AVEO's Tivozanib in Combination with Paclitaxel Demonstrates Safety in Patients with Metastatic Breast Cancer; Data Presented at San Antonio Breast Cancer Symposium

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Data Underscore Potential for Tivozanib to be Safely Combined with Other Anti-Cancer Agents

CAMBRIDGE, Mass. & SAN ANTONIO, Dec 10, 2010 (BUSINESS WIRE) -- AVEO Pharmaceuticals, Inc. (NASDAQ: AVO), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced preliminary results from an ongoing Phase 1b clinical trial evaluating the company's lead product candidate, tivozanib, a highly potent and selective inhibitor of VEGF receptors 1, 2, and 3, in combination with paclitaxel (Taxol(R)), a standard chemotherapy regimen, in patients with metastatic breast cancer. The combination was considered safe at the full recommended tivozanib dose (1.5 mg/day) and standard paclitaxel dose, and demonstrated encouraging clinical activity in patients with metastatic breast cancer. These data were presented in a poster session today at the 33rd Annual San Antonio Breast Cancer Symposium in San Antonio, Texas by Erica L. Mayer, M.D., M.P.H., medical oncologist, Breast Oncology Center at the Dana-Farber Cancer Institute and lead investigator in the study.

"In this Phase 1 study, the combination of tivozanib and weekly paclitaxel was tolerable for patients and demonstrated notable activity," said Dr. Mayer. "Further study of tivozanib in combination with anti-cancer agents such as paclitaxel is warranted in breast cancer."

The Phase 1b open-label, dose-escalation study assessed once-daily, oral tivozanib (sequential cohorts of 0.5, 1.0, and 1.5 mg/day for three weeks on, one week off) and paclitaxel (once-weekly intravenously for three weeks on, one week off) in 18 patients with metastatic breast cancer, all of whom had prior taxane therapy and most of whom had prior bevacizumab therapy. With a mean duration of treatment of 22.2 weeks, key findings included:

- Confirmed partial responses were observed in five of the 18 patients, as evaluated by standard Response Evaluation Criteria in Solid Tumors (RECIST)
- Objective response rate (ORR) was 28 percent and 44 percent of patients achieved disease control
- Median progression-free survival (PFS) was 10.4 months
- Drug-related adverse events were not observed in association with the combination that were more frequent or severe than those observed in previous studies with tivozanib or paclitaxel alone
- There were no unexpected drug-related serious adverse events in the study

"These data in patients with metastatic breast cancer, along with the data we anticipate generating from the recently initiated Phase 1b clinical trial evaluating tivozanib in combination with oral capecitabine, help to inform our strategic clinical development program for tivozanib," said William Slichenmyer, M.D., Sc.M., chief medical officer at AVEO. "We are encouraged by these first results in breast cancer as we evaluate opportunities to pursue additional indications outside of our potential lead indication for tivozanib in the treatment of advanced renal cell cancer."

About Tivozanib

Tivozanib, an investigational new drug, is a highly potent and selective inhibitor of VEGF receptors 1, 2 and 3, exhibiting picomolar inhibitory activity against all three receptors. Due to its potency and specificity, AVEO believes tivozanib may enable optimal inhibition of the VEGF pathway, while minimizing side effects associated with off-target activity. Such a profile may enable tivozanib to be more readily combined with standard chemotherapy as well as other targeted therapies, potentially increasing the breadth of its clinical utility. The EMA has granted AVEO orphan medicinal product designation for tivozanib for the treatment of advanced renal cell cancer (RCC).

AVEO recently completed patient enrollment ahead of schedule in TIVO-1, a global, randomized (1:1), controlled Phase 3 clinical trial evaluating tivozanib compared to sorafenib (Nexavar(R)) in patients with RCC. The company has initiated a series of clinical trials evaluating tivozanib in combination with other agents in multiple solid tumor settings, including an ongoing Phase 1b trial in combination with temsirolimus (Torisel(R)), an approved mTOR inhibitor, in patients with metastatic RCC; a Phase 1b trial in combination with the FOLFOX6 chemotherapy regimen in patients with advanced colorectal cancer and other gastrointestinal...
cancers; a Phase 1b trial in combination with paclitaxel (Taxol®) in patients with metastatic breast cancer; and a Phase 1b trial in combination with oral capecitabine (Xeloda®) in patients with advanced breast and colorectal cancers. A Phase 1b trial evaluating tivozanib as monotherapy in patients with non-small cell lung cancer is also being conducted.

AVEO is also utilizing its Human Response Platform(TM) in its efforts to help identify rational drug combinations and patient populations most likely to be responsive to these combination therapies.

About AVEO

AVEO Pharmaceuticals (NASDAQ: AVEO) integrates a proprietary cancer biology platform with drug development and commercial expertise in its efforts to discover and develop targeted cancer therapeutics. The company's lead product candidate, tivozanib, is an oral, triple VEGF receptor inhibitor with a highly differentiated profile. Tivozanib is currently being investigated in a global, randomized Phase 3 clinical trial called TIVO-1 comparing tivozanib to sorafenib in advanced kidney cancer, 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 antibody that is currently in Phase 2 development. AVEO's proprietary, integrated cancer biology platform offers the company a unique advantage in oncology drug development and has provided a discovery engine for high-value 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 anti-tumor activity and tolerability profile; tivozanib's potential to be combined safely with other anti-cancer agents, such as paclitaxel; tivozanib's effectiveness in fighting cancer; our cancer biology platform offering 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.

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