Aravive to Present Positive Updated Data from Phase 1b Trial of Batiraxcept in Combination with Cabozantinib for Treatment of Clear Cell Renal Cell Carcinoma at the 2023 ASCO Genitourinary (GU) Cancers Symposium

February 13, 2023

HOUSTON, Feb. 13, 2023 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, “the Company”), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced the presentation of updated results from its ongoing Phase 1b/2 trial of batiraxcept in clear cell renal cell carcinoma (ccRCC) at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium, taking place February 16-18, 2023 in San Francisco and virtually. The poster presentation will highlight updated results from the Phase 1b portion of the trial in 26 patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of immuno-oncology (IO)- and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies.

“We are pleased at the opportunity to present updated results from our Phase 1b trial of batiraxcept in ccRCC patients at this year’s ASCO GU meeting,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “Batiraxcept in combination with cabozantinib in ccRCC patients who have already received IO and VEGF-TKI treatment continues to yield highly encouraging results. Treatment is ongoing in the Phase 1b portion of the trial, and Phase 2 enrollment has been completed. We look forward to providing additional updates on this program throughout 2023.”

“We continue to be encouraged by the safety and clinical activity observed in the Phase 1b trial of batiraxcept in patients with ccRCC,” said Neil J. Shah, MBBS, Medical Oncologist, Memorial Sloan Kettering Cancer Center. “In addition to promising overall response rate and progression free survival data, baseline biomarker analysis may play a critical role in predicting response and will be further assessed throughout the Phase 2 and 3 trials. Importantly, the updated data continue to indicate the significant potential impact that dual AXL and VEGF inhibition by batiraxcept plus cabozantinib may have in patients who have failed prior VEGF-TKI treatments. Taken together, these findings remain promising and suggest that batiraxcept may serve as a much-needed treatment option for ccRCC patients on their second or later line of therapy.”

Poster Presentation Details:

Title:	A phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC)
Abstract Number:	666
Presenter:	Neil Shah, MBBS
Session:	Poster Session C: Renal Cell Cancer; Adrenal, Penile, Urethral and Testicular Cancers
Date/Time:	Saturday, February 18, 2023; 7:00 AM – 8:00 AM; 12:30 PM – 2:00 PM PST
Location:	Level 1 West Hall, Moscone West, San Francisco, CA and Virtual

As of January 17, 2023, safety, pharmacokinetics (PK), and pharmacodynamics (PD), and clinical activity of 15 mg/kg and 20 mg/kg batiraxcept in combination with 60 mg cabozantinib were evaluated in 26 patients with 2L+ ccRCC. Results highlighted in the poster include:

- Batiraxcept in combination with 60 mg cabozantinib has a manageable safety profile in previously treated ccRCC; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
- No dose limiting toxicities were observed at either dose of batiraxcept.
- A minimally efficacious concentration (MEC) of batiraxcept was determined to be > 12.2 mg/L, of which 19/26 patients achieved during Cycle 1, with no difference between 15 mg/kg and 20 mg/kg dose cohorts.
- 85% of patients (22/26) had a reduction in target lesions at the 8-week response assessment.
- 58% (15/26) of total population achieved a better response on batiraxcept plus cabozantinib than they did on prior therapy.
- Best overall response of partial response was observed in 42% (11/26) of the overall population, 57% (8/14) of the prior VEGF-TKI-treated group and 55% (11/20) of the biomarker high (sAXL/GAS6) group.
- 9-month progression free survival (PFS) rate was 65% in the overall population, 69% in the biomarker high group (n=20) and 75% in the prior VEGF-TKI, biomarker high group (n=11).
- Safety, PK/PD, and clinical activity results support a recommended Phase 2 dose of 15 mg/kg.

Batiraxcept was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with advanced or metastatic ccRCC who have progressed after 1 or 2 prior lines of systemic therapy, including both IO-based and VEGF-TKI-based therapies (either in combination or sequentially). Fast Track Designation was based on data submitted to the agency from 26 patients treated with 15 mg/kg or 20 mg/kg batiraxcept plus 60 mg cabozantinib in the Phase 1b ccRCC study as of September 26, 2022. Results showed no dose limiting toxicities at either dose of batiraxcept. In addition, data demonstrated clinical activity of batiraxcept plus cabozantinib in patients with metastatic ccRCC, with an objective response rate (ORR) of 57% and median PFS of 11.4 months in this population (n=14/26).

About Aravive
Aravive, Inc. is a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. Our lead product candidate, batiraxcept (formerly AVB-500), is an ultra-high affinity decoy protein that binds to GAS6, the sole ligand that activates AXL, thereby inhibiting

metastasis and tumor growth, and restoring sensitivity to anti-cancer agents. Batiraxcept has been granted Fast Track Designation by the U.S. FDA and Orphan Drug Designation by the European Commission in platinum-resistant recurrent ovarian cancer. Batiraxcept is in an active registrational Phase 3 trial in platinum resistant ovarian cancer (NCT04729608), a Phase 1b/2 trial in clear cell renal cell carcinoma (NCT04300140), and a Phase 1b/2 trial in pancreatic adenocarcinoma (NCT04983407). The Company is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. Additional information at 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 being encouraged by the safety and clinical activity observed in the Phase 1b trial of batiraxcept in patients with ccRCC , the baseline biomarker analysis playing a critical role in predicting response and being further assessed throughout the Phase 2 and 3 trials, the significant potential impact that dual AXL and VEGF inhibition by batiraxcept plus cabozantinib may have in patients who have failed prior VEGF-TKI treatments, the suggestion that batiraxcept may serve as a much-needed treatment option for ccRCC patients on their second or later line of therapy providing additional updates to the program throughout 2023, . 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 potential of batiraxcept as a treatment for advanced or metastatic clear cell renal cell carcinoma (ccRCC), the ability of the baseline biomarker analysis playing a role in predicting response, the ability to provide data when anticipated; the Company's dependence upon batiraxcept; batiraxcept's ability to have favorable results in clinical trials; 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; and 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, 2021, the Company’s Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2022, June 30, 2022 and September 30, 2022, respectively, 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.

Investor Relations Contact:
Corey Davis, Ph.D.
LifeSci Advisors, LLC
212-915-2577
cdavis@lifesciadvisors.com