

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): March 10, 2021

AVEO Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34655
(Commission
File Number)

04-3581650
(IRS Employer
Identification No.)

30 Winter Street
Boston, Massachusetts
(Address of principal executive offices)

02108
(Zip Code)

Registrant's telephone number, including area code: (857) 400-0101

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	AVEO	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

On March 10, 2021, AVEO Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration has approved FOTIVDA[®] (tivozanib) for the treatment of adults with relapsed or refractory advanced renal cell carcinoma who have received two or more prior systemic therapies, among other matters. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 [Press release issued by the Company on March 10, 2021.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AVEO Pharmaceuticals, Inc.

Date: March 10, 2021

By: /s/ Michael Bailey
Michael Bailey
President and Chief Executive Officer



AVEO Oncology Announces U.S. FDA Approval of FOTIVDA® (tivozanib) for the Treatment of Adult Patients with Relapsed or Refractory Advanced Renal Cell Carcinoma

- FOTIVDA is the First Therapy Approved for Adult Patients with Relapsed or Refractory Advanced Renal Cell Carcinoma Following Two or More Prior Systemic Therapies –

- AVEO Plans to Make FOTIVDA Available to Patients in the U.S. by March 31, 2021 -

- Company to Host Conference Call and Webcast today, March 10, 2021, at 6:00 PM ET -

BOSTON, Mass. – March 10, 2021– AVEO Oncology (Nasdaq: AVEO) today announced that the U.S. Food and Drug Administration (FDA) has approved FOTIVDA® (tivozanib) for the treatment of adults with relapsed or refractory advanced renal cell carcinoma (RCC) who have received two or more prior systemic therapies. FOTIVDA is an oral, next-generation vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

“Today’s approval of FOTIVDA provides a new tool for treating patients with kidney cancer who have relapsed or become refractory to two or more prior systemic therapies,” said Brian Rini, MD, Chief of Clinical Trials at Vanderbilt Ingram Cancer Center and principal investigator of the TIVO-3 trial. “With advances in RCC treatment, patients are living longer, increasing the need for proven, well tolerated treatment options in the relapsed or refractory setting. The TIVO-3 study is the first positive Phase 3 study in RCC patients who received two or more prior systemic therapies, and also the first Phase 3 RCC study to include a predefined population of patients who have received prior immunotherapy, the current standard of care in earlier-line treatment. With this approval, I believe FOTIVDA represents an attractive intervention, and expect it to play a meaningful role in the evolving RCC treatment landscape.”

“We believe in FOTIVDA’s potential to provide a differentiated treatment option for the growing number of individuals in the U.S. with relapsed or refractory RCC, and today marks the culmination of many years of hard work and determination of many individuals to bring this therapy to patients,” said Michael Bailey, president and chief executive officer of AVEO. “With today’s approval, AVEO begins its journey as a commercial-stage company, a noteworthy accomplishment in our industry. On behalf of the entire AVEO team, I would like to thank all the patients, their families, and caregivers whose tireless efforts made this day possible.”

“Relapsed or refractory RCC is a devastating disease for which patient outcomes can be limited due to the tradeoff between tolerability and efficacy,” said Dena Battle, president of KCCure. “The FDA approval of FOTIVDA represents an exciting, meaningful advancement by providing a new treatment option for this patient population.”

AVEO plans to make FOTIVDA available to patients in the U.S. by March 31, 2021.

The approval of FOTIVDA is based on AVEO's pivotal Phase 3 study, TIVO-3, comparing FOTIVDA to sorafenib in relapsed or refractory advanced RCC following two or more prior systemic therapies. The application is also supported by three additional trials in RCC and includes safety data from over 1,000 clinical trial subjects.

Patients (n=350) enrolled in the TIVO-3 study were randomized 1:1 to receive either FOTIVDA or sorafenib. The main efficacy outcome measure was progression-free survival (PFS), assessed by a blinded independent radiology review committee. Other efficacy endpoints were overall survival (OS) and objective response rate (ORR).

