



AVEO Announces Submission of Responses to the EMA Day 120 List of Questions for Marketing Authorization Application for Tivozanib in Renal Cell Carcinoma

CAMBRIDGE, Mass. – November 28, 2016 – AVEO Oncology (NASDAQ: AVEO) today announced that its development partner, EUSA Pharma, a specialty pharmaceutical company with a focus on oncology and oncology supportive care, has submitted its responses to the European Medicines Agency (EMA) Day 120 List of Questions. The Day 120 List of Questions were issued by the Committee for Medicinal Products for Human Use (CHMP) as part of the centralized review process of the Marketing Authorization Application (MAA) for tivozanib for the first-line treatment of advanced renal cell carcinoma (RCC). The next step in the filing process, the EMA Day 180 List of Outstanding Issues, is expected in the first quarter of 2017.

“This submission represents an important step forward in working toward an anticipated first half 2017 European approval decision, one of three potential key tivozanib-related milestones during this period,” said Michael Bailey, president and chief executive officer of AVEO. “Given tivozanib’s unique activity and safety profile, we believe the first line RCC market in Europe represents a meaningful commercial opportunity, and we look forward to working with EUSA Pharma to fully elucidate this potential. In addition to a potential European approval decision, we expect to have initial results from the Opdivo[®] combination TiNivo study in RCC and may see milestones from Ophthotech for tivozanib in acute macular degeneration in the first half of 2017.”

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 developing and commercializing 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 to develop and commercialize 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.

AVEO 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,” “seek,” 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: plans and strategies of AVEO and its partners and the potential achievement by AVEO and its partners of clinical, regulatory, manufacturing and other

development goals and milestones; AVEO's expectations regarding a registration decision in the EU for tivozanib, including timing thereof; the timing of enrollment and data readouts from the TiNivo trial; the commercial opportunity for tivozanib in the first line RCC market in Europe; the potential safety, efficacy, tolerability and other benefits of tivozanib in the treatment of renal cell carcinoma as a single agent or in combination with other therapies; and the potential for Ophthotech to achieve and pay milestones in the first half of 2017. 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; AVEO's 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; unplanned capital requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled "Risk Factors" in AVEO's most recent Annual Report on Form 10-K, its quarterly reports on Form 10-Q and its other filings with the SEC. 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.

AVEO Contact:
David Pitts, Argot Partners
(212) 600-1902
aveo@argotpartners.com