# Aravive Biologics Initiates Phase 1b Portion of Phase 1b/2 Clinical Trial of AVB-S6-500 in Platinum-Resistant Recurrent Ovarian Cancer

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HOUSTON, Dec. 11, 2018 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company, today announced that the company has begun treating patients in the Phase 1b portion of a Phase 1b/Phase 2 trial combining AVB-S6-500 with standard-of-care therapies in patients with platinum-resistant recurrent ovarian cancer.

“We are very pleased to initiate this first trial of AVB-S6-500 in patients with ovarian cancer,” said Gail McIntyre Ph.D., DABT, Senior Vice President of R&D at Aravive. “Our initial Phase 1 clinical trial of this agent in healthy volunteers showed a favorable safety and tolerability profile, with no reported serious adverse events and no adverse events that limited dosing in the trial. We also suppressed circulating free GAS6 across all dose levels and higher doses suppressed circulating free GAS6 for a longer duration than lower doses. We anticipate the measurement of circulating free GAS6 will be highly useful as a biomarker of drug activity in this new trial. A reduction in this biomarker has correlated to anti-tumor activity in preclinical studies.”

“We are excited to have begun enrollment in this clinical trial of platinum-resistant ovarian cancer,” said study investigator Bradley Monk, MD, FACOG, FACS, Professor, University of Arizona College of Medicine and Medical Director, US Oncology Research Network – Gynecologic Program. “There are limited therapeutic options for platinum-resistant patients and the GAS6/AXL pathway is known to drive progression and resistance to treatments in ovarian cancer. Agents with a favorable safety profile like AVB-S6-500 offer a great opportunity for improving outcomes for our patients.”

The open label Phase 1b safety lead-in portion of the trial will enroll patients with platinum-resistant recurrent ovarian cancer and aims to confirm the dose based on results from the healthy volunteer clinical trial of AVB-S6-500. The primary endpoint for the Phase 1b portion of the clinical trial is safety, and pharmacokinetic/pharmacodynamic measurements with secondary endpoints including preliminary activity measures. The clinical trial will also explore AVB-S6-500 effects on biomarkers (GAS6-AXL) in serum and tumor tissues.

Elevated GAS6 levels have been associated with poor prognosis in cancer. As a decoy molecule, AVB-S6-500 has been shown to neutralize GAS6 activity by binding to that molecule with very high affinity. In doing so, AVB-S6-500 selectively inhibits triggering of the GAS6-AXL signaling pathway. In preclinical studies, GAS6-AXL inhibition has shown activity, whether achieved by a single agent (including AVB-S6-500) or through combinations of a variety of anticancer therapies including radiation therapy, immuno-oncology agents, and chemotherapeutic drugs that affect DNA replication and repair.

**About Aravive**

Aravive, Inc. (Nasdaq: ARAV) is a clinical stage biopharmaceutical company focused on developing innovative therapies that target important survival pathways for cancer. Aravive’s lead candidate, AVB-S6-500, is a novel, high-affinity, soluble Fc-fusion protein designed to block the activation of the GAS6-AXL signaling pathway by intercepting the binding of GAS6 to its receptor AXL. AXL receptor signaling plays an important role in multiple types of malignancies by promoting metastasis, cancer cell survival, resistance to treatments, and immune suppression. Aravive has initiated the Phase 1b portion of a Phase 1b/2 clinical trial of AVB-S6-500 combined with standard of care therapies in patients with platinum-resistant recurrent ovarian cancer, and intends to expand development into additional tumor types. 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 Company's goals, intentions and expectations as to future plans or events, including statements regarding the measurement of circulating free GAS6 being highly useful as a biomarker of drug activity in the new trial, AVB-S6-500 offering the opportunity to improve outcomes for patients and the Company’s hope to expand development in 2019 into additional tumor types. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could 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 usefulness of circulating free GAS6 as a biomarker of drug activity in the new trial, the Company’s ability to expand development in 2019 into additional tumor types, AVB-S6-500’s ability to have favorable results in clinical trials or receive regulatory approval, including its ability to meet the primary and secondary endpoint for the Phase 1b portion of the clinical trial and show a clinical benefit against refractory and metastatic cancers; potential delays in the Company's clinical trials due to regulatory requirements or difficulty identifying qualified investigators or enrolling patients; the risk that AVB-S6-500 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-S6-500; if AVB-S6-500 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 proxy statement/prospectus/information statement filed with the SEC on September 6, 2018, the Company's Form S-4 filed with the SEC on August 3, 2018, as subsequently amended, Annual Report on Form 10-K and Form 10-K/A for the fiscal year ended December 31, 2017, Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, and recent Current Reports on Form 8-K, each as filed with or furnished to 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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