



## **AVEO Oncology Announces Immuno-Oncology Clinical Collaboration with AstraZeneca**

December 12, 2018

*Phase 1/2 Study will Evaluate Combination of IMFINZI® (durvalumab) and FOTIVDA® (tivozanib) in First-Line HCC*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 12, 2018-- AVEO Oncology (NASDAQ: AVEO) today announced that it has entered into a clinical collaboration with AstraZeneca to evaluate the safety and efficacy of AstraZeneca's IMFINZI® (durvalumab), a human monoclonal antibody directed against programmed death-ligand 1 (PD-L1), in combination with FOTIVDA® (tivozanib), AVEO's oral, once-daily, potent and highly-selective vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR-TKI) in first-line hepatocellular carcinoma (HCC), or liver cancer, in a Phase 1/2 study.

AVEO will serve as the study sponsor, with study costs shared equally by both parties and clinical drug supplied by each respective company. The Phase 1 portion of the study is expected to commence in 2019.

"We are thrilled to collaborate with AstraZeneca to explore another tivozanib-immunotherapy combination and look forward to understanding the potential of combining tivozanib with durvalumab in liver cancer," said Michael Bailey, president and chief executive officer of AVEO. "TKI-immunotherapy combinations have demonstrated important clinical potential across multiple tumor types, though toxicities associated with these combinations have limited their potential use. Our goal is to establish tivozanib as the TKI of choice for use with immunotherapies by demonstrating efficacy with reduced toxicity."

### **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 Durvalumab (IMFINZI®)**

Durvalumab (IMFINZI®) is a human monoclonal antibody that binds to PD-L1 and blocks the interaction of PD-L1 with PD-1 and CD80, countering the tumor's immune-evading tactics and releasing the inhibition of immune responses. As part of a broad development program, durvalumab is being investigated as monotherapy and in combination with immuno-oncology (IO) agents, small molecules, and chemotherapies across a range of tumors and stages of disease.

### **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: the potential efficacy, safety, and tolerability of tivozanib, as a single agent and in combination with durvalumab in liver cancer and other indications; timing for commencement of the Phase 1 portion of the study; the potential for tivozanib to address the limits of other TKI-immunotherapy combinations; the potential for tivozanib to be established as the TKI of choice for use with immunotherapies; AVEO's plans and strategies for commercialization of tivozanib in the United States and Europe; the potential for tivozanib in RCC,

HCC and other indications; 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 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 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; 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 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 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 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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