Aravive Announces Initiation of Investigator-Sponsored Phase 1/2 Study of AVB-500 in Combination with Avelumab in Patients with Advanced Urothelial Carcinoma (COAXIN)

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HOUSTON, March 24, 2020 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company, announced that the first patient has been dosed in an investigator-sponsored Phase 1/2 clinical trial of the company's GAS6/AXL inhibitor AVB-500 in combination with PD-L1 inhibitor avelumab in patients with advanced urothelial carcinoma (UC). The study is being led by Abhishek Tripathi, M.D., Assistant Professor of Medicine, Section of hematology/oncology at the University of Oklahoma Stephenson Cancer Center.

"Locally advanced or metastatic urothelial carcinoma is an aggressive cancer with poor long-term survival," said Dr. Tripathi. "Although immunotherapy results in durable responses in some patients, only a small proportion of patients respond and most eventually progress. Targeting additional mechanisms of immunosuppression and tumor growth such as GAS6/AXL signaling could be synergistic with immunotherapy and may improve outcomes in this challenging disease."

The COAXIN study is a multi-center, single arm, Phase 1/2 trial evaluating safety and preliminary antitumor efficacy of avelumab in combination with AVB-500 in patients with advanced UC. The trial starts with a Phase 1 cohort to establish the maximum tolerated dose (MTD) of AVB-500 in combination with avelumab and to allow for assessment of potential dose-limiting toxicities. The primary endpoint of the study is objective response rate. Secondary outcome measures include progression free survival, clinical benefit rate, duration of response and overall survival. The trial is listed on clinicaltrials.gov NCT04004442. Patient enrollment and continuation on study may be impacted by COVID-19.

About Urothelial Cancer
Globally, urothelial cancer accounts for approximately 450,000 new cancer cases and 165,000 deaths every year (World Cancer Report, 2013). Platinum-based combination chemotherapy has been the cornerstone of treatment for patients with incurable metastatic disease. Gemcitabine and cisplatin (GC) and conventional or dose-dense methotrexate, vinblastine, doxorubicin and cisplatin (MVAC) are the commonly utilized regimens in this setting. Although initial responses are seen in approximately 40% of patients, most eventually experience disease progression. A significant proportion of patients are ineligible for cisplatin due to suboptimal renal function, poor performance status, congestive heart failure, neuropathy or hearing loss. Until recently, single agent chemotherapy or best supportive care were the only treatment options for such patients and the median overall survival (OS) was around 5 to 7 months.

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 first 31 patients enrolled 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. An investigator-sponsored Phase 1/2 trial 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, clear cell renal cell carcinoma 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, such as targeting additional mechanisms of immunosuppression and tumor growth such as Gas6/AXL signaling could be synergistic with immunotherapy and may improve outcomes in this challenging disease, 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 2020 into additional oncology and fibrotic indications, the Company's dependence upon AVB-500, AVB-500's ability to have favorable results in clinical trials, the clinical trials of AVB-500 having results that are as favorable as those of preclinical and clinical studies, 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 outbreak; 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.

Contacts for Aravive:

Investors:
Christina Tartaglia
Stern Investor Relations
christina@sternir.com

Media:
Heidi Chokeir, Ph.D.
Canale Communications
heidi@canalecomm.com
619-203-5391

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