



AVEO Oncology Announces Completion of a CHMP Oral Explanation for Tivozanib as a Treatment of First-Line Renal Cell Carcinoma

CAMBRIDGE, Mass. – May 19, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced its European licensee for tivozanib, EUSA Pharma, has completed an oral explanation to the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), as part of the Marketing Authorization Application (MAA) review process for tivozanib as a treatment for patients with first-line renal cell carcinoma (RCC). It is expected that with the oral explanation complete, the CHMP will proceed to an opinion which they will submit to the European Commission (EC), which has the authority to approve medicines for use in the 28 countries in the European Union. The opinion is expected to be announced at a future CHMP meeting.

“We are pleased that the file continues to progress through the CHMP review process with EUSA having completed an oral explanation for tivozanib,” said Michael Bailey, president and chief executive officer of AVEO. “We believe tivozanib’s unique tolerability profile, together with the longest progression free survival from a Phase 3 first line RCC study, demonstrates its potential to enhance treatment options for RCC patients.”

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 gold standard treatment for advanced RCC in Europe, however, patients on current treatments can often experience significant side effects.^{iv,v}

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 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). 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 Company's expectation that the CHMP will proceed to an opinion in connection with its review process for tivozanib as a treatment for RCC, that they will announce such opinion at a future CHMP meeting and will submit such opinion to the EC; AVEO's beliefs about the potential therapeutic benefits of tivozanib as a treatment, including for RCC; AVEO's strategy, prospects, plans and objectives, including those that relate to advancing therapeutics, including tivozanib, and for leveraging collaborations. 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: whether the tivozanib file will continue to progress through the CHMP on the time frame and manner currently expected; AVEO's ability to enter into and maintain its third party collaboration agreements; the ability of AVEO and its licensees and other partners to achieve development and commercialization objectives under these arrangements, including, in the case of EUSA's, its plans to advance the development and commercialization of tivozanib in the European Union; 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 its MMA for tivozanib in the European Union. AVEO faces other risks relating to its business as well, including 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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ⁱCancer Research UK. Kidney Cancer, Types and Grades. Available at: <http://www.cancerresearchuk.org/about-cancer/kidney-cancer/stages-types-grades/types-grades>. Last accessed May 2017.

ⁱⁱCancer Research UK. Kidney Cancer Statistics. Available at: <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/kidney-cancer/mortality#heading-Five>. Last accessed May 2017.

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)