AVEO Oncology to Present TIVO-3 Data at the 2019 ASCO Genitourinary Cancers Symposium

CAMBRIDGE, Mass. – January 2, 2018 – AVEO Oncology (NASDAQ: AVEO) today announced that data from the Phase 3 TIVO-3 study of tivozanib (FOTIVDA®) versus sorafenib in refractory advanced or metastatic renal cell carcinoma (RCC) will be presented during an oral session at the 2019 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium being held February 14-16, 2019 in San Francisco.

Presentation Details

Title: TIVO-3: A phase III, randomized, controlled, multicenter, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced renal cell carcinoma (RCC)
Presenter: Brian Rini, MD, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University
Abstract Number: 541
Session Title: General Session 8: Evolving Management of Metastatic Renal Cell Carcinoma
Data and Time: February 16, 2019, 10:00 a.m.-11:30 a.m. PT

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.[1,2] 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. 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.

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 present data from the TIVO-3 study in the first half of 2019, including updated overall survival data; AVEO's plans and timing estimates regarding the potential submission of a New Drug Application to the FDA for tivozanib in the first half of 2019; AVEO's plans and strategies for commercialization of tivozanib in the United States and Europe; the potential for tivozanib in RCC and other indications, such as ocular conditions, and as either a monotherapy or combination therapy; AVEO's plan to seek a partner to develop the AV-353 platform; AVEO's plans regarding AV-380; AVEO's cash runway; and AVEO's strategy, prospects, plans and objectives, including its plans to advance its portfolio of targeted medicines. 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 the timing and costs of any product candidate seeking and obtaining regulatory approval; AVEO's ability to file an NDA for tivozanib in the timeframe it currently estimates or at all; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to achieve and 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 and technologies; 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 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, 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

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

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