Median PFS was 5.6 months (95% CI: 4.8, 7.3) in the FOTIVDA arm (n=175) compared with 3.9 months (95% CI: 3.7, 5.6) for those treated with sorafenib (HR 0.73; 95% CI: 0.56, 0.95; p=0.016). Median OS was 16.4 (95% CI: 13.4, 21.9) and 19.2 months (95% CI: 14.9, 24.2), for the FOTIVDA and sorafenib arms, respectively (HR 0.97; 95% CI: 0.75, 1.24). The ORR was 18% (95% CI: 12%, 24%) for the FOTIVDA arm and 8% (95% CI: 4%, 13%) for the sorafenib arm.

The most common (≥20%) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis. The most common grade 3 or 4 laboratory abnormalities (≥5%) were decreased sodium, increased lipase, and decreased phosphate.

The recommended tivozanib dose is 1.34 mg once daily with or without food for 21 days every 28 days on treatment followed by 7 days off treatment (28 day cycle) until disease progression or unacceptable toxicity.

Conference Call and Webcast Information

In connection with this announcement, AVEO will host a conference call and slide webcast today, March 10, 2021, at 6:00 PM Eastern Time. The call can be accessed by dialing (844) 882-7841 (U.S. and Canada) or (574) 990-9828 (international). The passcode for the conference call is 4648498. To access the live webcast and accompanying slide presentation, or the subsequent archived recording, please visit the Investors section of the AVEO website at www.aveooncology.com. The webcast will be recorded and available for replay on AVEO's website for two weeks.

About FOTIVDA® (tivozanib)

FOTIVDA® (tivozanib) is an oral, next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI). It is a potent, selective inhibitor of VEGFRs 1, 2, and 3 with a long half-life designed to improve efficacy and tolerability. AVEO received U.S. Food and Drug Administration (FDA) approval for FOTIVDA on March 10, 2021 for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. FOTIVDA was approved in August 2017 in the European Union and other countries in the territory of its partner EUSA Pharma (UK) Limited for the treatment of adult patients with advanced RCC. FOTIVDA has been shown to significantly reduce regulatory T-cell production in preclinical models¹. FOTIVDA was discovered by Kyowa Kirin.

INDICATIONS

FOTIVDA is indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypertension and Hypertensive Crisis: Control blood pressure prior to initiating FOTIVDA. Monitor for hypertension and treat as needed. For persistent hypertension despite use of anti-hypertensive medications, reduce the FOTIVDA dose.

Cardiac Failure: Monitor for signs or symptoms of cardiac failure throughout treatment with FOTIVDA.

Cardiac Ischemia and Arterial Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe arterial thromboembolic events, such as myocardial infarction and stroke.

Venous Thromboembolic Events: Closely monitor patients who are at increased risk for these events. Permanently discontinue FOTIVDA for severe venous thromboembolic events.

Hemorrhagic Events: Closely monitor patients who are at risk for or who have a history of bleeding.

Proteinuria: Monitor throughout treatment with FOTIVDA. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment with FOTIVDA.

Thyroid Dysfunction: Monitor before initiation and throughout treatment with FOTIVDA.

Risk of Impaired Wound Healing: Withhold FOTIVDA for at least 24 days before elective surgery. Do not administer for at least 2 weeks following major surgery and adequate wound healing. The safety of resumption of FOTIVDA after resolution of wound healing complications has not been established.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Discontinue FOTIVDA if signs or symptoms of RPLS occur.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Allergic Reactions to Tartrazine: The 0.89 mg capsule of FOTIVDA contains FD&C Yellow No.5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients.

ADVERSE REACTIONS

The most common (320%) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities (35%) were sodium decreased, lipase increased, and phosphate decreased.

DRUG INTERACTIONS

Strong CYP3A4 Inducers: Avoid coadministration of FOTIVDA with strong CYP3A4 inducers.

USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed.

Females and Males of Reproductive Potential: Can impair fertility.

Hepatic Impairment: Adjust dosage in patients with moderate hepatic impairment. Avoid use in patients with severe hepatic impairment.

To report SUSPECTED ADVERSE REACTIONS, contact AVEO Pharmaceuticals, Inc. at 1-833-FOTIVDA (1-833-368-4832) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see FOTIVDA Full Prescribing Information which is available at www.AVEOoncology.com.

