AVEO Oncology Announces Presentation of AV-380 Preclinical Data in Cancer Associated Cachexia at 2015 Annual Meeting of the American Association of Cancer Research

CAMBRIDGE, Mass. – April 20, 2015 – AVEO Oncology (NASDAQ:AVEO) today announced the presentation of results from a preclinical study of AV-380, the Company’s potent, humanized inhibitory antibody targeting growth differentiation factor 15 (GDF15), in a cachectic human tumor xenograft model with significantly increased plasma GDF15 levels. The data were presented in a poster titled “Effective treatment of cancer associated cachexia by AV-380, a GDF15 inhibitory antibody” at the 2015 Annual Meeting of the American Association of Cancer Research in Philadelphia from April 18-22.

One of the most lethal and debilitating effects of cancer is the development of cachexia. It affects the majority of advanced cancer patients and is thought to be responsible for approximately 30% of all cancer deaths. Cachexia is a complex metabolic syndrome associated with malnutrition and severe involuntary weight loss due to the loss of muscle and fat tissue, as well as the clinical manifestation of anemia, inflammation and suppression of immune functions. Current evidence suggests that a pro-inflammatory state may be responsible for many of the symptoms associated with cachexia. GDF15 is a pro-inflammatory cytokine whose elevated circulating levels are significantly correlated with cachexia in cachectic cancer patients and several animal models of cancer cachexia.

For the study, mice bearing HT-1080 were treated either with AV-380, or a control antibody. The effect on body weight, muscle/fat mass and organ sizes were assessed. Metabolic changes induced by the treatment were measured by a comprehensive laboratory animal monitoring system (CLAMS). Results demonstrated that the inhibition of GDF15 function results in the complete reversion of the phenotypic and metabolic changes associated with cancer-related anorexia-cachexia syndrome, or CACS, completely reverting body weight loss and restoring normal body composition of the tumor bearing mice. AV-380 treatment resulted in a catabolic to anabolic metabolic switch and increased food intake, energy expenditure, resting energy expenditure and physical activity. The data highlight the potential of AV-380 as a therapeutic intervention for the treatment for CACS.

“Cachexia is a prevalent, devastating consequence of multiple chronic disease states. The poor understanding of its molecular mechanisms has led to a therapeutic focus on specific symptoms with limited treatment effectiveness,” said Michael Needle, MD, chief medical officer of AVEO. “Our preclinical data show that inhibition of GDF15 results in a switch from catabolism to anabolism, suggesting that treatment with AV-380 may reverse the effects of cachexia. We remain encouraged by the potential of this therapeutic approach and continue to actively pursue partnerships to realize the full potential of AV-380 within and beyond cancer cachexia.”

A copy of the poster presentation is available on AVEO’s website at www.aveooncology.com.

About AV-380
AV-380 is a potential first-in-class GDF15 inhibitor, discovered using AVEO’s proprietary Human Response Platform™, which provides the Company unique insights into cancer and related disease biology. AVEO plans to evaluate opportunities for partnerships to expand the development of AV-380, including in cachexia associated with non-cancer indications, such as chronic heart failure, chronic kidney disease and chronic obstructive pulmonary disease, with the goal of leveraging the full potential of this asset.

**About Cachexia**

Cachexia is a serious and common complication in patients with advanced cancer and other chronic diseases, characterized by symptoms of unintentional weight loss, progressive muscle wasting and loss of appetite (anorexia). Cachexia affects some five million individuals in the United States¹. It is estimated that 60-80% of patients with advanced cancer have cachexia²,³ and approximately 30% of cancer patients die due to cachexia⁴.

**About AVEO**

AVEO Oncology (AVEO) is a biopharmaceutical company committed to developing targeted therapies through biomarker-driven insights to provide improvements in patient outcomes where significant unmet medical needs exist. AVEO’s proprietary Human Response Platform™ has delivered unique insights into cancer and related disease biology that AVEO is seeking to leverage in the clinical development strategy of its therapeutic candidates. 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 facts, contained in this press release are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “target,” “potential,” “objective,” “could,” “should,” “seek,” 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 role GDF15 may play in the development and progression of cancer cachexia; GDF15 as an important mechanism to target for therapeutic intervention; AV-380 as a potential therapeutic intervention for the treatment of CACS; and AVEO’s plans to pursue partnerships to realize the full potential of AV-380. 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 restructuring and strategic plans, including its plans to pursue partnerships for AV-380; AVEO’s ability to successfully enroll and complete clinical trials of its product candidates; AVEO’s ability to demonstrate to the satisfaction of the FDA, EMA or other equivalent foreign regulatory agencies, the safety, efficacy and clinically meaningful benefit of its product candidates; 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 and expenses related to AVEO’s ongoing shareholder litigation and SEC inquiry; 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” included in AVEO’s most recent Annual Report on Form 10-K, its quarterly reports on Form 10-Q and in 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 will cause its views to change. However, 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 subsequent to the date of this press release.

References


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