



AVEO Oncology Announces Publication of Phase 1b/2 Study of Tivozanib in Advanced, Inoperable Liver Cancer in the British Journal of Cancer

February 12, 2020

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb. 12, 2020-- AVEO Oncology (NASDAQ: AVEO) today announced the publication of results from a monotherapy trial of tivozanib, the Company's vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR-TKI), in patients with advanced, inoperable hepatocellular carcinoma (HCC) in the British Journal of Cancer. The article, titled "A multicentre phase 1b/2 study of tivozanib in patients with advanced inoperable hepatocellular carcinoma," is available online first via [this link](#).

For the Phase 1b/2 tivozanib study, a total of 27 patients were enrolled. The study sought to evaluate the safety, dosing, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of tivozanib in patients with advanced HCC. The recommended Phase 2 dose (RP2D) was determined to be 1.0 mg once daily for 21 days followed by 7 days off treatment on a 28-day cycle. Median progression free and overall survival were 24 weeks and 9 months, respectively, for patients treated at the RP2D, with an overall response rate of 21%. A significant decrease in soluble plasma VEGFR-2 was also observed, suggesting adequate target engagement.

"HCC represents the fastest rising cause of cancer-related death in the U.S., with five-year survival at approximately 26%," said Michael Bailey, president and chief executive officer. "This study is an important steppingstone in understanding tivozanib's safety and efficacy in HCC, and was the foundation for our ongoing Phase 1b/2 DEDUCTIVE study of tivozanib in combination with IMFINZI® (durvalumab). As we work toward our expected filing of a New Drug Application with the FDA this quarter for tivozanib in kidney cancer, we look forward to expanding our tivozanib-immunotherapy clinical strategy as part of our effort to maximize its long-term potential."

Enrollment is currently underway in a Phase 1b/2 DEDUCTIVE study of tivozanib in combination with IMFINZI® (durvalumab), AstraZeneca's human monoclonal antibody directed against programmed death-ligand 1 (PD-L1), in patients with HCC who have not received prior systemic therapy. The trial is being conducted as part of a clinical collaboration between AVEO and AstraZeneca.

"In a number of solid tumor indications, including metastatic liver cancer, VEGF-TKI/immunotherapy combinations are playing an increasingly important role in initial treatment selection," said Renuka Iyer, M.D., senior author of the publication and Professor of Oncology and Co-Director, Liver and Pancreas Tumor Center, Roswell Park Comprehensive Cancer Center. "Central to these combinations is the tolerability of the VEGF-TKI backbone. With an early efficacy signal and favorable tolerability profile demonstrated in this study, tivozanib shows great potential as a VEGF-TKI for such combinations. I look forward to seeing this potential elucidated in the ongoing DEDUCTIVE study of tivozanib and durvalumab in HCC."

About Tivozanib

Tivozanib (FOTIVDA®) is an oral, once-daily, vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) discovered by Kyowa Kirin and approved for the treatment of adult patients with advanced renal cell carcinoma (RCC) in the European Union plus Norway, New Zealand 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 is being studied in the TIVO-3 trial, which is intended to support a regulatory submission of tivozanib in the U.S. as a treatment for relapsed/refractory RCC. Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models³ and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC⁴. Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal, ovarian and breast cancers.

About AVEO

AVEO is developing and seeks to commercialize its oncology pipeline of products and product candidates in North America while leveraging partnerships to support development and commercialization in other geographies. Tivozanib (FOTIVDA®) is approved by the European Commission for the treatment of adult patients with advanced renal cell carcinoma in the European Union plus Norway, New Zealand and Iceland. Ficlitzumab (HGF MAb) is being studied in head and neck cancer and acute myeloid leukemia clinical trials and has reported data in pancreatic cancer. AVEO's earlier-stage pipeline includes AV-203 (anti-ErbB3 MAb), AV-380 (GDF15 MAb) and AV-353 (Notch 3 MAb) drug candidates being developed for various oncology indications. 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 within the meaning of the Private Securities Litigation Reform Act of 1995 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 potential for tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or advanced RCC; the advancement of AVEO's pipeline, including AVEO's plans with respect to the advancement of the DEDUCTIVE trial; AVEO's plans to submit an NDA for tivozanib; AVEO's plans to

expand its tivozanib-immunotherapy clinical strategy; the potential efficacy, safety, and tolerability of tivozanib, both as a stand-alone drug candidate and in combination with other therapies in several indications; AVEO's execution of its clinical and regulatory strategy for tivozanib; AVEO's plans and strategies for commercialization of tivozanib in the United States and Europe; and AVEO's strategy, prospects, plans and objectives for its product candidates and for the Company generally. 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, and the ability of its licensees, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy and clinically meaningful benefit of AVEO's product candidates, including, in particular, tivozanib and ficlatuzumab; AVEO's ability to successfully file an NDA for tivozanib; and AVEO's ability to enter into and maintain its third party collaboration and license agreements, and its ability, and the ability of its strategic partners, to achieve development and commercialization objectives under these arrangements. AVEO faces other risks relating to its business as well, including risks relating to the timing and costs of seeking and obtaining regulatory approval; AVEO's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with 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; 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 sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" included in AVEO's quarterly and annual reports on file with the Securities and Exchange Commission (SEC) and in other filings that AVEO makes with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release, and 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. Any reference to AVEO's website address in this press release is intended to be an inactive textual reference only and not an active hyperlink.

References

1. Fotivda (Tivozanib) SmPC August 2017
2. Motzer RJ, Nosov D, Eisen T, et al. J Clin Oncol 2013; 31(30): 3791-9.
3. Pawlowski N et al. AACR 2013. Poster 3971.
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