AVEO Oncology Announces Clinical Trial Collaboration and Supply Agreement with Eli Lilly and Company for ERBITUX® (cetuximab) in North America to Evaluate Ficlatuzumab and Cetuximab in Patients with Recurrent or Metastatic HNSCC

June 22, 2022

- This agreement follows AVEO's entry into a similar agreement with Merck KGaA, Darmstadt, Germany to provide cetuximab clinical drug supply outside of the U.S. and Canada -

- AVEO Currently Manufacturing Ficlatuzumab Clinical Supply; Potential Phase 3 Registrational Clinical Trial in HPV Negative R/M HNSCC Expected in 1H 2023 -

BOSTON, June 22, 2022 (GLOBE NEWSWIRE) -- AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company, today announced that it has entered into a clinical trial collaboration and supply agreement in North America with Eli Lilly and Company (Lilly) to evaluate ficlatuzumab in combination with ERBITUX® (cetuximab), an anti-EGFR antibody, in patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). Ficlatuzumab is AVEO's investigational potent humanized immunoglobulin G1 monoclonal antibody that targets hepatocyte growth factor.

"This clinical trial collaboration and supply agreement with Lilly follows a similar engagement we entered into with Merck KGaA, Darmstadt, Germany earlier this year, both of which we believe serve as validation for our ficlatuzumab clinical development plan. We expect these collaborations will play an important role in the advancement of the combination of ficlatuzumab and cetuximab," said Michael Bailey, president and chief executive officer of AVEO. "We reported positive Phase 2 clinical data last year that show ficlatuzumab in combination with cetuximab has the potential to play a meaningful role in the treatment of patients with human papillomavirus (HPV) negative R/M HNSCC, which is associated with particularly poor outcomes. We continue to be in discussions with regulators on the final design of a potential pivotal study for this combination therapy, which we expect to commence in the first half of 2023."

Under the terms of the agreement, Lilly will provide cetuximab clinical drug supply in the U.S. and Canada for AVEO's potential registrational study, which will assess ficlatuzumab with cetuximab in HPV negative R/M HNSCC. AVEO will serve as the study sponsor and will be responsible for trial execution.

In June 2021, AVEO announced positive results from a randomized Phase 2 study of ficlatuzumab alone or in combination with cetuximab in patients with pan-refractory metastatic HNSCC. Of note, patients with HPV negative disease, a subgroup normally associated with poorer outcomes, who received the ficlatuzumab and cetuximab combination demonstrated both a superior overall response rate, including two patients with complete responses, and median progression free survival superior to historical data for current standards of care. In September 2021, the FDA awarded Fast Track designation for the combination of ficlatuzumab and cetuximab in HPV negative relapsed/recurrent HNSCC. A copy of the presentation is available at www.aveooncology.com.

AVEO recently commenced manufacturing of ficlatuzumab clinical supply in the second quarter of 2022, with the potential registrational study expected to be initiated in the first half of 2023. AVEO expects to continue to discuss potential ficlatuzumab pivotal study designs with the FDA and to continue ongoing partnership dialogues.

About Ficlatuzumab

Ficlatuzumab (formerly known as AV-299) is a potent hepatocyte growth factor (HGF) immunoglobulin G1 (IgG1) inhibitory antibody that binds to the HGF ligand with high affinity and specificity. HGF is the natural ligand of c-Met and blocking HGF inhibits signaling through the HGF/c-Met signaling pathway. Ficlatuzumab is currently being evaluated in squamous cell carcinoma of the head and neck (HNSCC) and pancreatic cancer. The U.S. Food and Drug Administration designated as a Fast Track development program the investigation of ficlatuzumab and ERBITUX® (cetuximab) for relapsed/recurrent HNSCC in September 2021.

About AVEO Pharmaceuticals, Inc.

AVEO is a commercial-stage, oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer. AVEO currently markets FOTIVDA® (tivozanib) in the U.S. for the treatment of adult patients with relapsed or refractory renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO continues to develop FOTIVDA in immuno-oncology combinations in RCC and other indications, and has other investigational programs in clinical development. AVEO is committed to creating an environment of diversity, equity and inclusion to diversify representation within the Company.

ERBITUX® is a registered trademark owned by or licensed to Eli Lilly and Company, its subsidiaries, or affiliates.

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,” “design,” “expect,” “hope,” “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 for ficlatuzumab as a treatment option for patients with R/M HNSCC; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies in R/M HNSCC and other indications; the availability of clinical supplies of ficlatuzumab; the anticipated patient enrollment date for AVEO’s registrational study in HPV negative R/M HNSCC; the potential outcomes from a registrational study in ficlatuzumab with cetuximab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab in areas of unmet need; and AVEO’s strategy, prospects, plans and objectives for FOTIVDA, ficlatuzumab and its other product candidates and for AVEO generally. 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 collaborators and licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy, and clinically meaningful benefit of ficlatuzumab, and risks relating to the timing and costs of seeking and obtaining regulatory approvals; 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’s dependence on third-party vendors for the development, manufacture, supply, storage and distribution of ficlatuzumab; AVEO’s ability to obtain sufficient clinical supplies of its product candidates; the potential adverse effects of the COVID-19 pandemic on drug supply of ficlatuzumab, ability to successfully enroll a registrational study in R/M HNSCC, AVEO’s business continuity, financial condition, results of operations, liquidity and ability to commercialize FOTIVDA, manufacture clinical and commercial product and timely initiate new trials or complete its ongoing clinical trials; competitive factors; and those risks discussed in the sections titled “Risk Factor Summary,” “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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