Aravive Announces Independent Data Monitoring Committee Recommends Continuation of Phase Ib Study of AVB-500 In Recurrent Platinum Resistant Ovarian Cancer After Review of First Two Cohorts of Patients

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AVB-500 demonstrates favorable safety profile and full suppression of circulating GAS6 in cancer patients

HOUSTON, July 08, 2019 (GLOBE NEWSWIRE) -- Aravive, Inc. (Aravive) (NASDAQ:ARAV), a clinical-stage biopharmaceutical company, announced that the independent Data Monitoring Committtee (DMC) has reviewed the open-label data following the first 28-day treatment cycle for the first six patients in each of the two cohorts of the Phase 1b portion of the Phase 1b/Phase 2 trial of AVB-500 in patients with platinum-resistant recurrent ovarian cancer. The DMC did not identify safety concerns with AVB-500 (previously called AVB-S6-500). Importantly, data demonstrated suppression of serum GAS6 levels, a biomarker associated with efficacy in preclinical tumor models, with the current dose. The dosing regimen was predicted by the Phase 1 healthy volunteer study. The DMC unanimously recommended the study continue as planned and enroll additional patients into each cohort to collect additional preliminary efficacy, safety, biomarker and PK/PD data at the current dose. The company remains on track to report interim safety, pharmacodynamic, and pharmacokinetic data for the phase 1b portion in the third quarter of 2019.

“We are pleased that the safety profile of AVB-500 continues to be favorable, and are encouraged with the first demonstration of proof of mechanism in cancer patients as shown by suppression of circulating free GAS6 during the dosing interval,” said Jay Shepard, CEO of Aravive.

About Platinum-resistant, Recurrent Epithelial Ovarian Cancer
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. Each year in the United States, over 22,000 women develop ovarian cancer and there are approximately 14,240 attributed deaths annually.

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 confirm the dose based on results from the healthy volunteer clinical trial of AVB-500 (NCT03401528). 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 (previously called AVB-S6-500) 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 or 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 are correlated to poor prognosis and survival and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies.

A Phase 1 clinical trial in healthy volunteers (NCT03401528) investigating the safety, pharmacokinetics, and pharmacodynamics was completed last year. The study met the safety and tolerability endpoints and demonstrated clinical proof-of-mechanism for AVB-500 in neutralizing GAS6.

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 has initiated the phase 1b portion of a phase 1b/2 clinical trial of AVB-500 combined with standard of care therapies in patients with platinum-resistant ovarian cancer, and intends to expand development into additional oncology and fibrotic indications. 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 the Company's goals, intentions and expectations as to future plans or events, including statements regarding remaining on track to report interim safety, pharmacodynamic, and pharmacokinetic data for the phase 1b portion in the third quarter of 2019, the potential of AVB-500 to halt the biological programming that promotes disease progression and expanding development into additional oncology and fibrosis 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 expand development in 2019 into additional oncology and fibrotic indications, the Company’s dependence upon AVB-500, AVB-500’s ability to have favorable results in clinical trials, including continuing to have a favorable safety profile or 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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