Aravive Announces Positive Initial Results from Phase 1b Portion of the Phase1b/2 Study of AVB-500 in Combination with Cabozantinib in Clear Cell Renal Carcinoma

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Encouraging Pharmacokinetics, Pharmacodynamics and Safety Profile at 15mg/kg of AVB-500

HOUSTON, June 24, 2021 (GLOBE NEWSWIRE) -- Aravive Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases, today announced positive initial results from the Phase 1b portion of its Phase 1b/2 study in patients dosed with 15mg/kg of AVB-500 in combination with cabozantinib who have clear cell renal cell carcinoma (advanced stage kidney cancer). The data in three evaluable patients showed that AVB-500 was well tolerated with no unexpected findings.

Based on the pharmacokinetics, pharmacodynamics, and safety data at 15mg/kg of AVB-500, and approval by the Data and Safety Monitoring Board (DSMB), the Company plans to expand the dosing of 15mg/kg of AVB-500 to an additional three patients to determine the potential of initiating the Phase 2 portion with this dose. The Company also expects to continue to investigate higher doses of AVB-500 in the Phase 1b to obtain additional safety, pharmacokinetics, and pharmacodynamics information.

“We are pleased to announce the favorable results in the first cohort of our clear cell renal cell carcinoma Phase 1b study, as we continue to advance AVB-500 and evaluate its ability to address an urgent, high unmet medical need in patients with advanced kidney cancer who have very low survival rates,” said Gail McIntyre, Ph.D., Chief Executive Officer of Aravive. “We continue to focus on difficult-to-treat life threatening cancers with AVB-500, and in addition to our clear cell renal cell carcinoma clinical trial, our lead indication in paclitaxel resistant ovarian cancer is in a Phase 3 clinical trial, and we recently announced that we plan to initiate a Phase 1b/2 clinical trial in first-line metastatic pancreatic cancer in the second half of this year. We are enthusiastic about the clinical data with AVB-500 in combination with anticancer therapies that continue to show consistent PK/PD data and a favorable safety profile. These combinations may have the potential to be used in a range of different cancers.”

About the AVB-500 Phase 1b/2 Clinical Trial in Clear Cell Renal Cell Carcinoma (ccRCC)

Aravive initiated its Phase1b portion of the Phase 1b/2 trial of AVB-500 in ccRCC in March 2021. The Phase 1b portion of the clinical trial, a dose escalation study, is expected to enroll up to a total of 18 patients in three dosing arms (15 mg/kg, 20 mg/kg and 25 mg/kg) to evaluate tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of AVB-500 in combination with cabozantinib. The controlled, randomized, open-label Phase 2 portion of the clinical trial is expected to enroll up to 45 patients and investigate the recommended AVB-500 dose identified during the Phase 1b portion of the clinical trial in combination with cabozantinib versus cabozantinib alone. The primary endpoint is progression-free survival. The trial will enroll patients with advanced clear cell renal cell carcinoma (ccRCC) who have progressed on front-line treatment. The Phase 1b/2 trial is listed on clinicaltrials.gov NCT04300140.

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 innovative therapeutics designed to halt the progression of life-threatening diseases. Aravive is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. 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 successfully completed a Phase 1b trial of AVB-500 in platinum resistant ovarian cancer and has initiated a registrational Phase 3 trial of AVB-500 at a dose of 15 mg/kg. 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 is dosing patients in its Phase 1b/2 trial in clear cell renal cell carcinoma. 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 plans to expand the dosing of 15mg/kg of AVB-500 to an additional three patients to determine the potential of initiating the Phase 2 portion with this dose, investigating higher doses of AVB-500 in the Phase 1b to obtain additional safety, pharmacokinetics, and pharmacodynamics information, plans to initiate a Phase 1b/2 clinical trial in first-line metastatic pancreatic cancer in the second half of this year and the expected enrollment of the Phase 1b and Phase 2 portion of the trial of AVB-500 in ccRCC . 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 recruit for and enroll the expected number of patients into the Phase 1b and Phase 2 3 trial of AVB-500 in ccRCC as planned and continue dosing as planned 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, 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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