AVEO Pharmaceuticals' Tivozanib Clinical Data Featured at 2011 ASCO Gastrointestinal Cancers Symposium

January 21, 2011 6:31 AM ET

CAMBRIDGE, Mass., Jan 21, 2011 (BUSINESS WIRE) -- AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO) today announced that previously reported positive data from its Phase 1b clinical trial evaluating tivozanib, its lead product candidate designed to optimally block the VEGF pathway by inhibiting all three VEGF receptors, in combination with FOLFOX6, a standard chemotherapy regimen, in patients with advanced gastrointestinal (GI) cancers will be presented tomorrow at the American Society of Clinical Oncology (ASCO) 2011 Gastrointestinal Cancers Symposium. Results from this study, which were previously reported at the EORTC-NCI-AACR Symposium in Berlin in November 2010, showed the combination was tolerable and safe at the full recommended tivozanib dose (1.5 mg/day) and schedule and standard FOLFOX6 dose; and, partial responses in more than a third (35 percent) of patients evaluated (n=17) and disease control in 82 percent of patients.

William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO, said, "Based on the results of the combination trials conducted to-date, we believe that tivozanib's unique characteristics allow it to be combined with other anti-cancer agents at full dose and schedule. Throughout 2010, we presented data from Phase 1b studies in metastatic breast cancer, colorectal cancer and renal cell carcinoma (RCC) where tivozanib demonstrated combinability with Taxol$^{(R)}$, FOLFOX6 and Torisel$^{(R)}$, respectively. When reviewed together with the monotherapy data from our Phase 2 trial in RCC, we believe that there is significant potential for tivozanib across multiple tumor types."

The details for the AVEO poster presentation are as follows:

Date & Time: Saturday, January 22, 2011 from 6:45-7:45 a.m. (PST)

Session: General Poster Session C

Abstract Number: 549

Poster Title: A phase 1b, open-label, dose-escalation study of tivozanib and FOLFOX6 in patients with advanced gastrointestinal (GI) tumors

Poster Number: A194

Presenter: Jaroslaw Jac, M.D.

Following the presentation, the poster will be available in the publications section of the company's website at investor.aveopharma.com.

About Tivozanib

Tivozanib, an investigational new drug, is designed to optimally block the VEGF pathway by inhibiting all three VEGF receptors. Each of the three receptors of the VEGF pathway play an important role in angiogenesis (the formation of new blood vessels), which is critical in cancer cell growth. Tivozanib's high level of potency across VEGF receptors 1, 2 and 3 is designed to provide the most complete blockade of the VEGF pathway. Tivozanib's high level of selectivity for VEGF receptors 1, 2 and 3 is designed to minimize off-target toxicities, and its oral, one capsule, once-daily administration may enhance convenience for patients. Tivozanib has also demonstrated the ability to be combined with both targeted therapies and chemotherapies at the full dose and schedule[1-3]. AVEO is leveraging its Human Response Platform(TM) in order to enrich outcomes and minimize development risks for tivozanib.

In a large, multi-center, randomized Phase 2 clinical trial, the subset of patients with clear cell renal cell carcinoma (RCC) who had a prior nephrectomy receiving tivozanib therapy achieved 14.8 months progression free survival (PFS), the longest PFS reported for a single-agent therapy in this population[4]. The safety profile of tivozanib observed in the Phase 2 trial was notable for the minimal off-target toxicities often associated with VEGF, multi-targeted therapies. There was a low incidence of diarrhea, fatigue, stomatitis and hand-foot syndrome. Hypertension and dysphonia (hoarseness of voice), which are mechanism-related side effects associated with angiogenesis inhibitors, were the most commonly reported drug-related side effects, and both were manageable

and reversible[4]. AVEO has completed patient enrollment in TIVO-1, a global, randomized, controlled Phase 3 clinical trial evaluating the efficacy of tivozanib compared to sorafenib (Nexavar(R)) in this same patient population. AVEO expects to announce top-line data from TIVO-1 in mid-2011.

About AVEO

AVEO Pharmaceuticals (NASDAQ: AVEO) is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. The company's lead product candidate, tivozanib, is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in patients with advanced renal cell carcinoma, as well as additional clinical studies in other solid tumor types. AVEO's second most advanced product candidate, AV-299, is a potent, functional anti-HGF/c-MET pathway antibody that is currently in Phase 2 clinical development. AVEO's proprietary Human Response Platform(TM) is designed to offer the company a unique advantage in cancer drug development and has provided a discovery engine for multiple therapeutic targets. This approach has resulted in a promising pipeline of monoclonal antibodies against novel targets including HGF, ErbB3, RON, Notch and FGFR. For more information, please visit the company's website at www.aveopharma.com.

Forward-Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about: tivozanib's potential to be combined safely with other anti-cancer agents; tivozanib's potential effectiveness in fighting cancer; the anticipated timing of our announcement of top-line data from TIVO-1; the potential of our cancer biology platform to offer a unique advantage in oncology drug development; and other statements containing the words "believes," "anticipates," "plans," "expects," "will" and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: our ability to successfully research, develop and obtain and maintain regulatory approvals for tivozanib and our other product candidates; the possibility that favorable data from the Phase 1b clinical trial described in this press release and our other preclinical and clinical trials of tivozanib may not be predictive of the results in future preclinical and clinical trials; delays in data availability, or negative results from our clinical trials; our inability to obtain and maintain adequate protection for intellectual property rights relating to our product candidates and technologies; unplanned operating expenses; our inability to raise substantial additional funds to achieve our goals, including with respect to the further development of tivozanib; competition; general economic and industry conditions; and other factors discussed in the "Risk Factors" section of our most recent Form 10-Q filed with the Securities and Exchange Commission, and in other filings that we periodically make with the SEC. In addition, the forward-looking statements included in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

1. Kabbinavar FF, et al. Presented at the International Kidney Cancer Symposium; October 1-2, 2010; Chicago, IL.

2. Mayer EL, et al. Poster presented at the SABCS Annual Meeting; December 8-12, 2010; San Antonio, TX.

3. Eskens FALM, et al. Poster presented at the EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics; November 16-19, 2010; Berlin, Germany.

4. Bhargava P, et al. Poster presented at the ASCO Annual Meeting; June 4-8, 2010; Chicago, IL. Abstract 4599. In the tivozanib Phase 2 trial, the intent to treat patient population (n=272) achieved 11.8 months median PFS.

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