# Aravive Presents Detailed Results of Phase 1 Clinical Trial of AVB-S6-500 at the 2018 EORTC-NCI-AACR Symposium

November 13, 2018

HOUSTON, Nov. 13, 2018 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage biopharmaceutical company, today announced detailed results of its first-in-human Phase 1 clinical trial of AVB-S6-500 in healthy volunteers. As previously announced, the trial met the safety and tolerability endpoints for the trial and demonstrated clinical proof-of-mechanism for AVB-S6-500 in neutralizing GAS6, a key molecule in the AXL cancer survival pathway. These detailed data are being presented today in a poster presentation at the Molecular Targets and Cancer Therapeutics 2018 EORTC-NCI-AACR Symposium.

“The Phase 1 clinical trial in healthy volunteers demonstrated that AVB-S6-500 was well tolerated with an acceptable safety profile. Using the pharmacodynamic data generated from this clinical trial, we have identified a dose for our upcoming Phase 1b clinical trial in platinum-resistant recurrent ovarian cancer,” said Gail McIntyre Ph.D., DABT, Senior Vice President of R&D at Aravive.

The Phase 1 clinical trial was designed to assess safety, pharmacokinetics (PK) and pharmacodynamics (PD) of single ascending and repeat doses of AVB-S6-500. The clinical trial dosed 42 healthy volunteers in 5 dose cohorts. The single ascending dose portion consisted of 4 sequential dose escalation cohorts (1, 2.5, 5 and 10 mg/kg), whereas the repeat dose portion consisted of a single dose cohort (5mg/kg) receiving 4 weekly doses. Drug levels and serum GAS6 (sGAS6) levels were assessed using Aravive’s proprietary PD assay. Use of this proprietary PD assay expedited the AVB-S6-500 development program by guiding dose selection for future trials in cancer patients. This strategy minimizes administration of sub-pharmacologically active doses to cancer patients and identifies different dosing regimens to complement those of combination chemotherapy. The ability to test potential pharmacologically active doses from the start of the Phase 1b clinical trial offers the potential to assess signs of efficacy earlier in development.

There were no serious adverse events (AEs) and AVB-S6-500 was well tolerated across all doses. Serum GAS6 levels were suppressed for 22 and 29 days following single doses of 5 mg/kg and 10 mg/kg, respectively. Weekly administration of 5 mg/kg resulted in suppression of sGAS6 in 4 out of 6 subjects for at least 3 weeks after the fourth dose. Preclinical PK/PD modeling with Phase 1 healthy volunteer data and simulating increases in sGAS6 suggested that dosing regimens of 5 mg/kg every week or 10 mg/kg every other week would abrogate sGAS6 levels in cancer patients. Based on these data, Aravive has selected the 10 mg/kg every other week as the initial dose in the Phase 1b clinical trial of AVB-S6-500 in platinum-resistant recurrent ovarian cancer. The Phase 1b clinical trial of AVB-S6-500 in combination with standard of care chemotherapy in platinum-resistant recurrent ovarian cancer is expected to enroll its first patient before the end of 2018.

A copy of the poster presentation, entitled, "Expedited Development of AVB-S6 through the use of a Proprietary Biomarker in Healthy Volunteers to Guide Dosing in Oncology Studies," will be made available at www.aravive.com.

**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 expects to initiate 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 before the end of 2018, 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, the ability to test potential pharmacologically active doses from the start of the Phase 1b clinical trial offering the potential to assess signs of efficacy earlier in development, the expected timing of initiation of the Phase 1b portion of the Company’s Phase 1b/2 clinical trial in patients with platinum-resistant recurrent ovarian cancer, the expectation that dosing regimens of 5 mg/kg every week or 10 mg/kg every other week would abrogate sGAS6 levels in cancer patients and the plan to expand the development of AVB-S6-500 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 Company’s success being heavily dependent on AVB-S6-500 ; the risk that AVB-S6-500 may not 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-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.

Contacts:

*Investors:*
Mike Zanoni
Endurance Advisors
mzanoni@enduranceadvisors.com
610-442-8570

*Media:*
Joan Kureczka
Bioscribe, Inc.
Joan@bioscribe.com
415-821-2413

Source: Aravive, Inc.