About Advanced Renal Cell Carcinoma

According to the American Cancer Society's 2021 statistics, renal cell carcinoma (RCC) is the most common type of kidney cancer, which is among the ten most common cancers in both men and women. Approximately 73,750 new cases of kidney cancer will be diagnosed annually and about 14,830 people will die from this disease. In patients with late-stage disease, the five-year survival rate is 13%. Agents that target the vascular endothelial growth factor (VEGF) pathway have shown significant antitumor activity in RCC.² According to a 2019 publication, 50% of the approximately 10,000 patients who progress following two or more lines of therapy choose not to receive further treatment,³ which may be attributable to tolerability concerns and a lack of data to support evidence-based treatment decisions in this highly relapsed or refractory patient population.

About AVEO Pharmaceuticals, Inc.

AVEO is an oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for cancer patients. 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, FOTIVDA® (tivozanib), received U.S. Food and Drug Administration (FDA) approval on March 10, 2021 for the treatment of adult patients with relapsed or refractory renal cell carcinoma (RCC) following two or more prior systemic therapies. FOTIVDA® was approved in August 2017 in the European Union and other countries in the EUSA territory for the treatment of adult patients with advanced RCC. AVEO has previously reported promising early clinical data on ficlatuzumab

(anti-HGF IgG1 mAb) in head and neck cancer, pancreatic cancer and acute myeloid leukemia and is conducting a randomized Phase 2 confirmatory clinical trial of ficlatuzumab for the potential treatment of head and neck cancer. AVEO's pipeline of product candidates also includes AV-380 (anti-GDF15 IgG1 mAb). AVEO has previously reported the acceptance of its investigational new drug application in the U.S. for AV-380 and its initiation of a Phase 1 clinical trial for the potential treatment of cancer cachexia. AVEO's earlier-stage pipeline includes monoclonal antibodies in oncology development, including AV-203 (anti-ErbB3 mAb) and AV-353 (anti-Notch 3 mAb). AVEO is committed to creating an environment of diversity and inclusion.

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: AVEO's planned timing for making FOTIVDA available to patients in the U.S.; the potential for FOTIVDA as a treatment option for patients with relapsed/refractory or advanced RCC; the potential efficacy, safety, and tolerability of FOTIVDA, both as a stand-alone drug candidate and in combination with immunotherapy; AVEO's execution of its clinical and regulatory strategy for FOTIVDA; AVEO's plans and strategies for current and future clinical trials of FOTIVDA, ficlatuzumab and AV-380 and for commercialization of FOTIVDA in the United States; the advancement of AVEO's pipeline, including the advancement of ficlatuzumab in multiple clinical studies; the potential efficacy, safety and tolerability of ficlatuzumab, both as a stand-alone drug candidate and in combination with other therapies; the potential outcomes from studies of ficlatuzumab to provide AVEO with opportunities to pursue regulatory strategies; the potential clinical utility of ficlatuzumab in areas of unmet need; 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 to successfully implement its strategic plans, including its ability to successfully commercialize FOTIVDA and to obtain and maintain market and third party payor acceptance of FOTIVDA; AVEO's ability to raise the substantial additional funds required to successfully commercialize FOTIVDA; 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 risks relating to the timing and costs of seeking and obtaining regulatory approvals; AVEO's dependence on third-party vendors for the development, manufacture and supply of FOTIVDA and its product candidates; 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's and its collaborators' ability to successfully enroll and complete clinical trials; AVEO's ability to maintain compliance with regulatory requirements applicable to

FOTIVDA and its product candidates; AVEO's ability to obtain and maintain adequate protection for intellectual property rights relating to FOTIVDA and its product candidates; unplanned capital requirements; uncertainties related to AVEO's ability to access future borrowings under the Hercules loan facility, which turns on the achievement of milestones related to the approval and commercialization of FOTIVDA in the U.S.; adverse general economic, political, 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.

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. Pawlowski N et al. AACR 2013. Poster 3971
2. J Angulo and O Shapiro, *Cancers (Basel)* 2019 Sep; 11(9): 1227. [[10.3390/cancers11091227](https://doi.org/10.3390/cancers11091227)]
3. Decision Resources. RCC landscape and forecast. December 12, 2019.

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