AVEO Oncology Announces $2.8M Development Milestone Earned from Kyowa Kirin

August 5, 2020

BOSTON--(BUSINESS WIRE)--Aug. 5, 2020-- AVEO Oncology (Nasdaq: AVEO) today announced that it has earned a $2.8 million development milestone payment from partner Kyowa Kirin Co., Ltd. (Kyowa Kirin). The milestone relates to acceptance by the Japanese Pharmaceuticals and Medical Devices Agency of an investigational new drug (IND) application for tivozanib in a non-oncology indication being developed by Kyowa Kirin.

“This milestone marks an important step forward for AVEO’s non-oncology pipeline,” said Michael Bailey, president and chief executive officer of AVEO. “We believe tivozanib’s potential in non-oncology indications is significant, and we look forward to seeing Kyowa Kirin move this formulation into the clinic.”

Under the terms of AVEO’s agreement with Kyowa Kirin, in addition to the previously-paid upfront payment of $25 million to AVEO and waiver of AVEO’s obligation to make an $18 million milestone payment upon AVEO gaining U.S. marketing approval of tivozanib for renal cell carcinoma, and now the IND development milestone, Kyowa Kirin has also agreed to pay AVEO up to an additional $388 million in potential milestone payments upon the successful achievement of certain development, regulatory, and commercial objectives in non-oncology indications of tivozanib. Kyowa Kirin will also be obligated to make tiered royalty payments on the net sales of a product for these indications, ranging from a high single-digit to low double-digit percent.

About Tivozanib (FOTIVDA®)

Tivozanib (FOTIVDA®) is an oral, once-daily, next-generation 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, the United Kingdom, 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 activity and minimal dose modifications.[1,2] AVEO’s TIVO-3 trial is supporting a regulatory submission in the U.S. seeking marketing approval of tivozanib as a treatment for relapsed or refractory RCC. Tivozanib has been shown to significantly reduce regulatory T-cell production in preclinical models[3] and has demonstrated synergy in combination with nivolumab (anti PD-1) in a Phase 2 study in RCC.[4] Tivozanib has been investigated in several tumor types, including renal cell, hepatocellular, colorectal, ovarian and breast cancers. Tivozanib is also being studied by partner Kyowa Kirin in non-oncology indications.

About AVEO Pharmaceuticals, Inc.

AVEO is developing an oncology pipeline designed to provide a better life for patients with cancer. AVEO’s strategy is to focus its resources toward development and commercialization of its product candidates in North America, while leveraging partnerships to support development and commercialization in other geographies. AVEO’s lead candidate, tivozanib (FOTIVDA ®) is approved in the European Union, the United Kingdom, Norway, New Zealand and Iceland for the treatment of adult patients with advanced renal cell carcinoma. AVEO is working to develop and commercialize tivozanib in North America as a treatment for renal cell carcinoma and hepatocellular carcinoma. AVEO has previously reported promising early clinical data on ficlatuzumab (anti-HGF mAb) in head and neck cancer, acute myeloid leukemia and pancreatic cancer and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab in head and neck cancer. AVEO’s earlier-stage pipeline includes several monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb), AV-380 (anti-GDF15 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion as a foundation for innovation.

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,” “hope,” “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: tivozanib’s potential in non-oncology indications; the potential of AVEO to receive future milestone and royalty payments under its agreement with Kyowa Kirin; the potential for tivozanib as a treatment option for patients with advanced HCC or relapsed/refractory or advanced RCC, following earlier TKI and immunotherapy treatment; 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 current and future clinical trials of tivozanib, ficlatuzumab and AV-380 and for commercialization of tivozanib in the United States; 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: whether the results of TIVO-3 are sufficient to obtain marketing approval for tivozanib in the U.S., which turns on the ability of AVEO to demonstrate to the satisfaction of the FDA the safety and efficacy of tivozanib based upon the findings of TIVO-3, including its data with respect to PFS, the rate of adverse events, OS and other information that the FDA may determine for approval; 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; 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, including its ability to successfully launch and commercialize tivozanib if it may be approved for commercialization by the FDA; 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; the potential adverse effects of the COVID-19 pandemic on AVEO's business continuity, financial condition, results of operations, liquidity and ability to successfully and timely enroll, complete and read-out data from its clinical trials; 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.

References

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