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## **AVEO Initiates Phase 1b/2a Clinical Trial of Novel, Triple VEGF Receptor Inhibitor AV-951 in Non-Small Cell Lung Cancer**

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))-- AVEO Pharmaceuticals, Inc., a biotechnology company leveraging breakthrough discoveries in cancer biology to discover, develop and commercialize targeted oncology therapies, today announced the initiation of a Phase 1b/2a clinical trial of AV-951 as monotherapy for the treatment of advanced non-small cell lung cancer (NSCLC). This new trial expands on the Company's broad development program for AV-951, a novel triple VEGF receptor inhibitor being studied in multiple single agent and combination clinical trials across a variety of cancer types including renal cell carcinoma, breast cancer, colorectal cancer and now, lung cancer. The Company launched the Phase 1b portion of this new open-label study at leading cancer institutions in the U.S. to evaluate continuous, escalating daily doses of oral AV-951 over four weeks in approximately 21 patients with recurrent or progressive NSCLC, or who are non-responsive to standard therapy.

"The development of targeted therapies such as AV-951 is very important, as we have reached a ceiling with cytotoxic chemotherapy; even with the most active regimen, survival improvements have been modest with chemotherapy," said Karen Kelly, M.D., director of the University of Kansas Cancer Center. "We look forward to working with AV-951, a targeted, highly specific VEGF receptor inhibitor that can potentially reduce off-target toxicities and lead to more effective treatment regimens that meaningfully impact the lives of lung cancer patients."

Safety, tolerability and maximum tolerated dose (MTD) will be observed as the primary outcomes of the Phase 1b portion of this Phase 1b/2a trial. Once MTD is determined, the subsequent Phase 2a portion of the trial will evaluate over eight weeks the overall response rate to daily dosing with AV-951 in 21-41 patients with recurrent, progressive or non-responsive NSCLC and no prior exposure to anti-angiogenic therapy.

In parallel with this Phase 1b/2a combination trial, AVEO will study global and targeted gene expression patterns in all patients to evaluate biomarkers for response and patient selection. For more information about this and other AVEO clinical trials, please visit the NIH Clinical Trials web site at <http://www.clinicaltrials.gov>.

"This Phase 1b/2a clinical trial of AV-951 is an important addition to our robust development program for AV-951, the breadth of which speaks to our confidence in this unique angiogenesis inhibitor to become a broadly used cancer therapy," said Tuan Ha-Ngoc, president and chief executive officer of AVEO. "We exceeded enrollment in our lead Phase 2 trial of AV-951 as a single agent in renal cell carcinoma, and have ongoing combination trials of AV-951 in RCC, breast cancer and colorectal cancer.

AVEO continues to build a strong foundation of clinical support for AV-951 that we expect will validate our confidence in its potential benefit within the medical and patient communities.”

### **About AV-951**

AV-951 is a novel, highly potent and selective inhibitor of VEGF receptors 1, 2 and 3, exhibiting picomolar inhibitory activity against all three receptors. Angiogenesis inhibition has demonstrated benefit for patients with a wide range of cancer types, including renal cell carcinoma, metastatic breast cancer, colorectal cancer, and non-small cell lung cancer. Due to its potency and specificity, AVEO believes AV-951 may enable optimal inhibition of the VEGF pathway, while avoiding many side effects often associated with off-target binding. Such a profile may enable AV-951 to be more readily combined with standard chemotherapy as well as other targeted therapies, potentially increasing the breadth of its clinical utility. In addition, AVEO has evaluated AV-951 using its Human Response Platform (HRP™), a unique set of engineered tumor models that provide further insight into potential clinical settings, combinability with other anti-cancer agents, tumor subtypes and responsive patient populations.

In addition to this newly announced Phase 1b/2a trial of AV-951 as monotherapy for the treatment of advanced non-small cell lung cancer, AVEO is conducting a Phase 2 trial of AV-951 as monotherapy in advanced metastatic renal cell carcinoma (mRCC), and ongoing Phase 1b trials of AV-951: in combination with temsirolimus, an approved mTOR inhibitor, in patients with mRCC; in combination with the FOLFOX6 chemotherapy regimen in patients with advanced colorectal cancer and other gastrointestinal cancers; and in combination with paclitaxel in patients with metastatic breast cancer.

### **About AVEO**

AVEO is a late-stage biopharmaceutical company focused on the discovery and development of novel, targeted cancer therapeutics. AVEO's proprietary, integrated cancer biology platform enables the company to pursue highly efficient drug development strategies in oncology that increase the probability of clinical success and provides a discovery engine for high-value targets. This approach has resulted in a balanced pipeline of novel cancer therapies focused on well-validated targets (VEGFR, EGFR) and promising novel targets (HGF, FGFR), as well as collaborations with Eli Lilly, Merck, OSI Pharmaceuticals and Schering-Plough. The company's lead product, AV-951, a potential best-in-class triple VEGF receptor inhibitor, is in a Phase 2 clinical trial in more than 270 patients with metastatic renal cell cancer and is expected to enter Phase 3 development in 2009. Through a combination of internal drug discovery and selective in-licensing of targeted therapeutics, AVEO is building a diversified product pipeline and moving toward its vision of becoming a fully integrated biopharmaceutical company. For more information, please visit the company's website at [www.aveopharma.com](http://www.aveopharma.com).

## Contacts

Michael Christiano, AVEO Pharmaceuticals, Inc.  
617-299-5925  
or  
Caton Lovett, Pure Communications  
910-232-7166

Source: AVEO Pharmaceuticals, Inc.



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