



Aravive to Present New Preliminary Data from Phase 1b Trial Evaluating AVB-500 in Clear Cell Renal Cell Carcinoma at 2021 Society for Immunotherapy of Cancer Annual Meeting

October 1, 2021

HOUSTON, Oct. 01, 2021 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases, today announced that new preliminary safety, pharmacokinetic, pharmacodynamic, and clinical activity data from the Phase 1b portion of its open-label Phase 1b/2 trial evaluating AVB-500 in combination with cabozantinib in patients with clear cell renal cell carcinoma (ccRCC) will be presented at the Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting. The meeting is being held November 10-14, 2021 in Washington, D.C.

Poster Presentation Details:

Title: A Phase 1b/2 randomized study of AVB-S6-500 in combination with cabozantinib versus cabozantinib alone in patients with advanced clear cell renal cell carcinoma who have received front-line treatment

Presenter: Reshma Rangwala, M.D., Ph.D., Chief Medical Officer of Aravive

Date: November 13, 2021

Time: 7:00 AM – 8:30 PM ET

Location: Hall E

For additional information, please visit the SITC 36th Annual Meeting website: <https://www.sitcancer.org/2021/home>.

About the AVB-500 Phase 1b/2 ccRCC Trial

Aravive initiated the Phase 1b 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 approximately 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 approximately 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 is enrolling patients with advanced ccRCC who have progressed on front-line treatment. The Phase 1b/2 trial is listed on [clinicaltrials.gov](https://clinicaltrials.gov/NCT04300140) [NCT04300140](https://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, 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. 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 expected enrollment of approximately 18 patients in three dosing arms in the Phase 1b portion of the Phase 1b/2 trial of AVB-500 in ccRCC, the expected enrollment of approximately 45 patients and investigation of the recommended AVB-500 dose identified during the Phase 1b portion of the clinical trial in combination with cabozantinib versus cabozantinib alone in the open-label Phase 2 portion of the clinical trial 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.

Contacts:

Media:

Aulani Capuchin, Real Chemistry

acapuchin@realchemistry.com

(559) 355-2673

Investors:

Luke Heagle, Real Chemistry

lheagle@realchemistry.com

(910) 619-5764