AVEO Oncology Announces Submission of New Drug Application to U.S. FDA for Tivozanib in Patients with Relapsed or Refractory Renal Cell Carcinoma

March 31, 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 31, 2020-- AVEO Oncology (NASDAQ: AVEO) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tivozanib, the Company's vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR-TKI), as a treatment for relapsed or refractory renal cell carcinoma (RCC).

"NDA submission is a distinguishing milestone for any development stage biotechnology company, and our tivozanib NDA is an important step in our goal of providing an effective and more tolerable therapeutic option to patients with relapsed or refractory RCC," said Michael Bailey, president and chief executive officer. "The TIVO-3 study provides valuable insight into the potential sequencing of therapy following earlier TKI and immunotherapy treatment, an area of significant need for kidney cancer patients whose disease has relapsed or become refractory to multiple lines of therapy. All of us at AVEO offer our continued gratitude to the patients, caregivers, and investigators who participated in our clinical trials. We look forward to working closely with the FDA during their review process and remain hopeful that the study's overall survival (OS) hazard ratio (HR) will continue to favor tivozanib at the time of the final readout, expected by June 2020."

The NDA submission is based on the pivotal active comparator-controlled Phase 3 study, TIVO-3, comparing tivozanib to sorafenib in 3rd and 4th line RCC patients. The application is supported by three additional trials, including an active comparator-controlled supportive Phase 3 study, TIVO-1, comparing tivozanib to sorafenib, and two Phase 2 studies, Study 902, the open-label, crossover clinical study of tivozanib for patients who progressed on sorafenib in TIVO-1, as well as placebo-controlled Study 201 in first line RCC patients.

A final OS analysis of the TIVO-3 study will be conducted in the second quarter based on a May 1, 2020 data cutoff date. AVEO expects to report results from the final OS analysis by June 2020. The FDA and the Company agreed that if, during the review, the final analysis yields an OS HR above 1.00, the Company will withdraw its NDA.

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) discovered by Kyowa Kirin and approved for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union, the United Kingdom, Norway, New Zealand and Iceland. 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.[1,2] Tivozanib is being studied in the TIVO-3 trial, which is supporting a regulatory submission of tivozanib in the U.S. seeking marketing approval as a treatment for relapsed/refractory RCC. Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models[3] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC[4]. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal, ovarian and breast cancers.

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 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.

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," "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 tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or advanced RCC, and following earlier TKI and immunotherapy treatment; AVEO's hope that the OS hazard ratio for TIVO-3 will continue to favor tivozanib at the time of the final readout; AVEO's plan to conduct a final OS analysis in the second quarter based on a May 1, 2020 data cutoff date and to report results by June 2020; 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: the potential for unfavorable final OS data from the TIVO-3 trial; the potential for the FDA to not accept AVEO's NDA for filing; whether the results of TIVO-3 are sufficient to obtain marketing approval for tivozanib in the U.S., which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA the safety and efficacy of tivozanib based upon the findings of TIVO-3, including its data with respect to PFS, the rate of adverse events, OS and other information that the FDA may determine to be relevant to approvability; 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;; 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, including its ability to successfully launch and commercialize tivozanib if it may be approved for commercialization by the FDA; 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.

References

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3. Pawlowski N et al. AACR 2013. Poster 3971.
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