AVEO Oncology Announces Presentation of AV-203 Phase 1 Results at 2014 American Society of Clinical Oncology Annual Meeting

May 31, 2014

CAMBRIDGE, Mass. & CHICAGO—(BUSINESS WIRE)—May 31, 2014-- AVEO Oncology (NASDAQ:AVEO) today announced the presentation of results from a first-in-human Phase 1 study of AV-203, AVEO’s ErbB3 (HER3) inhibitory antibody candidate. Among the results, the study established a recommended Phase 2 dose of AV-203, demonstrated good tolerability and promising early signs of activity, and reached the maximum planned dose of AV-203 monotherapy. The results were presented in a poster, entitled “First-in-human Phase 1 dose-escalation study of AV-203, a monoclonal antibody against ErbB3 in patients with metastatic or advanced solid tumors” (Abstract #11113, Poster #395, S Hall A2), at the Tumor Biology General Poster Session of the American Society of Clinical Oncology 2014 Annual Meeting, taking place May 30 - June 3, 2014, in Chicago.

“ErbB3 is a promising target for the treatment of a wide range of cancers, as it is both an important tumor survival pathway and may serve as a resistance mechanism for widely-used therapies targeting EGFR and HER2, among others,” stated Dr. John Sarantopoulos of the Institute for Drug Development, Cancer Therapy and Research Center at the University of Texas Health Science Center at San Antonio. “The results we see in this first-in-human study of AV-203 demonstrate good tolerability and an early signal of activity consistent with preclinical data showing the potential for neuregulin-1, the only known ligand for ErbB3, to serve as a biomarker predictive of AV-203 anti-tumor activity. These data provide a rationale for further investigation of AV-203 as novel anticancer therapy.”

A total of 22 patients were evaluated in the Phase 1, open-label, dose-escalation study. Objectives included safety, tolerability, dose limiting toxicities (DLT), maximum tolerated dose and/or recommended phase 2 dose in patients with advanced solid tumors. Evaluation of NRG-1 as a predictive biomarker was an exploratory objective. Patients received 2, 5, 9, 14, or 20 mg/kg of AV-203 intravenously once every 2 weeks (2 times per 28 day cycle). AV-203 was found to be generally safe and well-tolerated, with diarrhea and decreased appetite as the most common treatment-emergent and treatment-related adverse events (all grade). Across all doses of AV-203, there was a single DLT that occurred in an elderly patient at the lowest dose cohort (inability to tolerate study drug). The recommended Phase 2 dose was established at 20mg/kg intravenously every 2 weeks. No anti-drug antibodies were detected, and pharmacokinetic results indicated a dose-proportional increase in levels of AV-203.

Among 22 evaluable patients, stable disease was the best response for 8 patients, including a partial response lasting 6 cycles and a long-term stable disease lasting at least 22 cycles (>98 weeks), resulting in a disease control rate of 36%. Neuregulin-1 (NRG-1, also known as heregulin or HRG) status, which AVEO’s preclinical studies suggest is predictive of AV-203 anti-tumor activity, was analyzed via RT-PCR. Of 14 subjects analyzed for NRG-1 expression, two patients were NRG-1 positive, one of whom, a patient with squamous non–small cell lung cancer, achieved a partial response. CLIA (Clinical Laboratory Improvements Amendment) validation is complete for an NRG-1 biomarker assay for potential use in patient selection in future clinical trials.

In March 2014, AVEO announced that it completed negotiations to reacquire worldwide rights for AV-203 from ex-US licensor Biogen Idec, a company which had previously announced plans to shift its therapeutic focus away from oncology.

About AV-203

AV-203 is a potent and selective ErbB3 (HER3) inhibitory antibody candidate designed to inhibit both ligand-dependent and ligand-independent ErbB3 signaling. ErbB3 is a receptor that is typically expressed in many human cancers, and AV-203 has demonstrated preclinical activity in a number of different tumor models including breast, head and neck, lung, ovarian and pancreatic cancers. Preclinical data also suggest that Neuregulin-1 (NRG-1) levels predict AV-203 anti-tumor activity. NRG-1, also known as heregulin (HRG), is the only known ligand of ErbB3, and the most potent activator of the ErbB3/HER2 complex.

About AVEO

AVEO Oncology (NASDAQ:AVEO) is a biopharmaceutical company committed to discovering and developing targeted therapies designed to provide substantial impact in the lives of people with cancer by addressing unmet medical needs. AVEO’s proprietary Human Response Platform™ provides the company unique insights into cancer and related disease biology and is being leveraged in the discovery and clinical development of its therapeutic candidates. For more information, please visit the company’s website at www.aveooncology.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “target,” “potential,” “could,” “should,” “seek,” or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about the potential for NRG-1 to serve as a biomarker predictive of AV-203 anti-tumor activity; the use of ErbB3 as a target for cancer treatment and ErbB3’s tendency to serve as a resistance mechanism; and plans and prospects for further investigation of AV-203 as an anti-cancer therapy, including its potential safety and efficacy in humans. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due.
to a number of important factors, including risks relating to: AVEO's ability to execute on its business strategy and enter into and maintain new strategic partnerships and collaboration agreements; AVEO's ability to successfully enroll and complete clinical trials and preclinical studies of its product candidates; AVEO's ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory agencies, the safety, efficacy and clinically meaningful benefit of its product candidates; AVEO's ability to achieve and maintain compliance with all regulatory requirements applicable to its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to its product candidates and technologies; developments and expenses related to AVEO's ongoing shareholder litigation and SEC inquiry; AVEO's ability to raise the substantial additional funds required to achieve its goals; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled “Risk Factors” included in AVEO's Quarterly Report on Form 10-Q filed with the SEC on May 7, 2014 and in its other filings with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release. AVEO anticipates that subsequent events and developments will cause its views to change. However, while AVEO may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing AVEO's views as of any date subsequent to the date of this press release.

Source: AVEO Oncology

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