



Aravive Announces Positive Preliminary Data from Phase 1b Trial Evaluating Batiraxcept (AVB-500) in Combination with Cabozantinib in Clear Cell Renal Cell Carcinoma to be Presented at 2021 Society for Immunotherapy of Cancer Annual Meeting

November 9, 2021

3 of 5 (60%) patients achieved a partial response

All 5 patients treated demonstrated tumor decrease from baseline

Batiraxcept has been generally well-tolerated with no dose-limiting toxicities

Aravive to host conference call and webcast on November 12 at 8:30 a.m. ET to discuss updated data

HOUSTON, Nov. 09, 2021 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers, today announced that positive new data from the Phase 1b portion of its open-label Phase 1b/2 trial evaluating batiraxcept (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 on November 13, 2021. The presentation will highlight interim safety, pharmacokinetic (PK), pharmacodynamic (PD), and clinical activity data.

"We are encouraged by the preliminary performance of batiraxcept in combination with cabozantinib in patients with clear cell renal cell carcinoma," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "These results highlight the potential of batiraxcept to improve outcomes for patients with advanced kidney cancer. We look forward to sharing these new clinical data with the research and medical community at this year's SITC Annual Meeting."

As of July 21, 2021, seven patients received at least one dose of batiraxcept 15 mg/kg in combination with cabozantinib, six patients were ongoing treatment, and five patients were evaluable for efficacy. No dose-limiting toxicities were observed. Trough levels at cycle 1 day 15 were above the minimal efficacious concentration identified from the Company's model informed drug development approach, and serum GAS6 levels were suppressed prior to cycle 2 day 1. A best overall response of partial response was observed in 3 of 5 patients (60%, unconfirmed as of July 21, 2021), based on investigator assessment, RECIST v 1.1 criteria. In addition, all patients demonstrated tumor decrease from baseline.

Aravive's presentation at the SITC Annual Meeting will include updated safety, PK, PD, and clinical activity data from a larger set of patients treated with batiraxcept 15 mg/kg in combination with cabozantinib as of October 16, 2021.

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>.

Conference Call Information

Aravive will host a conference call and webcast on November 12, 2021 at 8:30 a.m. ET to discuss these clinical data. The conference call may be accessed by dialing (877) 423-9813 (domestic) and (201) 689-8573 (international) and referring to conference ID 13724115. A webcast of the conference call will be available in the Investors section of the Aravive website at <https://ir.aravive.com/>. The archived webcast will be available on Aravive's website after the conference call.

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

Aravive initiated the Phase 1b portion of the Phase 1b/2 trial of batiraxcept 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 batiraxcept 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 batiraxcept 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 NCT04300140](https://clinicaltrials.gov/NCT04300140).

About Batiraxcept (AVB-500)

Batiraxcept 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, batiraxcept 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. Batiraxcept is currently being evaluated in multiple clinical trials and has been granted Fast Track designation by the U.S. Food and Drug Administration and orphan drug designation by the European Commission in platinum resistant recurrent ovarian cancer.

About Aravive

Aravive, Inc. is a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers. The Company is currently evaluating its lead therapeutic, batiraxcept (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 potential of batiraxcept (AVB-500) to improve outcomes for patients with advanced kidney cancer. 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 data from patients treated in the future with batiraxcept being consistent with the results reported, 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 batiraxcept, batiraxcept's ability to have favorable results in clinical trials and ISTs, the clinical trials of batiraxcept 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 batiraxcept 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 batiraxcept; if batiraxcept 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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