Aravive Announces Dose Escalation of AVB-500 in Recurrent Platinum Resistant Ovarian Cancer Phase 1b Trial

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Dose escalation of AVB-500 to 20mg/kg dose follows positive recommendation by independent Data Monitoring Committee review

Plan to initiate Phase 2/3 study in Platinum Resistant Ovarian Cancer by year end 2020

HOUSTON, Feb. 18, 2020 (GLOBE NEWSWIRE) -- Aravive, Inc. (Aravive) (NASDAQ:ARAV) today announced that the independent Data Monitoring Committtee (DMC) has reviewed the open-label data following the first 28-day treatment cycle for the three patients in each of the two 15 mg/kg dosing cohorts of the Phase 1b portion of the Phase 1b/Phase 2 clinical trial of AVB-500 in patients with platinum-resistant recurrent ovarian cancer (PROC) and unanimously recommended the study continue as planned with enrollment of patients into the 20mg/kg dose cohorts. The DMC did not identify any safety concerns with AVB-500.

On November 20, 2019, Aravive reported data from the first 31 patients treated at the 10mg/kg dose supporting a relationship between AVB-500 blood levels and anti-tumor response, confirming the company's strategy to investigate higher doses of AVB-500, specifically 15 and 20 mg/kg every two weeks.

"We are very pleased to receive this positive recommendation by the DMC and that AVB-500 continues to be well-tolerated as predicted from toxicology studies," said Laura Bonifacio, Pharm.D., Ph.D., vice president of clinical operations of Aravive. "Our data modeling has predicted a dose of 20 mg/kg should allow at least 90% of the patients to achieve the desired high drug exposure levels of AVB-500 that correlated to better outcomes in our clinical studies to date."

The company anticipates reporting safety and pharmacokinetic data from this Phase 1b trial in mid-2020 with plans to present preliminary efficacy in 2H 2020. The company plans to initiate a randomized Phase 2/3 study in PROC by end of 2020.

About Platinum-resistant, Recurrent Epithelial Ovarian Cancer (PROC) In the United States, ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. It is estimated that in 2020 in the United States, more than 21,000 women will develop ovarian cancer and there will be approximately 13,940 attributed deaths.

About the Phase Ib/Phase 2 Recurrent Platinum Resistant Ovarian Cancer Trial
The open label Phase 1b safety lead-in portion of the efficacy and safety study of AVB-500 in patients with platinum-resistant recurrent ovarian cancer is enrolling patients into two cohorts, one investigating a combination of AVB-500 with pegylated liposomal doxorubicin, and the other, a combination of AVB-500 with paclitaxel. The primary objectives are to assess safety and tolerability of the combinations and to identify the dose for the Phase 2 portion of the study. The clinical trial will also explore secondary endpoints including preliminary activity measures and effects on biomarkers (GAS6-AXL) in serum and tumor tissues. The trial is listed on clinicaltrials.gov NCT03639246.

About AVB-500
AVB-500 is a therapeutic recombinant fusion protein that has been shown to neutralize GAS6 activity by binding to GAS6 with very high affinity. In doing so, AVB-500 selectively inhibits the GAS6-AXL signaling pathway. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity, both as a single agent and in combination with a variety of anticancer therapies including radiation therapy, immuno-oncology agents and chemotherapeutic drugs that affect DNA replication and repair. Increased expression of AXL and GAS6 in tumors is correlated to poor prognosis and survival, and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies.

Aravive reported positive data from the first 31 patients enrolled in the Phase 1b portion of a Phase 1b/2 clinical trial of AVB-500 in platinum-resistant recurrent ovarian cancer. AVB-500 continues to be well tolerated with no dose limiting toxicities. An investigator-sponsored Phase 1 study of AVB-500, in combination with durvalumab in patients with platinum-resistant recurrent epithelial ovarian cancer, is also ongoing. Based on AVB-500's safety profile and specifically targeted mechanism of action, this drug candidate has the potential to be used both in combination with existing therapies, as well as a maintenance drug. The U.S. Food and Drug Administration granted Fast Track Designation to AVB-500 in platinum-resistant recurrent ovarian cancer.

About Aravive
Aravive, Inc. (Nasdaq: ARAV) is a clinical-stage biopharmaceutical company developing treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis. Aravive's lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, AVB-500 starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. The GAS6-AXL signaling pathway also plays a significant role in fibrogenesis. Aravive is evaluating AVB-500 in platinum-resistant ovarian cancer, clear cell renal cell carcinoma (ccRCC) and kidney fibrosis and intends to expand development into additional oncology and fibrotic indications. Aravive is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. For more information, please visit www.aravive.com.

Forward-Looking Statements
This communication contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended), express or implied, concerning a dose of 20 mg/kg should allow at least 90% of the patients to achieve the desired high drug exposure levels of AVB-500 that correlated to better outcomes in our clinical

studies to date, reporting safety and pharmacokinetic data from the Phase 1b study in mid-2020 with plans to present preliminary efficacy in 2H 2020, plans to initiate a randomized Phase 2/3 study in PROC by end of 2020, the potential of AVB-500 to be used both in combination with existing therapies, as well as a maintenance drug, the potential of AVB-500 to halt the biological programming that promotes disease progression and the expansion of the development of AVB-500 into additional oncology and fibrotic indications. Forward-looking statements are based on current beliefs and assumptions, are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those contained in any forward-looking statement as a result of various factors, including, but not limited to, risks and uncertainties related to: the Company's ability to achieve the desired high drug exposure levels of AVB-500, report data as planned, complete the Phase 1b portion of the Phase1b/2 in time to initiate a Phase 2/3 trial in PROC by end of 2020,expand development in 2020 into additional oncology and fibrotic indications, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials, the clinical trials of AVB-500 having results that are as favorable as those of preclinical studies, the ability to receive regulatory approval, potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; the risk that AVB-500 may cause serious side effects or have properties that delay or prevent regulatory approval or limit its commercial potential; the risk that the Company may encounter difficulties in manufacturing AVB-500; if AVB-500 is approved, risks associated with its market acceptance, including pricing and reimbursement; potential difficulties enforcing the Company's intellectual property rights; the Company's reliance on its licensor of intellectual property and financing needs. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in the Company's Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2018, recent Current Reports on Form 8-K and subsequent filings with the SEC. Except as required by applicable law, the Company undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

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