AVEO Oncology and Biodesix Announce Results from Phase 1b Study of Ficlatuzumab, Gemcitabine and Nab-paclitaxel in Advanced Pancreatic Cancer

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- Data Presented at the 2020 ASCO GI Cancers Symposium -

CAMBRIDGE, Mass. & BOULDER, Colo.--(BUSINESS WIRE)--Jan. 27, 2020-- AVEO Oncology (NASDAQ: AVEO) and Biodesix, Inc. today announced the presentation of results from an investigator-sponsored Phase 1b trial of ficlatuzumab, AVEO's potent hepatocyte growth factor (HGF) inhibitory antibody product candidate, in combination with nab-paclitaxel and gemcitabine in patients with previously untreated metastatic pancreatic ductal adenocarcinoma (PDAC). The results were presented during a poster session at the 2020 American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Cancers Symposium. A copy of the presentation, titled "Phase 1b Study of Gemcitabine, Nab-paclitaxel, and Ficlatuzumab in Patients with Advanced Pancreatic Cancer" (abstract 693), is available in the Publications & Presentations section of AVEO's website.

The study, which was based on preclinical findings demonstrating a synergistic effect of the combination in a preclinical model of PDAC, was designed to determine the maximum tolerated dose of ficlatuzumab when combined with gemcitabine and nab-paclitaxel. Secondary outcome measures included response rate and progression free survival. A total of 24 patients were enrolled. The average number of 28-day cycles received was 7.5 (range 1-15), with 3 patients remaining on active treatment. The combination was associated with a promising durable response rate relative to expectations for gemcitabine and nab-paclitaxel alone. This included a 29% partial response (PR) rate and 92% rate of disease control (PR + stable disease). Treatment with this regimen was associated with significant hypoalbuminemia and edema, and therefore a follow up safety study is under consideration of ficlatuzumab in combination with an alternate cytotoxic regimen.

"Pancreatic cancer remains among the most challenging diseases to treat, owing to late diagnoses, rapid progression and early mortality," said Kimberly Perez, MD, Dana-Farber Cancer Institute. "By targeting the c-MET pathway, ficlatuzumab inhibits the Prrx1b-HGF signaling associated with pancreatic development, pancreatitis, and carcinogenesis. These Phase 1b results show encouraging responses that support the further study of ficlatuzumab in pancreatic cancer."

"Ficlatuzumab continues to emerge as a promising clinical candidate, with these results adding to a growing body of clinical data in acute myeloid leukemia and head and neck cancer," said Michael Bailey, president and chief executive officer of AVEO. "As we continue to execute on our tivozanib Phase 3 clinical and U.S. registration strategy and move closer to its potential commercialization, we look forward to seeing ficlatuzumab progress in multiple clinical studies, with the goal of determining a pivotal strategy, assuming favorable study outcomes."

"Ficlatuzumab continues to demonstrate the potential for major clinical utility in areas of significant unmet need," said Scott Hutton, Chief Executive Officer of Biodesix. "We look forward to continuing our diagnostic development work alongside AVEO to help realize the full potential of this promising therapeutic candidate."

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 squamous cell carcinoma of the head and neck (SCCHN), metastatic pancreatic ductal cancer (PDAC), and acute myeloid leukemia (AML).

About AVEO

AVEO Pharmaceuticals is a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. The Company's lead candidate is tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, which AVEO is working to develop and commercialize in North America as a treatment for renal cell carcinoma (RCC), hepatocellular carcinoma (HCC) and other cancers. Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced RCC in the European Union plus Norway, New Zealand, and Iceland. AVEO is leveraging or seeks to leverage partnerships to develop and commercialize its pipeline of products and product candidates, including tivozanib in oncology and other indications in various geographies, and ficlatuzumab (HGF MAb) in head and neck cancer, pancreatic cancer and acute myeloid leukemia. AVEO's earlier-stage pipeline includes AV-203 (anti-ErbB3 MAb), AV-380 (GDF15 MAb) and AV-353 (Notch 3 MAb) for various oncology indications.

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

About Biodesix

Biodesix is a lung cancer diagnostic solutions 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 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 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 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," "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 advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies and tivozanib to commercialization; the potential efficacy, safety, and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies; the potential for outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab in areas of unmet need; the potential efficacy, safety, and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies in several indications; AVEO's execution of its clinical and regulatory strategy for tivozanib; AVEO's plans and strategies for commercialization of tivozanib in the United States and Europe; and AVEO's strategy, prospects, plans and objectives for its 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 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 website address in this press release is intended to be an inactive textual reference only and not an active hyperlink.

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