



AVEO Oncology Issues Statement Regarding Revised TIVO-3 Trial Guidance

CAMBRIDGE, Mass. – July 19, 2018 – AVEO Oncology (NASDAQ: AVEO) today issued the following statement regarding its recently revised guidance on the timing of topline data from the TIVO-3 study, its Phase 3 trial of tivozanib as a third-line treatment for advanced renal cell carcinoma.

“The Company expects to report topline results from the TIVO-3 study in the fourth quarter of 2018, approximately 6-8 weeks after the trial records 255 progression free survival (PFS) events. This change in guidance from the third quarter of 2018 is the result of PFS events occurring slower than forecasted, combined with ten patients being removed or ‘censored’ from the PFS event count. The one-time adjustment in the event count is the result of an administrative error that occurred from counting, as PFS events, the deaths of ten patients who had left the study without documented radiographic progression. These deaths will be counted only as overall survival (OS) events. Per regulatory guidance and the TIVO-3 protocol, among patients who leave the study without documented disease progression, only those who die within eight weeks of their last study assessment and have not started another therapy can be counted as a PFS event. Following the adjustment, and as of yesterday, the PFS event count is 243.”

“Study data remains blinded to the Company and no changes in study assumptions have been made. The administrative error was discovered as part of the data cleaning and review process. The data review process was initiated in an effort to shorten the data analysis period between reaching the 255 PFS events (database lock) and the announcement of topline data. By correcting the administrative error prior to database lock, the intended statistical powering of the study has been unaffected. The Company plans to announce when 255 PFS events have occurred and the topline data analysis for the trial has been initiated.”

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 oncology indications outside of North America, and at progressing its pipeline of novel therapeutic candidates in cancer and other areas of unmet medical need. Tivozanib (FOTIVDA[®]) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma in the European Union plus Norway and Iceland. 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, statements about: the Company’s plans and prospects for advancing its lead development programs, including its expectations regarding the timing for top line results from the Phase 3 TIVO-3 study of tivozanib in aRCC; advancement of AVEO’s pipeline; and AVEO’s strategy, prospects, plans and objectives, including as they pertain specifically to tivozanib and leveraging partnerships. 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 to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its collaborators, licensees and other strategic partners, to achieve development and commercialization objectives under these arrangements; and 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 tivozanib. AVEO faces other risks relating to its business as well, including risks relating to its and its collaborators’ 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 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” 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 may make with the SEC in the future. 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.

AVEO:

Argot Partners

David Pitts, 212-600-1902

aveo@argotpartners.com