AVEO Pharmaceuticals' Oral, Triple VEGF Receptor Inhibitor AV-951 Shows Robust Activity in Patients with Advanced Kidney Cancer

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272-Patient Phase 2 Data Show 91.7 Percent Disease Control Rate and Favorable Tolerability; Interim Results Being Presented at ASCO GU Indicate Highly Differentiated VEGFR Profile

CAMBRIDGE, Mass., February 25, 2009 – AVEO Pharmaceuticals, Inc., a biopharmaceutical company leveraging breakthrough discoveries in cancer biology to discover, develop and commercialize targeted oncology therapies, today announced positive interim results from a 272-patient Phase 2 clinical trial of AV-951, a novel, oral, triple VEGF receptor inhibitor, in patients with advanced renal cell carcinoma (RCC). As assessed by independent radiological review, patients with advanced RCC treated with AV-951 experienced a 91.7 percent disease control rate at 16 weeks. The data also demonstrate that AV-951 was well tolerated. These data are to be presented during an oral abstract session at the 2009 Genitourinary Cancers Symposium, a multidisciplinary symposium co-sponsored by the American Society of Clinical Oncology (ASCO), the American Society for Therapeutic Radiology and Oncology (ASTRO) and the Society of Urologic Oncology (SUO).

"Patients living with kidney cancer are in need of therapies with an improved therapeutic index, that can provide durable responses, as the on and off-target toxicities associated with many of the currently available VEGF receptor inhibitors often lead to treatment interruptions or discontinuation, all of which can negatively impact patients' overall treatment success," stated Robert Figlin, M.D., chair, Division of Medical Oncology and Therapeutics Research, and Arthur and Rosalie Kaplan Professor of Medical Oncology at the City of Hope Comprehensive Cancer Center in Duarte, CA. "The disease control rate achieved by kidney cancer patients treated with AV-951 in this trial, combined with its tolerability, builds upon a growing body of evidence demonstrating the potential role for AV-951 as a novel, oral treatment option for patients living with kidney cancer and other difficult-to-treat tumors."

The Phase 2 placebo-controlled, randomized discontinuation trial assessed the efficacy and safety of once-daily, oral AV-951 in 272 patients with locally advanced or metastatic RCC and no prior VEGF-targeted therapy. Key results include:

Disease control rate at 16 weeks was 88.8 percent (89.4% in clear cell RCC) by investigator ssessment and 91.7 percent (91.9% in clear cell RCC) by independent radiology assessment.

Objective response rate at 16 weeks was 26.4 percent (29.6% in clear cell RCC) by investigator assessment and 20.1 percent 20.6% in clear cell RCC) by independent radiology assessment using standard RECIST criteria.

Among patients with >25% tumor regression who continued uninterrupted treatment on AV-951, the median progression free survival (PFS) has not been reached during a follow-up duration of 12.6 months.

The most common treatment-related adverse events seen in this interim analysis were hypertension and dysphonia (hoarseness of voice), both of which were readily manageable and are recognized as "on-target" effects expected of a highly potent and selective VEGF receptor inhibitor. The safety profile of AV-951 observed in the trial was notable for the minimal off-target toxicities such as mucositis/stomatitis, fatigue, neutropenia and hand-foot syndrome.

"The activity of AV-951 in advanced renal cancer is indicative of its potential single-agent utility in the treatment of these difficult-to-treat tumors, while the favorable safety profile continues to reaffirm the potential for AV-951 combinability with other important cancer treatment regimens," said Tuan Ha-Ngoc, president and chief executive officer of AVEO. "These interim Phase 2 results clearly underscore the value of this novel agent, and we look forward to presenting the complete results from this trial, including PFS data, at an upcoming medical meeting later this year. With our recently initiated combination and single agent clinical trials in kidney, colorectal and breast cancers, as well as our plans to initiate a pivotal Phase 3 trial in advanced renal cancer later this year, AV-951 is poised for success among the anti-angiogenic agents currently available and in development."

AVEO has also initiated ongoing Phase 1b clinical 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 the Study

This Phase 2 placebo-controlled, randomized discontinuation trial assessed the efficacy and safety of once-daily, oral AV-951 in 272 metastatic renal cell carcinoma patients naïve to VEGF targeted therapy at more than 30 sites in Europe and India under a U.S. investigational new drug (IND) application. In this trial, all patients received 1.5 mg/d of AV-951 (three weeks on, one week off) for the first 16 weeks, after which time patients were evaluated for response. Those patients who achieved >25% tumor regression remained on therapy, while patients who experienced <25% change from baseline were randomized to receive AV-951 or placebo in a double-blind fashion. The primary endpoints of this trial are objective response rate at 16 weeks of treatment, percentage of patients who are progression free at 12 weeks following randomization (i.e., 28 weeks after study entry), and safety. For more information, please visit the NIH clinical trials website at http://www.clinicaltrials.gov.

About Renal Cell Carcinoma

Advanced RCC, a rare but serious type of kidney cancer, is among the most treatment-resistant tumors. Worldwide incidence of RCC is more than 200,000 cases annually. Recent estimates show that nearly 36,000 people in the U.S. developed RCC in 2006, and approximately 12,500 died due to progression of the disease. Although first-generation multikinase inhibitors are available for the treatment of RCC, there remains a significant need for improved therapies with greater tolerability.

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 maximal inhibition of the VEGF pathway, while avoiding side effects associated with off-target activity. 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 Phase 2 trial, AVEO is conducting 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 novel, triple VEGF receptor inhibitor, is in a Phase 2 clinical trial in 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.