Aravive Presents Updated Clinical Data at ASCO Showing Continued Best-in-Class Potential of Batiraxcept in Advanced or Metastatic clear cell Renal Cell Carcinoma (ccRCC)

May 26, 2022

- Abstract selected for oral discussion on Genitourinary Cancer on Saturday, June 4, 2022
- Development of biomarker offers the potential of a first in class targeted therapy in renal cancer
- Company has a registrational path for potential accelerated approval as well as full approval of batiraxcept in 2L+ ccRCC

HOUSTON, May 26, 2022 (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 Phase 1b/2 ccRCC data at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, taking place June 3-7, 2022 in Chicago. The abstract presents the updated response rate, landmark progression-free-survival data, and biomarker data.

“We are jubilant about the selection of the poster on the use of batiraxcept in 2L+ ccRCC for oral discussion at this year’s ASCO annual meeting,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “This is a rare opportunity provided only to select abstracts at this meeting. Batiraxcept continues to show best-in-class potential in advanced or metastatic clear cell renal carcinoma, platinum resistant ovarian cancer, and pancreatic cancer. Enrollment in the registration directed Phase 3 program in PROC remains on pace to complete this year and we look forward to providing updates on the renal and pancreatic cancer programs throughout 2022.”

Abstract 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) who have received front-line treatment (NCT04300140)*
Abstract Number:	4511 (Poster Discussion Session – Data will be presented)
Poster Session:	Genitourinary Cancer—Kidney and Bladder
Session Date:	Poster Presentation: Saturday, June 4, 2022, 1:15 PM - 4:15 PM CDT Discussion: Saturday, June 4, 2022, 4:30 PM CDT (5:30 PM EDT)

Abstract Title:	*A Phase 1b/2 study of batiraxcept (AVB-S6-500) in combination with cabozantinib, cabozantinib and nivolumab, and as monotherapy in patients with advanced or metastatic clear cell renal cell carcinoma (NCT04300140)*
Abstract Number:	TPS4599 (Trials in Progress poster – No data presented)
Poster Session:	Genitourinary Cancer—Kidney and Bladder
Session Date:	Saturday, June 4, 2022, 1:15 PM - 4:15 PM CDT

Of note, 100% of patients had received a prior immunotherapy, 77% of the patients were in the IMDC (International Metastatic RCC Database Consortium) Risk Score of intermediate or poor, and 39% of the patients had received 2 or more prior lines of therapy prior to study entry.

A summary of the interim Phase 1b results include (as of April 30, 2022, the cut-off date):

- Batiraxcept 15 mg/kg in combination with cabozantinib 60 mg has a manageable safety profile in previously treated ccRCC; no dose-limiting toxicities have been observed; a similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts.
- Batiraxcept given every 2 weeks suppressed serum GAS6 to below the level of quantitation in 25/26 patients (1 patient did not have an assessment), showing a clear pharmacokinetic (PK)/pharmacodynamic (PD) relationship; 23/26 patients had batiraxcept trough levels above the minimally efficacious concentration of 13.8 mg/L by Cycle 2.
- The confirmed + unconfirmed response rate in the total population was 46% with a 50% confirmed response rate in the 15mg/kg (RP2D) batiraxcept group.
- The proportion of patients in the total population who were progression free at 7 months was 71%.
- The proportion of patients in the total population who had a duration of response of at least 7 months was 75%.
- A baseline biomarker enriched the confirmed response rate in the RP2D (15mg/kg) biomarker high population to 67%, increased the proportion of patients progression free at 7 months to 91% and increased the proportion of patients who had a duration of response of at least 7 months to 80%.
- 58% (15/26) of total population achieved a better response on the batiraxcept trial than they did with their therapy prior to study entry, which was only 23%.
- The safety and clinical activity of this combination together with PK/PD data support a RP2D of 15 mg/kg.

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, inhibiting metastasis,

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 European Commission in PROC. 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 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 development of the biomarker offering the potential of a first in class targeted therapy in renal cancer, having a registrational path for potential accelerated approval as well as full approval of batiraxcept in 2L+ ccRCC, enrollment in the registration directed Phase 3 program in PROC remaining on pace to complete this year and providing updates on the renal and pancreatic cancer programs throughout 2022. 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 of the biomarker to offer the potential of a first in class targeted therapy in renal cancer, the ability to obtain accelerated approval as well as full approval of batiraxcept in 2L+ ccRCC ; the ability to report data from the current clinical trials in accordance with current timelines, 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, 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; 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, 2021, 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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