



Aravive Announces First Patient Dosed in Phase 2 Study of Batiraxcept in Clear Cell Renal Cell Carcinoma

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Preliminary top line data anticipated throughout 2022

HOUSTON, Jan. 31, 2022 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced that the Company has dosed the first patient in the Phase 2 portion of the Phase 1b/2 study of batiraxcept for the treatment of clear cell renal cell carcinoma (ccRCC).

"Safety and preliminary activity data from the Phase 1b study of batiraxcept in combination with cabozantinib in patients with 2L+ ccRCC gives us confidence to initiate the Phase 2 portion of the trial and expand the study to additional cohorts," said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. "I'm grateful to our team for their diligence and dedication to expedite the ccRCC program. The data reported to date shows clinically relevant benefit of adding batiraxcept to the current standard of care in ccRCC without adding to the toxicity profile. We will continue to update the ongoing Phase 1b portion of the study as data mature and anticipate providing clinical activity and safety updates of the P2 portion of the study throughout 2022."

The Phase 2 portion of the Phase 1b/2 clinical trial of batiraxcept in ccRCC is an open-label study in which 55 patients are anticipated to enroll across three parts. Part A is expected to enroll approximately 25 patients and will 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 standard of care nivolumab and cabozantinib in first-line ccRCC patients. 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. The primary endpoint of each part of the Phase 2 portion of the trial is objective response rate ("ORR") and key secondary endpoints include duration of response ("DOR"), progression free survival ("PFS"), and overall survival ("OS"). Additional information on the trials: [NCT04300140](https://clinicaltrials.gov/ct2/show/study/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. 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 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 restores 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). A P1B platinum-resistant ovarian cancer trial demonstrated more than a doubling of progression-free survival in a patient subgroup that represents the ongoing P3 population. 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. These statements are based upon current beliefs, expectation, and assumptions and include statements regarding continuing to update the ongoing Phase 1b portion of the study as data mature and providing clinical activity and safety updates of the Phase 2 portion of the study throughout 2022, enrollment of 55 patients in the Phase 2 portion of the Phase 1b/2 clinical trial of batiraxcept in ccRCC three parts, Part A enrolling approximately 25 patients and investigating batiraxcept 15 mg/kg in combination with cabozantinib in 2L+ ccRCC patients, Part B enrolling approximately 20 patients and evaluating batiraxcept 15 mg/kg in combination with standard of care nivolumab and cabozantinib in first-line ccRCC patients and Part C evaluating batiraxcept 15 mg/kg monotherapy in approximately 10 patients with ccRCC who are not eligible for curative intent therapies. These statements are subject to risks and uncertainties, including 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 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 and other factors described in Aravive's filings with the SEC. 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.