Aravive Announces First Patient Dosed in Phase 1b/2 Clinical Trial of AVB-500 for the Treatment of Pancreatic Adenocarcinoma

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Trial to Evaluate AVB-500 as a First-Line Treatment in Combination with Gemcitabine and Nab-Paclitaxel

Continues Expansion of AVB-500 in Multiple Oncology Indications and Combinations

HOUSTON, Aug. 09, 2021 (GLOBE NEWSWIRE) -- Aravive Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases, today announced the Company has dosed the first patient in the Phase 1b portion of its Phase 1b/2 trial of AVB-500 in combination with gemcitabine and nab-paclitaxel as a first-line treatment in patients with advanced or metastatic pancreatic adenocarcinoma. The Phase 1b portion of the clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of AVB-500 in combination with gemcitabine and nab-paclitaxel.

“We are pleased with the quick advancement of AVB-500 with the first patient dosed in our Phase 1b/2 pancreatic adenocarcinoma trial. This clinical trial addresses a very high unmet medical need in one of the most difficult-to-treat cancers with a high mortality rate,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “We continue to expand the development of AVB-500, as the Company now has three ongoing clinical trials of AVB-500. In addition to the pancreatic adenocarcinoma clinical trial, AVB-500 is currently being investigated in a Phase 3 clinical trial for platinum resistant ovarian cancer and a Phase 1b/2 clinical trial for clear cell renal cell carcinoma.”

The Phase 1b/2 clinical trial is designed to evaluate AVB-500 as a first-line therapy in combination with gemcitabine and nab-paclitaxel (Abraxane®) in patients with advanced or metastatic pancreatic adenocarcinoma eligible to receive gemcitabine and nab-paclitaxel combination therapy. The Phase 1b portion of the clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity in approximately 20 patients dosed with 15 mg/kg of AVB-500 in combination with gemcitabine and nab-paclitaxel. The randomized, controlled Phase 2 portion of the clinical trial is designed to evaluate approximately 60 patients dosed with 15 mg/kg of AVB-500 as a first-line therapy in combination with gemcitabine and nab-paclitaxel versus gemcitabine and nab-paclitaxel alone. The primary endpoint of the Phase 2 portion of the trial is progression-free survival. The secondary endpoints are objective response rate, duration of response, clinical benefit rate, safety and overall survival, and the exploratory endpoints are pharmacokinetics and pharmacodynamics. The Phase 1b/2 trial is listed on clinicaltrials.gov NCT04983407.

About Pancreatic Cancer
Pancreatic cancer is the seventh leading cause of cancer death worldwide. There were approximately 495,800 new cases of pancreatic cancer and 466,000 deaths from the disease worldwide in 2020. It is estimated that there will be approximately 60,400 new cases of pancreatic cancer and 48,200 deaths from the disease in the U.S. in 2021. Pancreatic cancer typically has a poor prognosis, and the five-year survival rate is approximately 11%. Pancreatic adenocarcinoma is the most common type of pancreatic cancer, and there is a clear, high, unmet medical need to improve patient survival with new effective treatments that are safe and well-tolerated. Pancreatic cancer is projected to become the third leading cause of cancer death worldwide by 2025 and the second leading cause of cancer death in the U.S. by 2030.

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, renal and pancreatic 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 multiple 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 innovative therapeutics to treat life-threatening diseases. Aravive’s lead therapeutic, AVB-500, is a first-in-class ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth, tumor metastasis, resistance to treatment and decreased survival. AVB-500 has the potential to be combined with multiple anticancer therapies across several tumor types, due to its novel mechanism of action and favorable safety profile. AVB-500 has been granted Fast Track Designation by the U.S. Food and Drug Administration in platinum resistant recurrent ovarian cancer. The Company is currently evaluating AVB-500 in a registrational Phase 3 trial in platinum resistant ovarian cancer, a Phase 1b/2 trial in second line plus, clear cell renal cell carcinoma, and a Phase 1b/2 trial in first-line treatment of pancreatic adenocarcinoma. The Company 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 within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions and includes statements regarding the pancreatic cancer statistical data and the potential of AVB-500 to be combined with multiple anticancer therapies across several tumor types. 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 ability to enroll the expected number of patients, 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 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, 2020, 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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