



AVEO Announces TIVO-3 Passes The First Safety Monitoring Committee Safety Review

CAMBRIDGE, Mass. – February 23, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced that its pivotal, Phase 3 TIVO-3 trial, a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC), has successfully completed the first safety review by the study’s Safety Monitoring Committee (SMC). The SMC concluded that no safety concern was observed for tivozanib and recommended that the study replace the small number of patients who dropped out prior to starting treatment.

As recently announced, the TIVO-3 trial is enrolling substantially ahead of schedule, and with the SMC recommendation to replace early dropouts the Company still expects to complete enrollment in June 2017, ahead of its prior guidance of August 2017. A pre-planned futility analysis of the trial is expected around midyear 2017, with topline data expected in the first quarter of 2018. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support regulatory approval of tivozanib in the U.S. as first and third line treatment for RCC.

“Tivozanib is a unique molecule in that its high selectivity for VEGF is designed to reduce off target toxicity, thereby increasing tolerability and its combinability with other agents, such as immunotherapies,” said Michael Needle, M.D., chief medical officer of AVEO. “We are very pleased to see the pace at which TIVO-3 is enrolling, and that it has completed its first safety review. We look forward to the futility analysis around midyear, and to other potential achievements in our tivozanib clinical program, including the expected first patient treated in the tivozanib and Opdivo® combination study, TiNivo, in early March.”

About Tivozanib

Tivozanib is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI). 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. Tivozanib has been investigated in several tumors types, including renal cell, colorectal and breast cancers.

About the TIVO-3 Trial

The Phase 3 TIVO-3 trial is a pivotal, randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC). The trial is expected to enroll approximately 322 patients with recurrent RCC who have failed at least two prior regimens, including VEGFR-TKI therapy (other than sorafenib). Eligible patients may also have received checkpoint inhibitor therapy in earlier lines of treatment. Patients will be randomized 1:1 to receive either tivozanib or sorafenib, with no crossover between arms. The primary endpoint of the study is progression free survival. Secondary endpoints include overall

survival, overall response rate, and safety and tolerability. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support regulatory approval of tivozanib in the U.S. as a first and third line treatment for RCC.

About AVEO

AVEO Oncology (AVEO) is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted therapeutics for oncology and other areas of unmet medical need. The company is focused on seeking to develop and commercialize its lead candidate tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, in North America as a treatment for renal cell carcinoma and other cancers. AVEO is leveraging multiple partnerships aimed at developing and commercializing tivozanib in non-oncologic indications worldwide and oncology indications outside of North America, as well as to progress its pipeline of novel therapeutic candidates in cancer and cachexia (wasting syndrome). 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 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: the expected timelines for completing enrollment, undergoing a futility analysis and receiving top-line data readouts in TIVO-3; the potential for the design of the TIVO-3 and TIVO-1 trials to support regulatory approval for first and third line indications in RCC in the U.S.; AVEO's plans to open clinical trial sites and begin dosing patients in the TiNIVO trial in March 2017, and the potential advancement of such trial; plans and strategies of AVEO and its partners and the potential achievement by AVEO and its partners of clinical, regulatory, commercial, manufacturing and other development goals and milestones; and the potential safety, efficacy, tolerability and other benefits of tivozanib in the treatment of renal cell carcinoma as a single agent or in combination with other therapies;. 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 to enter into and maintain its third party collaboration agreements, and its ability, and the ability of its licensees and other partners, to achieve development and commercialization objectives under these arrangements; AVEO's ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies the safety, efficacy and clinically meaningful benefit of AVEO's product candidates; AVEO's ability to successfully enroll and complete clinical trials, including the TIVO-3 and TiNivo studies; AVEO's ability to achieve and maintain compliance with all 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 and technologies; developments, expenses and outcomes related to AVEO's ongoing shareholder litigation; 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 section titled "Risk Factors" in AVEO's most recent Annual Report on Form 10-K, its quarterly reports on Form 10-Q and its other filings with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release. AVEO anticipates that 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.

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