AVEO Pharmaceuticals Regains Worldwide Rights to Develop and Commercialize Anti-HGF Antibody Candidate AV-299

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CAMBRIDGE, Mass., Sep 30, 2010 (BUSINESS WIRE) -- AVEO Pharmaceuticals, Inc. (NASDAQ: AVEO), a biopharmaceutical company focused on discovering, developing and commercializing cancer therapeutics, today announced that AVEO has regained worldwide rights from Merck (through its subsidiary, Schering Corporation) to develop and commercialize AV-299 (also known as SCH 900105), its anti-hepatocyte growth factor (HGF) antibody candidate.

AV-299 is a potent, functional anti-HGF antibody that was discovered by AVEO through its Human Response Platform(TM). Data from Phase 1 clinical trials of AV-299 indicate a favorable tolerability profile and good combinability with EGFR inhibitors, erlotinib (Tarceva(R)) and gefitinib (Iressa(R)). In June 2010, AVEO initiated a Phase 2 clinical trial evaluating AV-299 in combination with gefitinib versus gefitinib monotherapy in patients with non-small cell lung cancer (NSCLC). In conjunction with the Phase 2 trial initiation, AVEO received an $8.5 million milestone payment from Merck under the terms of the license agreement. Top-line efficacy data from the AV-299 Phase 2 trial are expected in late 2011.

"AVEO is very pleased to regain worldwide rights for the development and commercialization of AV-299," stated Tuan Ha-Ngoc, president and chief executive officer of AVEO Pharmaceuticals. "AVEO now holds significant commercialization rights to all oncology products in our pipeline, and we believe that we are well-positioned to move toward our goal of becoming a fully-integrated commercial organization. Our expected year-end 2010 cash balance remains unchanged, and we reaffirm that AVEO has sufficient capital to take us beyond data from TIVO-1, our ongoing Phase 3 clinical trial of tivozanib in patients with renal cell carcinoma. We look forward to sharing top-line TIVO-1 data in mid-2011."

"Merck is pleased with our history of collaborating with AVEO, and would welcome the opportunity to work with AVEO again in the future," said David Nicholson, Ph.D., senior vice president and head of worldwide licensing and knowledge management at Merck. "The decision to return this program to AVEO is a result of portfolio prioritization."

About AV-299 and the HGF/c-Met Pathway

The HGF/c-Met pathway is believed to play an important role in regulating tumor growth, invasion and metastasis, making it an exciting novel target in oncology. In addition, preclinical and clinical observations suggest that increased HGF and/or c-Met receptor amplification may confer resistance to EGFR inhibitors. Recently, encouraging Phase 2 clinical data were reported at the 2010 ASCO Annual Meeting with a small molecule c-Met inhibitor in combination with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) in patients with advanced, refractory NSCLC. These data signal the potential patient benefit from combination therapy of an EGFR TKI and an inhibitor of the HGF/c-Met pathway.

AV-299 is a potent, functional anti-HGF antibody that was discovered by AVEO through its Human Response Platform(TM) (HRP). In AVEO's proprietary tumor models with elevated HGF/c-Met signaling, AV-299 exhibited strong additive anti-tumor effect when given in combination with other approved anti-cancer agents such as erlotinib (Tarceva(R)), cetuximab (Erbitux(R)) and temozolomide (Temodar(R)). In additional preclinical studies, AV-299 was more effective at inhibiting tumor growth (at the dose tested) than other anti-HGF antibodies currently in clinical development.

Data from a recently completed a Phase 1 clinical trial with AV-299 showed a favorable combinability and tolerability profile with no dose-limiting toxicities up to the highest dose tested (20 mg/kg, bi-weekly). Based on the promising preclinical data and Phase 1 results, in June 2010, AVEO initiated a Phase 2 clinical trial evaluating AV-299 in combination with gefitinib (Iressa(TM)) versus gefitinib monotherapy in patients with NSCLC. Top-line efficacy data from the ongoing Phase 2 trial are expected in late 2011.

Background on the AVEO-Merck License Agreement

In April 2007, AVEO entered into a Research, Development and Commercialization Agreement with Schering Corporation, under which the company was granted worldwide rights to develop and commercialize AV-299. Under the terms of the agreement, Merck funded all research and development expenses and was obligated to pay development milestones, and, as applicable, royalties on product sales. AVEO retained primary responsibility for certain development activities through completion

of the first Phase 2 proof-of-concept trial, and for conducting translational research to guide the clinical development of AV-299, as well as the option to co-promote AV-299 in the U.S. for certain oncology indications.

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, 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 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.

AVEO's Forward-looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements about the potential for AV-299 to be a first-in-class product candidate, AV-299's favorable combinability and tolerability profile, the timing of top-line data from the AV-299 phase 2 clinical study and the tivozanib Phase 3clinical study, AVEO becoming a fully-integrated commercial organization, AVEO's estimates for itsfinancial performance, AVEO's views with respect to the sufficiency of its capital, the future opportunity of a collaboration between us and Merck, the role of HGF/c-Met pathway in regulating tumor growth, invasion and metastasis, the potential benefit from combination therapy of an EGFR TKI and an inhibitor of the HGF/c-Met pathways, our cancer biology platform increasing the probability of clinical success and providing a discovery engine for high-value targets, and other statements containing the words "believes," "anticipates," "plans," "expects," 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 AV-299,tivozanib and our other product candidates; the possibility that favorable data from our Phase 1 clinical trials of AV-299 may not be predictive of the results in our Phase 2 clinical trial; delays in data availability, or negative results from our Phase 2 clinical trial of AV-299; 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 and AV-299; 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.

Tarceva(R) and Iressa(R) are registered trademarks of OSI Pharmaceuticals, Inc. and the AstraZeneca group of companies, respectively.

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