Aravive Announces Fast Track Designation of Batiraxcept for Treatment of ccRCC

November 29, 2022

FDA decision based on new Phase 1b data: Objective Response Rate (ORR) of 57% and median Progression-Free Survival (PFS) of 11.4 months in patients with advanced or metastatic clear cell renal cell carcinoma (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

HOUSTON, Nov. 29, 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 U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to the company’s lead program, batiraxcept, for treatment of patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC) who have progressed after 1 or 2 prior lines of systemic therapy that include both immuno-oncology (IO)-based and vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)-based therapies (either in combination or sequentially).

Fast Track is a process designed to facilitate the development and expedite the review of investigational drugs to treat serious conditions and fill an unmet medical need. Drugs that receive Fast Track designation may be eligible for more frequent communications and meetings with the FDA to discuss the drug's development plan, including the design of the proposed clinical trials, use of biomarkers and the extent of data needed to support approval. Drugs with Fast Track Designation may also qualify for accelerated and priority review of new drug applications if relevant criteria are met.

The Fast Track Designation was based on new data submitted to the agency from the P1b clear cell renal cell cancer (ccRCC) study (AVB500-RCC-003; NCT04300140). As of September 26, 2022, 26 previously treated (second line or greater) patients with ccRCC have been treated with batiraxcept in the Phase 1b portion of a Phase 1b/2 trial at doses of 15 mg/kg (n=16) and 20 mg/kg (n=10), plus cabozantinib 60 mg daily. There were no dose limiting toxicities observed at either dose. Clinical data from this study demonstrate that batiraxcept has the potential to increase the clinical activity of cabozantinib in patients with metastatic ccRCC who have progressed following IO- and VEGF-TKI-based therapies (N=14 of the 26 patients) as the Objective Response Rate (ORR) was 57% and median Progression-Free Survival (PFS) was 11.4 months in this population.

“The majority of patients with kidney cancer develop resistance to frontline treatment and there is a clinical need for novel agents to improve upon treatment options in the refractory setting,” said Kathryn Beckermann, M.D., Ph.D., Assistant Professor, Division of Hematology and Oncology, Vanderbilt University Medical Center, and lead investigator for the trial. “Response rates to single agent targeted kinase inhibitors are approximately 30% with a PFS of approximately 7 months. The early data seen with batiraxcept including biomarker development, response rate, and progression-free survival are promising.”

“A review of the literature suggests that the clinical activity of cabozantinib is lower in those patients who have progressed following a VEGF-TKI-based therapy compared to patients who have progressed on IO or IO/IO therapy. Since preclinical data published by Xiao in 2019[1] observed that batiraxcept may restore TKI sensitivity, it makes sense that the combination of batiraxcept and cabozantinib may exhibit its greatest impact in those patients who have failed prior VEGF-TKI therapies,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “Understanding the P1b ccRCC data has allowed us to identify the most appropriate patient population in which to evaluate batiraxcept in combination with cabozantinib and potentially the quickest path to approval in this population with an unmet medical need.”

[1] Cancer Res 2019;79:5758–68

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 the potential of batiraxcept to increase the clinical activity of cabozantinib in patients with metastatic ccRCC who have progressed following IO- and VEGF-TKI-based therapies and the combination of batiraxcept and cabozantinib exhibiting its greatest impact in those patients who have failed prior VEGF-TKI therapies. 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 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