



AVEO Oncology Announces \$2M Milestone Payment from EUSA Pharma Related to German Commercialization of FOTIVDA®

CAMBRIDGE, Mass. – November 15, 2018 – AVEO Oncology (NASDAQ: AVEO) today announced the triggering of a \$2 million milestone payment to AVEO from EUSA Pharma. The milestone payment relates to the commercial launch and reimbursement in Germany of FOTIVDA® (tivozanib) as a first line treatment of adult patients with advanced renal cell carcinoma (RCC). In the European Union, Norway and Iceland, tivozanib is indicated for the first line treatment of adult patients with RCC and for adult patients who are vascular endothelial growth factor receptor (VEGFR) and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for RCC. Tivozanib is an oral, once-daily, potent and highly-selective vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR-TKI).

EUSA Pharma is the licensee for tivozanib in Europe, North and South Africa, Latin America and Australasia. The milestone payment is subject to a 30% sublicense fee due to AVEO's partner Kyowa Hakko Kirin and is incremental to the previously-disclosed cash, cash equivalents and marketable securities at September 30, 2018, which AVEO reported would fund operations into the second quarter of 2019.

“Germany is among a growing list of countries in the European Union that recognize the benefit of expanding patient access to FOTIVDA®,” said Michael Bailey, president and chief executive officer. “As our partner EUSA continues to advance FOTIVDA® in the approved European commercial market, we continue to work toward retrieving overall survival data not yet collected at the preliminary OS analysis of our pivotal TIVO-3 study, and toward the potential submission of a New Drug Application with the FDA for tivozanib as a treatment for advanced or metastatic RCC, a milestone we expect to reach in the first half of 2019.”

Under the terms of their December 2015 agreement, EUSA Pharma has agreed to pay AVEO up to \$384 million in future research and development funding and milestone payments, assuming successful achievement of specified development, regulatory and commercialization objectives, as well as a tiered royalty ranging from a low double-digit up to mid-twenty percent on net sales of tivozanib in the agreement's territories. Thirty percent of milestone and royalty payments received by AVEO, excluding research and development funding, are due to Kyowa Hakko Kirin (KHK) as a sublicensing fee in Europe. In the United States, the royalty obligation to KHK ranges from the low- to mid-teens on net sales.

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, enabling potentially enhanced activity when used in combination with immune modulating therapy.³ 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 and prospects for advancing its lead development programs, including its -plans to retrieve overall survival data for the TIVO-3 study; its plans and estimates regarding the potential submission of a New Drug Application to the FDA for tivozanib in the first half of 2019; the potential efficacy, safety, and tolerability profile of tivozanib; potential payments under AVEO’s license agreement with EUSA Pharma; AVEO’s plans and strategies for commercialization of tivozanib in the United States and Europe; the potential for tivozanib in other indications, 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. 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 that receives regulatory approval; its ability to file an NDA for tivozanib in the timeframe it currently estimates; 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; 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. 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. 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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