AVEO Oncology and Biodesix Announce Results from Two Investigator-Sponsored Phase 1 Studies of HGF Targeted Antibody Ficlatuzumab at the 2017 ASCO Annual Meeting

Announce Expected Initiation of an Investigator-Initiated, Randomized, Phase 2, Multicenter Trial of Ficlatuzumab and Cetuximab in HNSCC in 2H 2017

AVEO Announces Trial in Progress Poster Also Presented Highlighting Phase 3 TIVO-3 Study of Tivozanib in RCC

CAMBRIDGE, Mass. – June 5, 2017 – AVEO Oncology (NASDAQ: AVEO) and Biodesix, Inc., co-development partners, today announced the presentation of results from two investigatorsponsored Phase 1 studies of ficlatuzumab at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting taking place in Chicago, Illinois. The first is a study of ficlatuzumab in combination with the EGFR inhibitor cetuximab in patients with cetuximabresistant, metastatic head and neck squamous cell carcinoma (HNSCC), and the second is a study of ficlatuzumab in combination with high-dose cytarabine in patients with high risk relapsed or refractory acute myeloid leukemia (AML). Ficlatuzumab is a humanized IgG1 antibody that binds to the HGF ligand with high affinity and specificity to inhibit the biological activities of the HGF/cMet pathway.

"HGF is an important pathway for resistance and proliferation in a number of cancer models, serving as a means to overcome EGFR inhibition in HNSCC, and as an adverse prognostic factor in AML," said Michael Needle, chief medical officer of AVEO. "In a Phase 1 study in patients with cetuximab-resistant recurrent/metastatic HNSCC, the addition of ficlatuzumab to the EGFRtargeted antibody cetuximab resulted in a disease control rate of 67%, and prolonged progression free and overall survival compared to historical controls, in addition to being well tolerated. With continued, strong investigator support, we look forward to the expected initiation, in the second half of 2017, of a randomized, Phase 2, multicenter, investigator-initiated trial to confirm these findings. We also look forward to the completion of the ongoing investigator-sponsored study in AML, which has demonstrated early signs of tolerability and activity, including a 50% complete response rate in the relapsed/refractory setting."

"Median PFS for cetuximab monotherapy in the naïve setting is only two months, as with the median PFS for nivolumab or single-agent chemotherapy in the platinum-refractory setting, suggesting an urgent need for new therapies," said Julie E. Bauman, MD, MPH, Professor of Medicine, Chief, Division of Hematology/Oncology, Associate Director of Translational Research, University of Arizona Cancer Center. "Although a small cohort, the fact that we observed significant responses and PFS of 6 months in a refractory population in this study suggests important biologic activity."

AVEO also announced that a Trials in Progress presentation highlighting the ongoing Phase 3, randomized, controlled, multi-center, open-label TIVO-3 study comparing tivozanib, the Company's potent, selective, long half-life inhibitor of all three vascular endothelial growth factor (VEGF) receptors, to sorafenib in subjects with refractory advanced renal cell carcinoma.

The posters are available at www.aveooncology.com. Details of the posters are below:

Phase I study of the anti-HGF mononclonal antibody (mAb), ficlatuzumab, and cetuximab in cetuximab-resistant, recurrent/metastatic (R/M) head and neck squamous cell carcinoma (HNSCC)

Presenter: Julie E. Bauman, MD, MPH, Chief, Division of Hematology and Oncology, Associate Director, Translational Research, University of Arizona Cancer Center
Abstract Number: 6038
Session: Head and Neck Cancer
Date and Time: Monday, June 5, 2017, 1:15-4:45 PM CT

In this phase I study, 12 patients with R/M HNSCC who had disease recurrence within 6 months of cetuximab radiation or progression within 6 months of cetuximab treatment in the recurrent metastatic setting were treated with a ficlatuzumab/cetuximab combination. The primary objective was to establish the recommended Phase 2 dose (RP2D) for ficlatuzumab, with the secondary objectives being to evaluate preliminary clinical efficacy of RP2D and to evaluate the relationship between preliminary efficacy and 1) baseline tumor p-Met expression and 2) serum Veristrat.

Cetuximab was administered every 2 weeks at 500 mg/m^2, and ficlatuzumab dose tiers were 10 mg/kg (tier 1) or 20 mg/kg IV every 2 weeks (tier 2), with inter-patient escalation or de-escalation based on cumulative dose-limiting toxicities (DLT). RP2D was set at tier 2 if no DLTs were observed after 8 enrolled patients, with expansion continuing to 12 patients. Three patients were treated at dose tier 1 and 9 at dose tier 2. The RP2D is ficlatuzumab 20 mg/kg and cetuximab 500 mg/m^2 every 2 weeks. The overall response rate was 17% (1 PR at tier 1; 1 at tier 2) and 50% of patients had stable disease, for a disease control rate of 67%. Median PFS and OS at RP2D were 6.0 mos (90% CI=2 mos-NR) and 8.2 mos (90% CI=2.7 mos-NR).

