



## **AVEO Oncology Announces NDA Timing Update**

**CAMBRIDGE, Mass. – January 31, 2019** – AVEO Oncology (NASDAQ: AVEO) today announced that it has accepted the recommendation of the U.S. Food and Drug Administration (FDA) not to submit a New Drug Application (NDA) for tivozanib (FOTIVDA®) with the preliminary overall survival (OS) results from the Phase 3 TIVO-3 trial. The FDA indicated that these preliminary OS results do not allay their concerns about the potential detriment in OS outlined in the complete response letter dated June 6, 2013. The Company now plans to make a NDA filing decision following the availability of more mature OS results.

As disclosed in November 2018, a preliminary analysis of the secondary endpoint of OS in the TIVO-3 trial showed a hazard ratio (HR) > 1. The Company previously planned to conduct the final OS analysis in August 2019. Due to the longer-than-expected median OS in both arms, and following discussions with the FDA, the Company plans to designate the August 2019 OS analysis as interim. Results of this analysis are expected to be reported in the fourth quarter.

Since initially conducting the preliminary analysis of the OS endpoint in November 2018, the Company has identified the survival status of a group of patients that were previously lost to follow up. With the identification of these OS events, the October 4, 2018 preliminary OS HR was revised from 1.06 to 1.12. The Company has not performed any OS analyses beyond the preliminary October 4, 2018 data cut-off date.

AVEO intends to present detailed results of the TIVO-3 study, the Company's Phase 3 randomized, controlled, multi-center, open-label study comparing tivozanib to sorafenib in 350 subjects with highly refractory advanced or metastatic Renal Cell Carcinoma (RCC) during an oral session at the 2019 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) being held February 14-16, 2019 in San Francisco.

“We are hopeful that the positive PFS outcome will translate into an improved hazard ratio when we evaluate a more mature interim OS outcome in the fourth quarter of 2019,” said Michael Bailey, president and chief executive officer of AVEO. “We look forward to continuing to work with the FDA to determine tivozanib's benefit-risk profile as a single agent in RCC patients.”

### **About Tivozanib (FOTIVDA®)**

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) discovered by Kyowa Hakko Kirin and approved for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway 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.<sup>1,2</sup> Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models<sup>3</sup>, and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC.

Tivozanib has been investigated in several tumors types, including renal cell, hepatocellular, colorectal and breast cancers.

### **About AVEO**

AVEO Pharmaceuticals, Inc. (the “Company” or “AVEO”) is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted medicines for oncology and other areas of unmet medical need. The Company’s strategy is to retain North American rights to its oncology portfolio while securing partners in development and commercialization outside of North America. The Company is seeking to develop and commercialize its lead candidate tivozanib in North America as a treatment for advanced or metastatic renal cell carcinoma (“RCC”). The Company has outlicensed tivozanib (FOTIVDA®) for oncological indications in Europe and other territories outside of North America. Tivozanib is approved in the European Union, as well as Norway and Iceland, for the first-line treatment of adult patients with RCC and for adult patients who are vascular endothelial growth factor receptor and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for RCC. The Company has entered into partnerships for the development and commercialization of AV-203 (CAN017) and ficlatuzumab, both clinical stage assets in oncology. The Company is currently seeking a partner to develop the AV-353 platform, a preclinical asset, worldwide for the potential treatment of pulmonary arterial hypertension and oncology. In addition, a new formulation of tivozanib is being explored in ocular conditions. The Company has recently regained the rights to its AV-380 program for the potential treatment of cachexia and is considering a variety of options to advance the program’s development.

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, statements about: AVEO’s plans to make a NDA filing decision following the availability of more mature OS results; AVEO’s plans to complete an interim OS analysis for the TIVO-3 trial in August 2019 and to report the results of this analysis in the fourth quarter; AVEO’s plans to present TIVO-3 data at ASCO GU; AVEO’s expectation that the OS outcome will be more mature by August 2019; AVEO’s hope that the positive PFS outcome will translate into an improved hazard ratio; AVEO’s intent to continue to work with the FDA to determine tivozanib’s risk-benefit profile as a single agent in RCC; the efficacy, safety, and tolerability of tivozanib, as a single agent and in combination with other therapies in several indications, such as RCC and HCC; AVEO’s plans and strategies for commercialization of tivozanib in the United States and Europe; AVEO’s plan to seek a partner to develop the AV-353 platform; AVEO’s plans regarding AV-380 and AVEO’s other 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: 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 as it relates to the TIVO-3 trial and tivozanib; AVEO's ability to successfully file an NDA for tivozanib on the timeline it anticipates, or at all; 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; 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

- <sup>1</sup>. Fotivda (Tivozanib) SmPC August 2017
- <sup>2</sup>. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9.
- <sup>3</sup>. Pawlowski N et al. AACR 2013. Poster 3971.

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