AVEO Oncology Announces Positive CHMP Opinion for Tivozanib as a Treatment of Advanced Renal Cell Carcinoma

CAMBRIDGE, Mass. – June 23, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has recommended FOTIVDA™ (tivozanib) for approval as a treatment for patients with advanced renal cell carcinoma (RCC). The CHMP's recommendation is now referred to the European Commission (EC). The EC, which typically adheres to the recommendation of the CHMP, but is not obligated to do so, is expected to make its final decision in about 67 days. If approved by the EC, marketing authorization for tivozanib will be granted in all 28 countries of the European Union, Norway, Iceland and Liechtenstein. EUSA Pharma, a specialty pharmaceutical company with a focus on oncology and oncology supportive care, is the European licensee for tivozanib.

"A positive opinion from the CHMP is a critical step in our goal of obtaining regulatory approval of tivozanib as a treatment for RCC," said Michael Bailey, president and chief executive officer of AVEO. "Tivozanib's unique tolerability profile together with the longest progression free survival reported in a Phase 3 first line RCC study, have the potential to fill an unmet patient need for better tolerated treatment in this disease. Further, we believe this tolerability profile could enable immune-oncology combinations such as those in the Phase 1/2 TiNivo study, which combines the PD-1 inhibitor Opdivo® (nivolumab) with tivozanib and recently advanced to Phase 2."

Mr. Bailey concluded: "If the European Commission grants marketing approval for tivozanib, it would trigger a $4 million research and development reimbursement payment from EUSA, and AVEO will also be eligible for up to $12 million in additional milestones from EUSA based on member state reimbursement and regulatory approvals. These payments would add significant resources to our balance sheet as we work toward the anticipated readout of our U.S. pivotal trial in third-line RCC, the TIVO-3 trial, in the first quarter of 2018."

Under the terms of their December 2015 agreement, EUSA Pharma has agreed to pay AVEO up to $394 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.

RCC is the most common form of kidney cancer,[i] which accounts for an estimated 49,000 deaths in Europe each year.[ii] It is expected to be one of the fastest increasing cancers over the next ten years.[iii] Tyrosine Kinase Inhibitor (TKI) vascular endothelial growth factor (VEGF) inhibitors are the standard of care treatment for advanced RCC in Europe, however, patients on current

treatments can often experience significant side effects.[iv,v] If approved for use in the European Union, tivozanib would be indicated for use in adult patients with advanced RCC who are VEGFR and mTOR pathway inhibitor-naïve and are either untreated or who have failed prior therapy with interferon-alpha (IFN-α) or interleukin-2 (IL-2).

About Tivozanib

Tivozanib is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI). 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. Tivozanib has been investigated in several tumors types, including renal cell, 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. 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, cachexia (wasting syndrome) and Pulmonary Arterial Hypertension (PAH). 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," "will," "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 for tivozanib to be approved by the EC as a treatment for RCC; the potential benefits of tivozanib both as a stand-alone agent and in combination with other therapies; AVEO's expectations regarding the receipt of payments under its agreement with EUSA and the potential for such payments, if received, to favorably impact its financial condition; AVEO's and its collaborators' future discovery, development and commercialization plans and efforts, including without limitation with respect to tivozanib, ficlatuzumab and AVEO's other programs and platforms; 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 agreements, and its ability, and the ability of its

licensees and other 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 without limitation risks relating to the ability of EUSA to successfully obtain approval of tivozanib from the EC. 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.

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[iii] Cancer Research UK. Kidney cancer rates are increasing, so what's fuelling the surge? Available at: http://scienceblog.cancerresearchuk.org/2017/04/24/kidney-cancer-rates-are-increasing-so-whats-fuelling-the-surge/. Last accessed May 2017.
[iv] Motzer R.J; Nosov D et al. Tivozanib Versus Sorafenib As Initial Targeted Therapy for Patients With Metastatic Renal Cell Carcinoma: Results From a Phase III Trial. Journal of Clinical Oncology. Volume 31. 2013: 30:3791
[v] Wong MKK, Mohamed AF et al. Selecting renal cell carcinoma therapy: Ranking of patient perspective on toxicities. J Clin Oncol 30: 303s, 2012 (suppl; abstr 4608)