Aravive Initiates a Phase 2a Clinical Trial of AVB-500 in Patients with Kidney Fibrosis

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HOUSTON, Dec. 20, 2019 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company, today announced that the company has begun enrolling patients in the Phase 2a clinical trial of AVB-500 in patients with kidney fibrosis, specifically IgA Nephropathy (IgAN) (NCT04042623).

“We are very pleased to initiate this first trial of AVB500 in patients with renal fibrosis,” said Gail McIntyre Ph.D., DABT, CSO at Aravive. “GAS6 is more highly expressed in human IgAN tissues than normal kidney tissue, GAS6 levels correlate with severity of the disease and inhibition of the pathway preclinically has demonstrated a positive effect.”

This is an open-label Phase 2a clinical study designed to evaluate the safety and efficacy of AVB500 in patients with biopsy-proven IgAN and excreting 1-3 grams of protein daily in their urine. The primary endpoints will be safety of AVB500 in the population and efficacy of AVB500 treatment on decreasing the amount of protein in the urine.

IgAN, also known as Berger's disease, is a kidney disease that occurs when an antibody called immunoglobulin A builds up in the kidneys. This results in local inflammation that, over time, damages the kidneys. Preclinical studies have demonstrated that GAS6 acts as a mitogen, stimulating mesangial cell proliferation through binding to its cell-surface receptor AXL and an AXL decoy protein can inhibit mesangial cell proliferation by interfering with the GAS6/AXL pathway. IgA nephropathy usually progresses slowly over years and patients can develop end-stage kidney failure, requiring dialysis. No cure exists for IgAN, but certain medications can slow its course.

About AVB-500
AVB-500 is a therapeutic recombinant fusion protein that has been shown to neutralize GAS6 activity by binding to GAS6 with very high affinity. In doing so, AVB-500 selectively inhibits the GAS6-AXL signaling pathway. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity, both as a single agent and 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 is correlated to poor prognosis and survival, and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies.

Aravive reported positive data from the expansion cohort in the Phase 1b portion of a Phase 1b/2 clinical trial of AVB-500 in platinum-resistant recurrent ovarian cancer. AVB-500 continues to be well tolerated with no dose limiting toxicities. An investigator-sponsored Phase 1 study of AVB-500, in combination with durvalumab in patients with platinum-resistant recurrent epithelial ovarian cancer, is also ongoing. Based on AVB-500’s safety profile and specifically targeted mechanism of action, this drug candidate has the potential to be used both in combination with existing therapies, as well as a maintenance drug. The U.S. Food and Drug Administration granted Fast Track Designation to AVB-500 in platinum-resistant recurrent ovarian cancer.

About Aravive
Aravive, Inc. (Nasdaq: ARAV) is a clinical-stage biopharmaceutical company developing treatments designed to halt the progression of life-threatening diseases, including cancer and fibrosis. Aravive’s lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway. By capturing serum GAS6, AVB-500 starves the AXL pathway of its signal, potentially halting the biological programming that promotes disease progression. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. The GAS6-AXL signaling pathway also plays a significant role in fibrogenesis. Aravive is evaluating AVB-500 in platinum-resistant ovarian cancer and kidney fibrosis and intends to expand development into additional oncology and fibrotic indications. Aravive is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. For more information, please visit www.aravive.com.

Forward-Looking Statements
This communication contains forward-looking statements (including within the meaning of Section 21E of the United States Securities Exchange Act of 1934, as amended, and Section 27A of the United States Securities Act of 1933, as amended), express or implied, concerning the potential of AVB-500 to be used both in combination with existing therapies, as well as a maintenance drug, the potential of AVB-500 to halt the biological programming that promotes disease progression and the expansion of the development of AVB-500 into additional oncology and fibrotic indications. 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 Company’s ability to expand development in 2019 into additional oncology and fibrotic indications, the Company’s dependence upon AVB-500, AVB-500’s ability to have favorable results in clinical trials or 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 AVB-500 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 AVB-500; if AVB-500 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 and Form 10-K/A for the fiscal year ended December 31, 2018, 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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