



AVEO Oncology Announces \$2M Milestone Payment From EUSA Pharma Related To Commercialization of FOTIVDA[®] in Spain

CAMBRIDGE, Mass. – April 23, 2019 – 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 reimbursement approval and commercial launch in Spain of FOTIVDA[®] (tivozanib) as a first line treatment of adult patients with advanced renal cell carcinoma (RCC). Commercial launch in Spain is the third of five EU5 country launches to trigger a \$2 million payment under the terms of AVEO’s license agreement with EUSA Pharma. 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.

“We are pleased to see Spain recognize the benefit of patient access to FOTIVDA[®] and continued expansion of the FOTIVDA[®] commercial footprint in Europe,” said Michael Bailey, president and chief executive officer of AVEO. “We continue to work toward reporting more mature interim overall survival results from our TIVO-3 study in the fourth quarter of 2019, and remain confident in the significant commercial potential for a VEGF therapy that has demonstrated activity and tolerability in all lines of RCC therapy, including highly refractory patients with prior exposure to PD-1 therapy.”

EUSA Pharma is the licensee for tivozanib in Europe, North and South Africa, Latin America and Australasia. Under the terms of their December 2015 agreement, EUSA Pharma has agreed to pay AVEO up to \$382 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 would range from the low- to mid-teens on net sales upon approval and commercialization.

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 models³ and has

demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal and breast cancers. In addition, a new formulation of tivozanib is in pre-clinical development for the treatment of age-related macular degeneration.

About AVEO

AVEO Pharmaceuticals, Inc. (the “Company” or “AVEO”) is a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. The Company is working to develop and commercialize its lead candidate tivozanib in North America as a treatment for RCC. The Company has sublicensed 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 also has clinical collaborations to study tivozanib in combination with immune checkpoint inhibitors in RCC and in hepatocellular carcinoma. In addition, a new formulation of tivozanib is in pre-clinical development for the treatment of age-related macular degeneration. As part of the Company’s strategy, the Company has also entered into partnerships to help fund the development and commercialization of its other product candidates. Ficlatazumab, a hepatocyte growth factor inhibitory antibody, is currently being tested in several investigator sponsored studies jointly funded by the Company and one of its development partners for the potential treatment of squamous cell carcinoma of the head and neck, AML, and pancreatic cancer. The Company’s partner for AV-203, an anti-ErbB3 monoclonal antibody, is planning to initiate clinical studies in China in 2019 in esophageal squamous cell carcinoma and has committed to funding the development of AV-203 through proof-of-concept. The Company has recently regained the rights to AV-380, a humanized IgG1 inhibitory monoclonal antibody targeting growth differentiation factor 15, a divergent member of the TGF- β family, for the potential treatment of cancer cachexia, and is working to initiate preclinical toxicology studies mid-2019 to support the potential filing of an investigational new drug application with the FDA. The Company is evaluating options for the development of its preclinical AV-353 platform which targets the Notch 3 pathway.

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: the potential commercial opportunity for tivozanib; 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 expectation that the OS outcome will be more mature by August 2019; the potential efficacy,

safety, and tolerability of tivozanib, as a single agent and in combination with other therapies in several indications, such as RCC and hepatocellular carcinoma; plans and strategies for commercialization of tivozanib in the United States and Europe; 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 and European regulators the safety, efficacy and clinically meaningful benefit of AVEO's product candidates, including, in particular, tivozanib; AVEO's ability to successfully file an NDA and obtain FDA approval for tivozanib in the United States; 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, including, in particular, EUSA Pharma, 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

- 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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