AVEO Oncology and Biodesix to Discontinue CyFi-2 Study of Ficlatuzumab in Relapsed and Refractory AML in Response to Public Health Crisis

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CAMBRIDGE, Mass. & BOULDER, Colo.--(BUSINESS WIRE)--Mar. 27, 2020-- AVEO Oncology (NASDAQ: AVEO) and Biodesix, Inc. today announced the discontinuation of their CyFi-2 study, a randomized Phase 2 clinical study evaluating ficlatuzumab, AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody product candidate, in combination with high-dose cytarabine vs. high-dose cytarabine alone in patients with relapsed and refractory acute myeloid leukemia (AML). This decision is being taken due to the urgent shift among clinical sites toward efforts to combat the COVID-19 pandemic, which has impacted the feasibility of completing the study within the shelf-life of the current ficlatuzumab clinical trial supply. The study has not yet begun patient enrollment.

"While this is a difficult decision, as we remain optimistic about the potential of ficlatuzumab in AML, we believe it is necessary in light of the COVID-19 pandemic and its effect on the states where the CyFi-2 study was to take place," said Michael Bailey, president and chief executive officer of AVEO. "Our investigators have been informed of the closure, and we greatly appreciate their enthusiasm for the study. We remain committed to the practice of scientific discovery and will focus our resources and efforts on our ongoing initiatives."

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 a clinical study of patients with squamous cell carcinoma of the head and neck (HNSCC).

About AVEO

AVEO is developing an oncology pipeline designed to provide a better life for patients with cancer. AVEO's strategy is to focus its resources toward development and commercialization of its product candidates in North America, while leveraging partnerships to support development and commercialization in other geographies. AVEO's lead candidate, tivozanib (FOTIVDA®) is approved in the European Union, the United Kingdom, Norway, New Zealand and Iceland for the treatment of adult patients with advanced renal cell carcinoma. AVEO is working to develop and commercialize tivozanib in North America as a treatment for renal cell carcinoma, hepatocellular carcinoma and other cancers. Ficlatuzumab (HGF MAb) is in a Phase 2 clinical trial in head and neck cancer and has reported early clinical data in pancreatic cancer. AVEO's earlier-stage pipeline includes several monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 MAb), AV-380 (GDF15 MAb) and AV-353 (Notch 3 MAb). For more information, please visit the Company's website at www.aveooncology.com.

About Biodesix

Biodesix is a lung cancer diagnostic solutions company covering the continuum of patient care from early risk classification of lung nodules through treatment guidance in late stage cancer. The Company develops blood-based diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix is the first company to offer four approved, non-invasive tests for patients with lung cancer or suspicious lung nodules. The Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 72 hours, expediting time to treatment. The Nodify XL2™ test and the Nodify CDT™ test evaluate the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. Biodesix also collaborates with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges. 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 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 fact, contained in this press release are forward-looking statements. The words "anticipate," "believe," "designed to," "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: AVEO's strategy, prospects, plans and objectives for ficlatuzumab and its other product candidates and for the Company generally. 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, tivozanib and ficlatuzumab; AVEO's ability to successfully file an NDA for tivozanib; 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 impact of the novel coronavirus (COVID-19) outbreak on AVEO's clinical trials and other business operations; 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; the outcome of litigation; 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 website address or a third-party website address in this press release is intended to be an inactive textual reference only and not an active hyperlink.

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