



AVEO Announces EUSA Pharma Granted Positive NICE Recommendation for FOTIVDA® (tivozanib) as First Line Treatment for Advanced Renal Cell Carcinoma

-Recommendation Triggers \$2M Milestone Payment from EUSA to AVEO-

CAMBRIDGE, Mass.– February [12], 2018 – AVEO Oncology (NASDAQ: AVEO) today announced that the United Kingdom’s National Institute for Health and Care Excellence (NICE) has published a Final Appraisal Determination (FAD) recommending FOTIVDA® (tivozanib) for the first line treatment of adult patients with advanced renal cell carcinoma (aRCC). In the European Union, Norway and Iceland, tivozanib is indicated for the first line treatment of adult patients with aRCC 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 aRCC.¹ 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 positive recommendation triggers a \$2M milestone payment to AVEO from EUSA Pharma.

“The recommendation from NICE marks the first European Union reimbursement approval for FOTIVDA, helping ensure broadening patient access to FOTIVDA in key European markets following its launch in Germany in the fall of 2017,” said Michael Bailey, president and chief executive officer of AVEO. “This recommendation underscores the strength and commercial-stage value of our partnership with EUSA Pharma, and triggers a \$2 million milestone payment to AVEO. We continue to execute on our strategic plans, and we have had a very productive 2018 thus far, with the recent presentation of positive preliminary data from our tivozanib and nivolumab combination TiNivo study in RCC and an investigator sponsored study of tivozanib in liver cancer. We look forward to several potential additional key milestones in 2018, including further EU reimbursement decisions as well as topline data in the second quarter from our Phase 3 TIVO-3 study.”

Under the terms of their December 2015 agreement, EUSA Pharma has agreed to pay AVEO up to \$386 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. As part of a North American registration plan, tivozanib is currently being studied in the Phase 3 TIVO-3 trial, a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced RCC. Tivozanib has been investigated in several tumors types, including renal cell, hepatocellular, colorectal and breast cancers.

About AVEO

AVEO Oncology (AVEO) is a biopharmaceutical company dedicated to advancing a broad portfolio of targeted therapeutics for oncology and other areas of unmet medical need. The Company is focused on seeking to develop and commercialize its lead candidate tivozanib, a potent, selective, long half-life inhibitor of vascular endothelial growth factor 1, 2 and 3 receptors, in North America as a treatment for renal cell carcinoma and other cancers. AVEO is leveraging multiple partnerships aimed at developing and commercializing tivozanib in oncology indications outside of North America, and at progressing its pipeline of novel therapeutic candidates in cancer and cachexia (wasting syndrome). Tivozanib (FOTIVDA[®]) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway and Iceland. 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 expected timeline for further EU reimbursement decisions as well as reporting data from TIVO-3 ; potential payments under AVEO's license agreement with EUSA; and AVEO's strategy, prospects, plans and objectives, including as they pertain specifically to tivozanib. 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; AVEO's ability, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies 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 its 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; developments, expenses and outcomes related to AVEO's ongoing shareholder litigation; 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 section titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" included in AVEO's Annual Report on Form 10-K for the year ended December 31, 2016, its quarterly reports on Form 10-Q 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.

References

¹. Fotivda (Tivozanib) SmPC August 2017

². Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9.

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