Aravive Announces Phase 3 Trial Design for Batiraxcept in Clear Cell Renal Cell Carcinoma

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- Trial initiation anticipated in 2H 2023 with topline data anticipated in 2H 2025
- Updated Phase 1b/2 ccRCC data to be presented at ASCO 2023

HOUSTON, May 16, 2023 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, “the Company”), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced that the Company has received guidance from the U.S. Food and Drug Administration (FDA) on a registrational Phase 3 trial design for batiraxcept in clear cell renal cell carcinoma (ccRCC) at an End-of-Phase 2 (EOP2) meeting.

“We are very pleased to be advancing batiraxcept into Phase 3 development in ccRCC, having successfully completed our EOP2 meeting with the FDA,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “We believe our trial design and planned endpoint analyses are consistent with the FDA's guidance, and we look forward to initiating our registrational Phase 3 trial in the second half of 2023. Topline results are expected in 2025 and, if successful, will support a supplemental biologics license application (sBLA) submission in ccRCC.”

The randomized, double-blind, registrational Phase 3 trial is designed to evaluate efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with cabozantinib compared to cabozantinib alone. The trial is expected to enroll approximately 300 patients with histologically confirmed advanced or metastatic ccRCC who have progressed after one or two prior lines of systemic therapy, which include immuno-oncology (IO)-based and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies (either in combination or sequentially). Patients who were previously treated with cabozantinib are excluded from the trial. This ccRCC population was chosen based upon results from our Phase 1/2 trial which demonstrated a benefit in both median PFS and ORR with the addition of batiraxcept to cabozantinib in patients who had failed prior IO and VEGF-TKI treatments. The global trial is planned to be conducted at approximately 100 sites in the U.S. and around the world. The primary endpoint is progression-free survival, and secondary endpoints include overall survival, duration of response, and objective response rates. Batiraxcept was granted Fast Track Designation by the FDA for ccRCC in November 2022.

About Aravive
Aravive, Inc. is a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. 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 for both clear cell renal cell carcinoma and platinum-resistant ovarian cancer 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 Phase 3 trial initiation in 2H 2023 with topline data in 2H 2025, the trial design and planned endpoint analyses being consistent with FDA's guidance, topline results supporting a supplemental biologics license application submission in ccRCC, enrolling in the trial approximately 300 patients with histologically confirmed advanced or metastatic ccRCC who have progressed after one or two prior lines of systemic therapy, conducting the trial at approximately 100 sites in the U.S. and around the world. 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 patients as anticipated at the planned sites, the ability to initiate the trial when anticipated and 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 and the cash runway being sufficient to sustain operations into the fourth quarter of 2023 and beyond the readout on the Company’s Phase 3 Ovarian cancer trial. 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, 2022, the Company’s Quarterly Reports on Form 10-Q for the fiscal quarter ended March 31, 2023, 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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