# AVEO Oncology Reports First Quarter 2016 Financial Results and Provides Business Update

May 10, 2016

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 10, 2016-- AVEO Oncology (NASDAQ:AVEO) today reported financial results for the first quarter ended March 31, 2016.

“We achieved several important goals in the first quarter critical to advancing the corporate strategy we outlined early in 2015. This includes the submission and validation of an MAA filing in Europe for tivozanib in front-line RCC by our partner EUSA Pharma and the licensing of AV-203 outside of North America by CANbridge Life Sciences. In addition, we also announced the filing of provisional patent applications and the initiation of partnership discussions for AV-353, a legacy discovery program which we will look to develop and commercialize in PAH through a global partnership.” said Michael Bailey, president and chief executive officer. “These accomplishments, coupled with our noteworthy progress in 2015, have allowed us to retain significant North American rights to develop our three oncology-focused clinical programs, while positioning five programs to be advanced by partners. We believe these initiatives have the potential to unlock significant future value for patients as well as our shareholders.”

Mr. Bailey concluded: “Our next steps in the development of tivozanib in North America include the potential initiation of TIVO-3, a Phase 3 U.S. pivotal study of tivozanib designed to support a first- and third-line indication in renal cell cancer (RCC), and a tivozanib-PD1 combination study in RCC. The Company continues to work toward the potential initiation of patient enrollment in the TIVO-3 Study in the second quarter of 2016.”

**Recent Highlights**

- **Filing of Provisional Patent Applications for AV-353, a Notch 3-Specific Inhibitor Antibody for PAH.** In May 2016, AVEO announced that it had filed provisional patent applications with the United States Patent and Trademark Office covering composition of matter claims for AV-353, the Company’s potent inhibitory antibody specific to Notch 3 for development in Pulmonary Arterial Hypertension (PAH). These patent applications are the second set of applications related to AV-353 and the Company’s Notch 3 antibody program. Current treatments in PAH focus only on controlling symptoms by avoiding vasoconstriction and increasing vasodilation of vessels and do not reverse the underlying cause of the disease. In contrast, with the results of a recently concluded research study supported by AVEO, AV-353 has generated a growing body of preclinical data that supports AV-353’s ability to potentially reverse the disease phenotype, which would represent a potential disease-modifying approach to treatment. Consistent with the Company’s focus on developing oncology therapeutics, AVEO is currently seeking an appropriate partner to develop and commercialize AV-353 worldwide in PAH.
- **Exclusive Licensing Agreement for AV-203 Outside of North America with CANbridge Life Sciences.** In March 2016 AVEO and CANbridge Life Sciences announced an exclusive collaboration and license agreement in which AVEO has granted CANbridge worldwide rights, excluding the United States, Canada, and Mexico, to AV-203, AVEO’s clinical-stage ErbB3 (HER3) inhibitory antibody candidate. CANbridge plans to develop AV-203 first in esophageal squamous cell cancer (ESCC). Under the terms of the agreement, CANbridge is obligated to pay AVEO an upfront payment of $1 million plus up to $133 million in potential reimbursement and milestone payments, assuming the successful achievement of specified development, regulatory and commercialization objectives. AVEO is also eligible for a tiered royalty, with a percentage range in the low double digits, on net sales of AV-203 in CANbridge’s territories. CANbridge will be responsible for costs associated with the execution of a development plan that includes additional manufacturing requirements as well as pre-clinical and clinical studies necessary to demonstrate proof-of-concept for AV-203 as a treatment for ESCC, including a Phase IIa proof-of-concept study meeting mutually agreed upon criteria. Following completion of the proof-of-concept studies, AVEO and CANbridge will negotiate a possible agreement under which the parties may co-develop AV-203, with each party bearing a percentage of the cost of global development activities based on respective geographic rights.
- **Submission and validation of a European Marketing Authorization Application for Tivozanib in Renal Cell Carcinoma.** In February 2016, AVEO and its European partner, EUSA Pharma announced that EUSA Pharma submitted and received a validation notice for the Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for tivozanib as a first line treatment for renal cell carcinoma (RCC).
- **Acceptance of Registration Dossier for Tivozanib in RCC by the Ministry of Health of the Russian Federation.** In February 2016, AVEO announced that a registration dossier seeking to obtain marketing authorization of tivozanib as a first line treatment of advanced RCC has been accepted by the Ministry of Health of the Russian Federation.

The dossier was submitted in December 2015 by Pharmstandard Group, AVEO's licensing partner in Russia, Ukraine and CIS.

- **Receipt of $3.5 Million AV-380 Inventory Reimbursement Payment from Novartis.** AVEO previously announced that Novartis exercised its right under its license agreement for AV-380, AVEO's first-in-class, potent, humanized inhibitory antibody targeting growth differentiation factor 15 (GDF15), to acquire AVEO's inventory of clinical quality drug substance. This reimbursement payment of approximately $3.5 million was received in the first quarter of 2016.

