



AVEO and Biodesix Announce Positive Results from Phase Ib Ficlatusumab-Cytarabine Trial in Patients with Relapsed and Refractory AML

- Data presented during poster session at the AACR 2019 Annual Meeting -

CAMBRIDGE, Mass. – April 1, 2019 – AVEO Oncology (NASDAQ: AVEO) and Biodesix, Inc. today announced results from an investigator-sponsored Phase Ib expansion cohort of ficlatuzumab, AVEO’s potent hepatocyte growth factor (HGF) inhibitory antibody product candidate, in combination with cytarabine in patients with relapsed and refractory acute myeloid leukemia (AML). The results were presented in a poster session at the American Association for Cancer Research (AACR) 2019 Annual Meeting. The presentation, titled, “CyFi: Results from a phase Ib expansion cohort of ficlatuzumab (Fi) combined with high-dose cytarabine (Cy) in patients with high risk relapsed or refractory acute myeloid leukemia (AML)” (abstract CT078/2) is available in the Publications & Presentations section of AVEO’s website.

Elevated serum HGF level is an adverse prognostic factor associated with worse survival in AML and other cancers. Pre-clinical models have shown that myeloid blasts produce HGF and that blocking the HGF/c-Met pathway sensitizes blasts to cell death. The Phase Ib trial, which was funded by Gateway for Cancer Research and is being conducted at the UCSF Medical Center under the direction of Charalambos Andreadis, M.D., Associate Professor of Clinical Medicine, Director, Clinical Research Support Office, UCSF Helen Diller Family Comprehensive Cancer Center, was designed to assess the safety, tolerability and preliminary efficacy of ficlatuzumab with cytarabine in AML patients who are refractory to first line therapy (7+3) or have relapsed within one year of induction, a population known to have poor outcomes.

The maximally tolerated dose was 20 mg/kg of ficlatuzumab on day 1 followed by 2 g/m² cytarabine daily on days 2-7. Of 12 patients who received ficlatuzumab and cytarabine at the maximally tolerated dose, one of whom was non-evaluable, 6 achieved a complete response (CR). Of 18 patients enrolled in the study, 17 were evaluable and 9 achieved a CR. The most frequent grade 3/4 treatment emergent adverse events observed were febrile neutropenia, LFT abnormalities, and electrolyte disturbance. There was one death from sepsis and multi-organ failure that was determined to be disease related, and one patient withdrew from the study due to grade 4 gastrointestinal bleed, determined to be likely ficlatuzumab related. scRNA sequencing identified a TNF alpha and IFN gamma inflammatory signature that correlated with response to ficlatuzumab at count recovery.

“Patients with AML who are refractory to induction therapy or relapse within one year have poor outcomes,” said Dr. Andreadis. “Elevated serum HGF level is an adverse prognostic factor, and these results demonstrate that the anti-HGF antibody ficlatuzumab combined with cytarabine holds potential to affect outcomes in patients with relapsed or refractory AML. We look forward to potentially evaluating ficlatuzumab in larger outcome studies in AML.”

“In addition to an attractive tolerability profile observed to date, we also see the potential to identify biomarkers of response using RNA sequencing. In light of these data, we believe that further evaluation in this patient population is warranted, and we look forward to considering additional studies with our partners at Biodesix as a potential next step for the program,” said Michael Bailey, president and chief executive officer of AVEO.

“We look forward to supporting ficlatuzumab’s biomarker development initiatives with a broad set of diagnostic technologies,” said Paul Beresford, chief business officer of Biodesix.

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. have a worldwide agreement to develop and commercialize ficlatuzumab. Ficlatuzumab is currently being evaluated in investigator-sponsored trials in squamous cell carcinoma of the head and neck (HNSCC), metastatic pancreatic ductal cancer (PDAC), and acute myeloid leukemia (AML).

About AVEO

AVEO Pharmaceuticals, Inc. (the “Company” or “AVEO”) is a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. The Company is working to develop and commercialize its lead candidate tivozanib in North America as a treatment for RCC. The Company has sublicensed tivozanib (FOTIVDA[®]) for oncological indications in Europe and other territories outside of North America. Tivozanib is approved in the European Union, as well as Norway and Iceland, for the first-line treatment of adult patients with RCC and for adult patients who are vascular endothelial growth factor receptor and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for RCC. The Company also has clinical collaborations to study tivozanib in combination with immune checkpoint inhibitors in RCC and in hepatocellular carcinoma. In addition, a new formulation of tivozanib is in pre-clinical development for the treatment of age-related macular degeneration. As part of the Company’s strategy, the Company has also entered into partnerships to help fund the development and commercialization of its other product candidates. Ficlatuzumab, a HGF inhibitory antibody, is currently being tested in several investigator sponsored studies jointly funded by the Company and one of its development partners for the potential treatment of HNSCC, AML, and pancreatic cancer. The Company’s partner for AV-203, an anti-ErbB3 monoclonal antibody, is planning to initiate clinical studies in China in 2019 in esophageal squamous cell carcinoma and has committed to funding the development of AV-203 through proof-of-concept. The Company has recently regained the rights to AV-380, a humanized IgG1 inhibitory monoclonal antibody targeting growth differentiation factor 15, a divergent member of the TGF- β family, for the potential treatment of cancer cachexia, and is working to initiate preclinical toxicology studies in 2019 to support the potential filing of an investigational new drug application with the FDA. The Company is evaluating options for the development of its preclinical AV-353 platform which targets the Notch 3 pathway.

For more information, please visit the Company’s website at www.aveooncology.com.

About Biodesix

Biodesix is a lung cancer diagnostic company addressing the continuum of patient care from early diagnosis of lung nodules through late stage cancer. The company develops diagnostic tests addressing important clinical questions by combining simple blood draws and multi-omics with the power of artificial intelligence. Biodesix is the first company to offer three best-in class tests for patients with non-small cell lung cancer, and multiple pipeline tests including one with the potential to identify patients who may benefit from immunotherapies. The Biodesix Lung Reflex strategy integrates the GeneStrat[®] and VeriStrat[®] tests to support treatment decisions with results in 72 hours. The Nodify XL2[™] nodule test, which will be commercially available in the second half of 2019, evaluates the risk of malignancy, enabling physicians to triage patients to the most appropriate course of action. Biodesix also partners with the world's leading biotechnology and pharmaceutical companies to develop companion diagnostics. For more information about Biodesix, please visit www.biodesix.com.

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 potential safety, tolerability and efficacy of the ficlatuzumab-cytarabine combination; the potential to identify biomarkers of response in the relapsed/refractory AML population; and AVEO's plans to further evaluate the ficlatuzumab-cytarabine combination in the relapsed/refractory AML population. 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, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy and clinically meaningful benefit of AVEO's product candidates, including, in particular, ficlatuzumab; and AVEO's ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements. AVEO faces other risks relating to its business as well, including risks relating to the timing and costs of seeking and obtaining regulatory approval; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with 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; 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 tivozanib; unplanned capital requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the sections titled “Risk Factors” and “Management's

Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources” included in AVEO’s quarterly and annual reports on file with the Securities and Exchange Commission (SEC) and in other filings that AVEO makes with the SEC. The forward-looking statements in this press release represent AVEO’s views as of the date of this press release, and 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. Any reference to AVEO’s and Biodesix’s website addresses in this press release are intended to be inactive textual references only and not active hyperlinks.

AVEO Contact:

David Pitts, Argot Partners
(212) 600-1902
aveo@argotpartners.com

Biodesix Contact:

Kena Hudson
Kena@HudBio.com
(510) 908-0966