Aravive Announces Phase 3 Trial Design for AVB-500 in Platinum Resistant Ovarian Cancer

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Pivotal Trial Expected to be Initiated During 1Q21

HOUSTON, Nov. 19, 2020 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative therapeutics, today announced the Company has received guidance from the U.S. Food and Drug Administration (FDA) on a Phase 3 trial design for AVB-500 in platinum resistant ovarian cancer (PROC). The global, randomized, double-blind, placebo-controlled adaptive trial is designed to evaluate efficacy and tolerability of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel.

“We look forward to advancing AVB-500 into a pivotal Phase 3 trial in platinum resistant ovarian cancer, following the promising results from our Phase 1b trial and productive conversations with the FDA,” said Gail McIntyre, Ph.D., Chief Executive Officer of Aravive. “With agreement from the FDA that our preclinical and clinical pharmacology programs are now complete, we anticipate that this trial, if successful, could support the submission of a biologics license application to the FDA. We plan to initiate the trial in the first quarter of 2021, with an interim analysis expected a year later.”

The pivotal, adaptive Phase 3 trial is expected to enroll approximately 300-400 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy. This global trial is planned to be conducted at approximately 100 sites in the U.S. and Europe. The primary endpoint for the trial is progression free survival, and secondary endpoints include overall survival, objective response rate, duration of response, quality of life, clinical benefit rate, and pharmacokinetic and pharmacodynamic profile. Prospectively defined interim analyses will investigate treatment differences in patients who have previously received bevacizumab versus those who have not and will explore the biomarkers identified in the Phase 1b trial in an effort to test the hypotheses generated from the Phase 1b data. Based on the interim analyses, the trial can be adapted to include only those patients who have not previously been treated with bevacizumab and/or whose baseline serum biomarker results meet the identified threshold.

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 preclinical models. In doing so, AVB-500 selectively inhibits the GAS6-AXL signaling pathway, which is upregulated in multiple cancer types including ovarian cancer. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity 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 has been correlated with poor prognosis and decreased survival and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies. AVB-500 is currently being evaluated in clinical trials and has been granted Fast Track Designation by the U.S. Food and Drug Administration in platinum resistant recurrent ovarian cancer. Analysis of all safety data to date showed that AVB-500 has been generally well-tolerated with no dose-limiting toxicities or unexpected safety signals.

About Aravive
Aravive, Inc. is a clinical-stage oncology company developing transformative therapeutics designed to halt the progression of life-threatening diseases. Aravive’s lead therapeutic, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth. Aravive recently successfully completed a Phase 1b trial of AVB-500 in platinum resistant ovarian cancer and selected 15 mg/kg as the dose for the Phase 3 trial. While the Phase 1b trial of AVB-500 in platinum resistant ovarian cancer was a safety trial and not powered to demonstrate efficacy, all 5 patients in the 15 mg/kg cohort experienced clinical benefit, with 1 complete response, 2 partial responses, and 2 stable disease. The Company also intends to initiate a Phase 1b/Phase 2 trial of AVB-500 in clear cell renal cell carcinoma later this year. 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, such statements regarding advancing AVB-500 into a pivotal Phase 3 trial during first quarter 2021, the trial supporting the submission of a biologics license application to the FDA, conducting an interim analysis a year later, enrollment of approximately 300-400 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy, the trial being conducted at approximately 100 sites in the U.S. and Europe. 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: our ability to initiate a pivotal trial during first quarter 2021, the trial supporting the submission of a biologics license application to the FDA, our ability to conduct an interim analysis a year later, as planned, our ability to enroll approximately 300-400 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy as planned, our ability to conduct the trial at approximately 100 sites in the U.S. and Europe as planned, our ability to initiate a Phase 1b/Phase 2 trial of AVB-500 in clear cell renal cell carcinoma as planned later this year, the impact of COVID-19 on the Company's clinical strategy, clinical trials, supply chain and fundraising, the Company's ability to expand development into additional oncology indications, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials and ISTs, the clinical trials of AVB-500 having results that are as favorable as those of preclinical and clinical trials, 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 especially in light of the COVID-19 pandemic; 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 for the fiscal year ended December 31, 2019, 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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