



## **AVEO Oncology Announces Phase 1/2 TiNivo Trial of Tivozanib and Opdivo® (nivolumab) in RCC Advances to Phase 2**

**CAMBRIDGE, Mass. – June 8, 2017** – AVEO Oncology (NASDAQ:AVEO) today announced that its Phase 1/2 AVEO-sponsored TiNivo trial evaluating tivozanib in combination with Bristol-Myers Squibb’s anti-PD-1 therapy, Opdivo® (nivolumab), in subjects with advanced renal cell carcinoma (RCC) has progressed to the Phase 2 portion of the trial.

Advancement of the study into the Phase 2 expansion follows the successful completion of the Phase 1 dose escalation portion of the trial, where tivozanib was administered in two escalating dose cohorts in combination with nivolumab at a constant 240 mg every 2 weeks (n=6). The combination was well tolerated to the full dose and schedule of single agent tivozanib, with no dose limiting toxicities. The full dose tivozanib regimen of 1.5 mg daily for 21 days, followed by a 7 day rest period, is the recommended Phase 2 dose (RP2D) for the expansion portion of the trial, which is expected to enroll up to an additional 20 subjects. The TiNivo study is being led by the Institut Gustave Roussy in Paris under the direction of Bernard Escudier, MD, Chairman of the Genitourinary Oncology Committee. Phase 1 results from the ongoing study will be submitted for presentation at an upcoming scientific meeting.

“The promise of delivering synergistic activity by combining VEGF TKIs and PD-1s in renal cell carcinoma hinges on the tolerability of the combination,” said Dr. Escudier. “Tivozanib has a uniquely favorable tolerability profile as demonstrated in past single agent and combination studies. These initial results are very promising in that we see both evidence of a uniquely tolerable combination as well as early and meaningful activity. I look forward to enrolling the expansion cohort and to establishing a broader understanding for the potential of this compelling combination.”

“Together with the longest progression free survival from a Phase 3 first line RCC study, tivozanib’s tolerability is distinct from other VEGF TKIs, which we believe better position it for use in combination with immunotherapy and other agents,” said Michael Bailey, president and chief executive officer of AVEO. “As our registration strategy for single agent tivozanib reaches key inflection points, with a European regulatory decision expected in the near-term and readout of our US registration-directed TIVO-3 study expected in the first quarter of 2018, our attention is increasing on tivozanib immuno-oncology combinations that have the potential to deliver significantly improved outcomes and tolerability to patients. The TiNivo trial is an important first step in this effort, and we share Dr. Escudier’s enthusiasm for the completion of this trial.”

### **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 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 cachexia (wasting syndrome). For more information, please visit the company's website at [www.aveooncology.com](http://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, statement about: the potential safety, tolerability and clinical benefits of combining VEGF TKIs and PD-1s in general, and tivozanib and nivolumab specifically; plans relating to the expansion portion of the TiNivo trial; the expected timing of top-line data readouts in TIVO-3; AVEO's expectations regarding the timing for a registration decision in the EU for tivozanib; 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, including without limitation risks relating to the ability of AVEO's licensee to successfully obtain approval of its MMA for tivozanib in the EU. AVEO faces other risks relating to its business as well, including its 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; 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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