AVEO Announces Submission of Response to Tivozanib Marketing Authorization Application Day 180 List of Outstanding Issues

CAMBRIDGE, Mass. – April 13, 2017 – AVEO Oncology (NASDAQ: AVEO) today announced that its European licensee for tivozanib, EUSA Pharma, has submitted responses to the European Medicines Agency (EMA) Day 180 List of Outstanding Issues (LOI) related to the Marketing Authorization Application (MAA) for tivozanib as a first-line treatment for renal cell carcinoma. With submission of the response complete, EUSA remains tentatively scheduled to provide an oral explanation to the EMA's Committee for Medicinal Products for Human Use (CHMP) at its May 2017 meeting.

"Responding to the Day 180 List of Outstanding Issues is another important step in the tivozanib MAA, and we continue to work with EUSA Pharma in their effort to seek regulatory approval for tivozanib in Europe," said Michael Bailey, president and chief executive officer of AVEO. "This includes supporting EUSA as they proceed toward a planned oral explanation to the CHMP in May, while at the same time we continue to advance our registration strategy for tivozanib in the United States. We look forward to providing updates on these dual paths as we complete the final phase of the European approval process and work toward our goal of full enrollment in our U.S. registration-directed TIVO-3 study."

As previously announced, the Day 180 LOI signified that the MAA is not approvable at that time, and outlines outstanding deficiencies, which are then required to be satisfactorily addressed in an oral explanation and/or in writing prior to a final application decision.

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 non-oncologic indications worldwide and oncology indications outside of North America, as well as to progress 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: EUSA's planned meeting with CHMP in May 2017; AVEO's plan to provide updates on both the European and U.S. approval process; AVEO's plan to work toward full enrollment in its U.S. registration-directed TIVO-3 study; plans and strategies of AVEO and its partners and the potential for continued progress and achievement by AVEO and its partners of clinical, regulatory, and commercial, goals for AVEO's other product candidates; and the potential safety, efficacy, tolerability and other benefits of tivozanib in the treatment of renal cell carcinoma. AVEO has based its forward-looking statements on assumptions that may prove to be incorrect. As a result, readers are cautioned not to place undue reliance on these forward-looking statements. 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, including EUSA, 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 the EMA and the FDA; AVEO's ability to successfully enroll and complete clinical trials, including the TIVO-3 trial; 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 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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