overall safety profile was comparable between arms. The most common toxicities included diarrhea, nausea, fatigue, neutropenia and hypertension. Serious AEs were reported for 46.3% of patients in the tivozanib group compared with 48.3% in the bevacizumab group. These interim results suggest that the combination of tivozanib plus mFOLFOX6 is comparable to bevacizumab plus mFOLFOX6 in
the intent-to-treat population, with an acceptable safety profile. A prespecified interim futility analysis for superiority resulted in discontinuation of the study.

“These data demonstrate the potential for tivozanib, an oral therapy, to deliver similar results to standard-of-care therapy, bevacizumab, an IV therapy, when used in combination with FOLFOX in the intent-to-treat population,” said Al B. Benson III, MD, FACP, Professor of Medicine at the Feinberg School of Medicine, Associate Director for Clinical Investigations at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, and principal investigator of the study. “Given a promising trend in the predefined LDH high biomarker population at this interim analysis, I look forward to results from further follow-up in this study.”

Title: Phase 2 clinical evaluation of preclinically defined biomarkers for vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) tivozanib in renal cell carcinoma (RCC)

Date/Poster/Location: Sunday, September 28, 2014 at 12:45 p.m. (CEST); #233P; Poster Area

Despite significant effort, identifying predictive biomarkers for VEGF-targeted therapies remains challenging. Using population-based tumor models, AVEO identified a population of infiltrating myeloid cells associated with resistance to tivozanib. In this Phase 2, single arm trial (BATON-RCC) of tivozanib monotherapy in nephrectomized, targeted therapy-naïve RCC (n=105; 90 clear cell histology), certain myeloid cell biomarkers (immunohistochemistry [IHC] and ribonucleic acid [RNA]) were evaluated.

The study results demonstrated that low myeloid signature score was associated with significantly longer PFS compared to high myeloid signature based on a median cutoff (14.7 months vs. 8.3 months; hazard ratio [HR] 0.49, p=0.035; 95% CI 0.25-0.96), and as a continuous variable (p=0.03; n=63). The IHC score exhibited a similar trend but was not significant. These results suggest a low myeloid signature score in RCC patients may predict a positive clinical response when treated with tivozanib, including significantly increased PFS.

“The myeloid signature identified in this study, which was associated with significantly longer progression free survival, is an important finding, and may serve as a predictive biomarker for VEGF-targeted therapies such as tivozanib,” said Thomas Hutson, DO, PharmD, Medical Oncologist, Texas Oncology-Baylor Charles A. Sammons Cancer Center, and principal investigator of the study. “These findings warrant further study in a prospectively defined patient population.”

Copies of the poster presentations are available on AVEO’s website at www.aveooncology.com.

About Colorectal Cancer

The American Cancer Society estimates that more than 140,000 men and women in the U.S. will be diagnosed with colorectal cancer (CRC) and nearly 50,000 will die of the disease in the U.S. in 2011. CRC is the third most commonly diagnosed cancer in both men and women and the third leading cause of cancer death in the U.S. In Europe, it is estimated that almost 180,000 men and women are diagnosed with CRC and that nearly 80,000 die from the disease each year.
About Renal Cell Carcinoma (Kidney Cancer)

Advanced renal cell carcinoma (RCC or kidney cancer), is the ninth most commonly diagnosed cancer in men and women in the U.S. Worldwide it is estimated that more than 250,000 people are diagnosed and more than 100,000 people die from the disease each year. RCC accounts for more than 90 percent of all kidney cancers.

About Tivozanib

Tivozanib is an oral, once-daily, investigational vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI). It is a potent, selective and long half-life inhibitor of all three VEGF receptors and is designed to optimize VEGF blockade while minimizing off-target toxicities, potentially resulting in improved efficacy and minimal dose modifications. Tivozanib has been evaluated in several tumors types, including renal cell, colorectal and breast cancers.

About AVEO

AVEO Oncology (NASDAQ: AVEO) is a biopharmaceutical company committed to discovering and developing targeted therapies designed to provide substantial impact in the lives of people with cancer by addressing unmet medical needs. AVEO’s proprietary Human Response Platform™ provides the company unique insights into cancer and related disease biology and is being leveraged in the discovery and clinical development of its therapeutic candidates. For more information, please visit the company’s website at www.aveo.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO 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 potential avenues for the development of tivozanib and its value; the ability of AVEO to realize partnership opportunities; the trends in the predefined LDH high biomarker population; and the ability for the myeloid signature to serve as a biomarker for VEGF-targeted therapies. 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: AVEO’s ability to execute on its business strategy and enter into and maintain new strategic partnerships and collaboration agreements; AVEO’s ability to successfully enroll and complete clinical trials and preclinical studies of its product candidates; AVEO’s ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory agencies, the safety, efficacy and clinically meaningful benefit of its product candidates; AVEO’s ability to achieve and maintain compliance with all
regulatory requirements applicable to its product candidates; AVEO’s ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; developments and expenses related to AVEO’s ongoing shareholder litigation and SEC inquiry; AVEO’s ability to raise the substantial additional funds required to achieve its goals; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled “Risk Factors” included in AVEO’s most recent Quarterly Report on Form 10-Q and in its other filings with the SEC. 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.

References

1 American Cancer Society. Available at: http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/index
4 Cancer Research UK. Available at: http://info.cancerresearchuk.org/cancerstats/world/the-global-picture/#Common;

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