**First Quarter 2016 Financial Highlights**

- AVEO ended Q1 2016 with $23.8 million in cash, cash equivalents and marketable securities. The reduction in cash over base operations was primarily attributable to clinical trial startup costs related to the TIVO-3 study and a significant pay down in accounts payable quarter over quarter.
- Total collaboration revenue in Q1 2016 was approximately $1.2 million compared with $0.1 million for Q1 2015. The increase was primarily due to an additional $1.0 million in revenue recognized in the first quarter of 2016 in connection with our out-licensing agreement with CANbridge, which was executed in March 2016.
- Research and development (R&D) expense was $6.0 million in Q1 2016 compared with $2.7 million for Q1 2015. The increase was primarily attributable to an increase in tivozanib clinical trial costs associated with our preparation for a planned Phase 3 trial.
- General and administrative (G&A) expense was $2.5 million in Q1 2016 compared with $3.3 million for Q1 2015. The decrease was primarily the result of a decrease in external legal costs associated with various ongoing legal matters, and a decrease in employee compensation, consulting, facilities and IT costs as a result of our decreased headcount and the reduction of our utilized facility space following our January 2015 restructuring.
- There was no restructuring and lease exit expense in Q1 2016, compared with $4.3 million for Q1 2015. The expenses incurred during the three months ended March 31, 2015 related to the January 2015 restructuring, which was substantially completed in March 2015.
- Net loss for Q1 2016 was $7.7 million, or a loss of $0.13 per basic and diluted share, compared with net loss of $10.9 million, or a loss of $0.21 per basic and diluted share for Q1 2015.

**Financial Guidance**

AVEO believe that its cash resources would allow the Company to fund its current operations into the fourth quarter of 2017. This estimate does not include the payment of potential licensing milestones to third parties or the uncommitted costs of conducting any contemplated clinical trials (such as a second phase 3 trial and PD-1 combination trial for tivozanib in RCC), and assumes no milestone payments from our partners, no additional funding from new partnership agreements, no equity financings, no debt financings, no accelerated repayment thereof and no further sales of equity under our ATM.

**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 developing and commercializing 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 to develop and commercialize tivozanib in non-oncologic indications worldwide and oncology indications outside of North America, as well as to progress its pipeline of novel therapeutic candidates in cancer and cachexia (wasting syndrome). 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 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," "could," "should," "seek," "would" "look forward," 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 Company's execution of its business strategies in 2016; the Company's expectations and projections regarding its development programs both domestically and abroad, including its expectation that it could begin patient enrollment in the TIVO-3 study in the second quarter of 2016; and the Company's estimate that its cash resources would allow the Company to fund its current operations into the fourth quarter of 2017. 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 maintain its third party collaboration agreements, and its ability, and the ability of its licensees, 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; AVEO's ability to successfully implement its strategic plans; AVEO's ability to successfully enroll and complete clinical trials of its product candidates, including its planned TIVO-3 study; AVEO's ability to achieve and maintain compliance with all regulatory requirements applicable to its product candidates; AVEO's ability to enter into collaboration or license agreements relating to its AV-353 program; AVEO's ability to reach a co-development agreement with CANbridge relating to its AV-203 program; 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 and SEC investigation; AVEO's ability to raise the substantial additional funds required to achieve its goals; unplanned capital

requirements; adverse general economic and industry conditions; competitive factors; and those risks discussed in the section titled “Risk Factors” in AVEO’s most recent Annual Report on Form 10-K, its quarterly reports on Form 10-Q and its other filings with the SEC. 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.

**AVEO Pharmaceuticals, Inc.**
**Condensed Consolidated Statements of Operations**
**(In thousands, except per share amounts)**
**(Unaudited)**

| | For the Three Months Ended March 31, | |
|---|---|---|
| | **2016** | **2015** |
| Collaboration revenue | $ 1,203 | $ 134 |
| Operating expenses: | | |
| Research and development | 5,972 | 2,695 |
| General and administrative | 2,463 | 3,255 |
| Restructuring and lease exit | - | 4,333 |
| | 8,435 | 10,283 |
| Loss from operations | (7,232) | (10,149) |
| Other income and expense: | | |
| Other expense), net | (9) | (14) |
| Interest expense | (386) | (716) |
| Interest income | 17 | 5 |
| Other expense, net | (378) | (725) |
| Provision for income taxes | (100) | - |
| Net loss | (7,710) | (10,874) |
| Net loss per share - basic and diluted | $ (0.13) | $ (0.21) |
| Weighted average number of common shares outstanding | 58,166 | 52,638 |

**Consolidated Balance Sheet Data**
**(In thousands)**
**(Unaudited)**

| | **March 31, 2016** | **December 31, 2015** |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and marketable securities | $ 23,805 | $ 34,135 |
| Accounts receivable | 1,736 | 4,641 |
| Prepaid expenses and other current assets | 5,123 | 1,600 |
| Property and equipment, net | 18 | 23 |
| Other assets | 124 | 143 |
| Total assets | $ 30,806 | $ 40,542 |
| **Liabilities and stockholders’ equity** | | |
| Accounts payable and accrued expenses | $ 3,183 | $ 5,531 |
| Total loans payable | 9,556 | 9,471 |
| Total deferred revenue | 3,492 | 3,695 |

| | | |
|---|---|---|
| Other liabilities | 4,660 | 4,618 |
| Stockholder's equity | 9,915 | 17,227 |
| Total liabilities and stockholders' equity | $ 30,806 | $ 40,542 |

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