



AVEO Oncology and EUSA Pharma Announce TiNivo Combination Study Opt-in

Exercise of Option Triggers \$2.0 Million Research and Development Payment to AVEO

CAMBRIDGE, Mass., USA and HEMEL HEMPSTEAD, England – September 20, 2017 – AVEO Oncology (NASDAQ: AVEO) and EUSA Pharma today announced that EUSA Pharma, under its multi-territory licensing agreement with AVEO for FOTIVDA[®] (tivozanib), has opted into the Phase 1/2 TiNivo study. Under terms of the agreement, EUSA may utilize data from the study for regulatory or commercial purposes in exchange for a research and development funding payment totaling \$2.0 million. EUSA's decision follows approval in August of tivozanib by the European Commission for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway and Iceland.

The TiNivo trial is a Phase 1/2 trial of tivozanib in combination with Bristol-Myers Squibb's OPDIVO[®] (nivolumab), an immune checkpoint, or PD-1, inhibitor, for the treatment of RCC. The TiNivo trial is being led by the Institut Gustave Roussy in Paris under the direction of Bernard Escudier, MD, Chairman of the Genitourinary Oncology Committee. In June, AVEO announced the advancement of the trial into the Phase 2 expansion portion following successful completion of the Phase 1 dose escalation portion. The combination was well tolerated to the full dose and schedule of single agent tivozanib, with no dose limiting toxicities. The expansion portion of the trial is expected to enroll an additional 20 subjects. Phase 1 results from the ongoing study have been submitted for presentation at a scientific meeting taking place in the fourth quarter.

*"We look forward to working with EUSA in helping shape the future direction of FOTIVDA[®] in an evolving treatment landscape for advanced RCC," said **Michael Bailey**, president and chief executive officer of AVEO. "Immunotherapy is defining an important role as an early treatment option for this disease, creating an opportunity to investigate the role of TKIs following immunotherapy or in combination with immunotherapy. Having already demonstrated superior PFS and an improved side effect profile compared to sorafenib in the pivotal TIVO-1 study, FOTIVDA[®] is currently being evaluated in an ongoing third line pivotal trial stratifying for prior immunotherapy, and is well positioned to play a role in this evolving treatment landscape."*

***Lee Morley**, EUSA Pharma's Chief Executive Officer said, "Following the recent European approval of FOTIVDA[®] for the first-line treatment of patients with advanced RCC, emerging data from the TiNivo study indicates the potential for FOTIVDA[®] in this setting. With our partner AVEO and the RCC community, we are committed to the ongoing development of FOTIVDA[®] and look forward to investigating new and innovative treatment options for patients with advanced RCC."*

Under the terms of their December 2015 agreement, EUSA Pharma has agreed to pay AVEO up to \$388 million in future milestone payments and research and development funding, assuming successful achievement of specified development, regulatory and commercialization objectives. In addition, a tiered royalty will be due to AVEO ranging from a low double-digit up to mid-twenty percent on net sales of tivozanib in the agreement's territories. With European approval, AVEO will be eligible for up to \$12 million in milestones from EUSA based on reimbursement and regulatory approvals. In the territories licensed to EUSA, thirty percent of milestone and royalty payments received by AVEO, excluding research and development payments such as the one announced today, are due to Kyowa Hakko Kirin (KHK) as a sublicensing fee. In the territories retained by AVEO, the royalty obligation to KHK ranges from the low- to mid-teens on net sales.

About Tivozanib (FOTIVDA®)

An over-expression of VEGF protein, and a resulting increase in tumour blood supply (angiogenesis), is a common feature of RCC.¹ VEGFR-TKIs reduce the supply of blood to the tumour and are the recommended first-line treatment for advanced RCC in Europe, however, patients often experience significant side effects, including fatigue, diarrhoea, and hand-foot syndrome.

In the global Phase III trial (TIVO-1)¹ of over 500 patients with advanced RCC, tivozanib demonstrated a significant PFS benefit versus sorafenib (11.9 vs. 9.1 months in the overall patient population [HR, 0.797; 95% CI, 0.639 to 0.993; P =.042], and 12.7 vs. 9.1 months in treatment-naïve patients [HR, 0.756; 95% CI, 0.580 to 0.985; P =.037]).¹ There was also an improved side-effect profile versus sorafenib, with significantly fewer patients on tivozanib (14% versus 43%) requiring a dose reduction due to AEs; and less than 5% of patients experiencing severe side effects (grade 3&4, such as diarrhoea, asthenia (physical weakness) and hand-foot syndrome. Hypertension (44%) and dysphonia (21%) were the most commonly reported AEs on tivozanib.¹

Under EUSA Pharma's license agreement with AVEO, announced in December 2015, the company holds exclusive commercialization rights to tivozanib in RCC in Europe and in a number of other territories outside North America, including South America and South Africa. Under the terms of the agreement, EUSA Pharma will undertake and fund the commercialization of the product in its territories, assuming licensing. AVEO retains the rights to commercialize the product in North America. Tivozanib was discovered by Kyowa Hakko Kirin.

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), with the ultimate goal of creating high-value medicines for the patients we serve. For more information, please visit the company's website at www.aveooncology.com.

About EUSA Pharma

Founded in March 2015, EUSA Pharma is a specialty pharmaceutical company with a focus on oncology and oncology supportive care. The company has commercial operations in the US and Europe, and a wider distribution network in approximately 40 countries around the world. EUSA Pharma is led by an experienced management team with a strong record of building successful specialty pharmaceutical companies, and is supported by significant funding raised from leading life science investor EW Healthcare Partners.

For more information visit www.eusapharma.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: clinical, regulatory and commercial plans of AVEO and its partner EUSA Pharma to progress the development of FOTIVDA® (tivozanib); the role and expected benefits of tivozanib and other TKIs on a stand-alone basis, or in combination with or following immunotherapy; the expected enrollment of the TiNivo trial and presentation of TiNivo results; expectations about the potential for additional payments by EUSA Pharma; the value of AVEO's partnerships in advancing its pipeline; 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 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 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.

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References

¹ 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

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