CyFi: A phase I study exploring the role of cMET pathway inhibition with ficlatuzumab (Fi) combined with high-dose cytarabine (Cy) in patients with high risk relapsed or refractory acute myeloid leukemia (AML)

Presenter: Charalambos (Babid) Andreadis, MD, Hematologic Malignancies and Blood and Marrow Transplantation Program, University of California, San Francisco
Abstract Number: 7040
Session: Hematologic Malignancies – Leukemia, Myelodyplastic Syndromes, and Allotransplant
Date and Time: Monday, June 5, 2017, 8:00-11:30 AM CT

In this ongoing study, the safety and tolerability of ficlatuzumab in combination with cytarabine was assessed in 9 patients with high risk relapsed or refractory acute myeloid leukemia. Ficlatuzumab was given in escalated dosing of 10, 15, or 20 mg/kg for 4 doses every 2 weeks,

starting on day 0, and cytarabine was given at a fixed dose of $2g/m^2$ on days 2-7, using a 3x3 design. Dose-limiting toxicity (DLT) was defined based on toxicities attributable to the combination and unexpected with AML or high-dose cytarabine. Peripheral blood mononuclear cells and serum were collected at defined time points to assess HGF levels and activation of the cMet pathway. The results showed no DLTs, and the combination has proven well tolerated. The most frequent grade 3-4 adverse events were febrile neutropenia (56%), ventricular tachycardia (22%), respiratory distress (11%), electrolyte disturbance (11%). There was 1 death from sepsis and multi-organ failure on day 23, during count recovery. Of the 8 evaluable patients, 4 achieved a CR (50%), all in the 2nd dose cohort. All patients had detectable circulating HGF levels at baseline and levels increased following exposure to Fi by an average of 193% (p value). Baseline levels or change from baseline were not associated with response.

Title: Tivo-3: A phase 3, randomized, controlled, multi-center, open-label study to compare tivozanib hydrochloride to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC)
Presenter: Brian I. Rini, MD, FACP, Professor of Medicine, Lerner College of Medicine,
Leader, GU Program, Department of Hematology and Oncology, Cleveland Clinic Taussig Cancer Institute
Abstract Number: TPS4600
Session: Genitourinary (Non-prostate) Cancer
Date and Time: Sunday, June 4, 2017, 8:00-11:30 AM CT

About Ficlatuzumab

Ficlatuzumab (formerly known as AV-299) is a potent hepatocyte growth factor (HGF) inhibitory antibody that binds to the HGF ligand with high affinity and specificity to inhibit HGF/c-Met biological activities. AVEO and Biodesix, Inc. currently divide all worldwide development costs for ficlatuzumab and are seeking a commercialization partner. Ficlatuzumab is currently being evaluated in investigator-sponsored trials in squamous cell carcinoma of the head and neck (HNSCC) and acute myeloid leukemia (AML).

About Tivozanib

Tivozanib is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI). It is a potent, selective and long half-life inhibitor of all three VEGF receptors and is designed to optimize VEGF blockade while minimizing off-target toxicities, potentially resulting in improved efficacy and minimal dose modifications. Tivozanib has been investigated in several tumors types, including renal cell, colorectal and breast cancers.

About AVEO

AVEO Oncology (AVEO) is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted therapeutics for oncology and other areas of unmet medical need. The Company is focused on seeking to develop and commercialize its lead candidate tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, in North America as a treatment for renal cell carcinoma and other cancers. AVEO is leveraging

multiple partnerships aimed at developing and commercializing tivozanib in oncology indications outside of North America, and at progressing its pipeline of novel therapeutic candidates in cancer and cachexia (wasting syndrome). For more information, please visit the company's website at www.aveooncology.com.

About Biodesix

Biodesix® is a molecular diagnostics company advancing the development of innovative, multiomic blood tests in oncology to enable precision medicine. Biodesix discovers, develops and commercializes multivariate protein and genomic liquid biopsy tests, including the GeneStrat® and VeriStrat® tests, that deliver results within 72 hours. The company is changing the standard of care by providing physicians with diagnostic tests and with the Biodesix Lung Reflex™ testing strategy, for better therapeutic guidance, more accurate prognosis and enhanced disease monitoring to improve patient outcomes. At the forefront of personalized medicine, Biodesix is developing new tests to identify patients who may benefit from immunotherapies. In addition to developing novel diagnostics independently, the company partners with biotechnology and pharmaceutical companies to develop companion diagnostics for use with therapeutic agents.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. The words "anticipate," "believe," "expect," "intend," "may," "plan," "potential," "could," "should," "would," "seek," "look forward," "advance," "goal," "strategy," 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 safety, efficacy and clinical benefits of ficlatuzumab in HNSCC and AML; plans to initiate an investigator-initiated, randomized, phase 2, multicenter trial of ficlatuzumab and cetuximab in HNSCC in the second half of 2017; expected completion of the ongoing investigator sponsored study of ficlatuzumab in AML; AVEO's and its collaborators' future discovery, development and commercialization plans and efforts, including without limitation with respect to tivozanib, ficlatuzumab and AVEO's other programs and platforms; and AVEO's strategy, prospects, plans and objectives. AVEO has based its expectations and estimates on assumptions that may prove to be incorrect. As a result, readers are cautioned not to place undue reliance on these expectations and estimates. 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 enter into and maintain its third party collaboration agreements; the ability of AVEO and its licensees and other partners to achieve development and commercialization objectives under these arrangements; AVEO's ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies the safety, efficacy and clinically meaningful benefit of AVEO's product candidates; AVEO's ability and the ability of investigators and collaborators to successfully enroll and complete clinical trials, including the ficlatuzumab, TIVO-3 and TiNivo studies; 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, expenses and outcomes related to AVEO's ongoing

shareholder litigation; AVEO's ability to successfully implement its strategic plans; AVEO's ability to raise the substantial additional funds required to achieve its goals, including those goals pertaining to the development and commercialization of ficlatuzumab and tivozanib; unplanned capital requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" included in AVEO's Annual Report on Form 10-K for the year ended December 31, 2016, its quarterly reports on Form 10-Q and in other filings that AVEO may make with the SEC in the future. 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 may cause its views to change. 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 other than the date of this press release.

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