Aravive Announces Positive Updated Data and New Biomarker Data from Phase 1b Study of Batiraxcept in Clear Cell Renal Cell Carcinoma

March 3, 2022

- *46% Best Overall Response Rate in the ITT Population*
- *63% Best Overall Response Rate in the sAXL/GAS6 Biomarker High Population*
- *6-month Progression-Free Survival Rate in the ITT Population of 79%*
- *6-month Progression-Free Survival Rate of 91% in the 15 mg/kg Biomarker High Population*
- *3-month Duration of Response of 100%*

HOUSTON, March 03, 2022 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced positive new data from the Phase 1b portion of the ongoing Phase 1b/2 trial of batiraxcept in clear cell renal cell cancer (ccRCC) and new data from a biomarker high subgroup.

As of February 4, 2022, 26 ccRCC patients have been treated with batiraxcept at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily in previously treated (2L+) patients with ccRCC. Demographics of the evaluated 26 patients are representative of a 2L+ ccRCC population, with all patients having received a prior immunotherapy. Key findings include:

- No dose limiting toxicities observed at either the 15 mg/kg or 20 mg/kg batiraxcept dose in combination with cabozantinib
- At a median follow-up of 4.9 months on February 4, 2022, 92% of patients remain on study
- Best overall response rate (ORR) in the ITT population is 46% (12/26)
    - In the 15 mg/kg population, best ORR is 56% (9/16)
    - In the 20 mg/kg population, best ORR is 30% (3/10)
    - No patient has had progressive disease as their best response
- The 6-month progression-free survival (PFS) rate in the ITT population is 79%
- Median duration of response (DOR) has not been reached; the 3-month DOR is 100%

Biomarker Data
As previously reported, a key finding from the Company's Phase 1b trial of batiraxcept in platinum-resistant ovarian cancer is an observable correlation of baseline levels of serum soluble AXL (sAXL)/GAS6 to clinical activity. As such, one of the objectives of the ongoing Phase 1b/2 ccRCC trial is to measure the correlation of baseline sAXL/GAS6 with radiographic response in patients with ccRCC treated with batiraxcept plus cabozantinib. Ratios of sAXL/GAS6 were evaluated retrospectively.

Among the 26 patients treated in the ccRCC trial, 25 were evaluable for baseline sAXL/GAS6. A high ratio optimized a patient's ability to respond to batiraxcept plus cabozantinib. Key findings from biomarker high patients include:

- Best ORR rate in the biomarker high population is 63% (12/19)
    - In the 15 mg/kg population, best ORR is 75% (9/12)
    - In the 20 mg/kg population, best ORR is 43% (3/7)
- The 6-month PFS rate in the biomarker high population is 77%, with a 6-month PFS rate of 91% in the 15 mg/kg biomarker high group
- Median DOR has not been reached in the biomarker high subgroup; the 3-month DOR is 100%

The safety and clinical activity data continue to support 15 mg/kg batiraxcept as an appropriate dose to study in combination with cabozantinib in the Phase 2 ccRCC portion of the study.

"We are very encouraged by the best overall response rate and 6-month progression-free survival rate observed in the Phase 1b trial of batiraxcept in patients with ccRCC," said Kathryn Beckermann, M.D., Ph.D., Assistant Professor, Division of Hematology and Oncology, Vanderbilt University Medical Center, and lead investigator for the trial. "These data are compelling as the objective response rate in the cabozantinib alone groups of the METEOR and CANTATA studies were 17% and 28%, respectively, and the 6-month progression-free survival rates for cabozantinib from these studies ranged from 55-65%. Additionally, objective response rates for other preferred National Comprehensive Cancer Network regimens range from

25-37%. These early data suggest batiraxcept adds to cabozantinib clinical activity and potentially provides a much-needed therapy for this group of patients with refractory clear cell renal cell carcinoma."

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

The Phase 1b trial is evaluating batiraxcept at doses of 15 mg/kg and 20 mg/kg, plus cabozantinib 60 mg daily in previously treated (2L+) patients with ccRCC. Prior treatment with cabozantinib was not allowed. The primary objective is safety; secondary and exploratory objectives include identification of the recommended phase 2 dose (RP2D), objective response rate, and duration of response (DOR). Given baseline levels of serum soluble AXL (sAXL)/GAS6 correlated to clinical activity in the Company's Phase 1b trial of batiraxcept in platinum-resistant ovarian cancer, one of the objectives of the ccRCC trial is to correlate baseline sAXL/GAS6 with ORR in patients with ccRCC treated with batiraxcept plus cabozantinib.

The open-label Phase 2 portion of the clinical trial initiated earlier this year and is expected to enroll 55 patients across three parts. Part A is expected to enroll approximately 25 patients and investigate batiraxcept 15 mg/kg in combination with cabozantinib in 2L+ ccRCC patients. Part B is expected to enroll approximately 20 patients and evaluate batiraxcept 15 mg/kg in combination with nivolumab and cabozantinib as a potential front-line treatment for ccRCC. Part C is expected to evaluate batiraxcept 15 mg/kg monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies.

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). Additional information at www.aravive.com.

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Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 on our current expectations and projections about future events. 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 include statements regarding the suggestion that batiraxcept adds to cabozantinib clinical activity and potentially provides a much-needed therapy for this group of patients with refractory clear cell renal cell carcinoma, the expected enrollment in Part A of approximately 25 patients, Part B of approximately 20 patients and Part C of approximately 10 patients with 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 potential of batiraxcept to serve as a breakthrough therapy for this clear cell renal cell patient population, 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.