



AVEO Oncology and EUSA Pharma Announce Encouraging Preliminary Results from Phase 2 Portion of the TiNivo Study in Renal Cell Carcinoma

*Data Presented at the 2018 American Society of Clinical Oncology
Genitourinary Cancers Symposium (ASCO GU)*

CAMBRIDGE, Mass., USA and HEMEL HEMPSTEAD, England – February 10, 2018 – AVEO Oncology (NASDAQ: AVEO) and EUSA Pharma today announced the presentation of preliminary results from the Phase 2 portion of the TiNivo study, a Phase 1b/2 multicenter trial of oral (PO) tivozanib (FOTIVDA[®]) in combination with intravenous (IV) nivolumab (OPDIVO[®], Bristol-Myers Squibb), an immune checkpoint, or PD-1, inhibitor, for the treatment of metastatic renal cell carcinoma (mRCC). The results were presented today at the 2018 American Society of Clinical Oncology’s Genitourinary Cancers Symposium (ASCO GU), in a poster presentation titled “Tivozanib combined with nivolumab: Phase Ib/II study in metastatic renal cell carcinoma (mRCC)” (Abstract 618). A copy of the presentation is available at www.aveooncology.com or further information can be obtained via [EUSA Pharma Medical Information](#).

The Phase 1/2 study has enrolled a total of 27 patients. The Phase 2 portion of the study (n=21) was designed to assess the safety, tolerability, and anti-tumor activity of the full dose and schedule of PO tivozanib (1.5 mg/QD for 21 days followed by a 7-day rest period), as established in the Phase 1 portion of the study (n=6), in combination with IV nivolumab (240 mg every 2 weeks). The combination was generally well tolerated. Treatment-related Grade 3/4 adverse events occurred in 44% of patients, the most common of which was hypertension.

Preliminary efficacy was assessed in 14 patients treated with the full dose and schedule of PO tivozanib in combination with IV nivolumab and enrolled at least 4 months prior to the data cutoff date. Of these, seven had received at least one prior systemic therapy. An objective response rate was observed in 64% of patients (partial responses), and a disease control rate (partial response + stable disease) was observed in 100% of patients. At the time of data collection, 11 of 14 evaluable patients remained on study.

“These preliminary data continue to support the rationale for choosing a high-specificity VEGF inhibitor TKI, such as tivozanib, in building upon the benefit of immune checkpoint therapy in renal cancer,” said Doctor Bernard Escudier, MD, ex-Chairman of the Genitourinary Oncology Committee, Gustave Roussy, and lead investigator of the study. “Combining VEGF TKIs and immune checkpoint inhibitors has been hampered by toxicity, potentially emerging with the use of other TKIs, while minimal off-target toxicities have been observed with tivozanib in this combination. These results open the possibility for triple-combination therapy using tivozanib, nivolumab and ipilimumab, an immune system activator targeting CTLA-4.”

“We believe that VEGF TKI-immunotherapy combinations are the obvious next step in the evolution of treatment within mRCC, which underscores the need for a VEGF therapy with best-in-class safety,” said Michael Needle, M.D., chief medical officer of AVEO. “The preliminary



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activity and favorable safety profile observed thus far in the TiNivo study are encouraging and support the further exploration of tivozanib combinations with immuno-oncology therapies. In addition to the TiNivo study, we continue to look forward to topline data in the second quarter of 2018 from our Phase 3 TIVO-3 study, which, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of mRCC, is designed to support a request for regulatory approval of tivozanib in North America as a first and third line treatment for mRCC.”

Lee Morley, EUSA Pharma’s Chief Executive Officer said, “We are excited by the continued development potential for tivozanib and the data arising from initial studies in combination with checkpoint inhibitors. As an effective TKI with a favorable tolerability profile, we are already launching tivozanib across the EU in line with its recent approval as monotherapy in the first line setting, and on the basis of the TiNivo study, we look forward to the potential to develop new innovative treatment options for patients in the future.”

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) discovered by Kyowa Hakko Kirin and approved for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway and Iceland. 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.^{1,2} Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models, enabling potentially enhanced activity when used in combination with immune modulating therapy. As part of a North American registration plan, Tivozanib is currently being studied in the Phase 3 TIVO-3 trial, a randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in subjects with refractory advanced RCC. Tivozanib has been investigated in several tumors types, including renal cell, hepatocellular, 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). Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway and Iceland. 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: the expected benefits of combining TKIs and checkpoint inhibitors; the expected timeline for reporting topline data from TIVO-3; 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 and license 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 collaborators and 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 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.

References

1. Fotivda (Tivozanib) SmPC August 2017
2. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9.

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