Aravive and AstraZeneca Announce Initiation of Randomized Phase 1/2 Study of AVB-500 in Combination with Durvalumab in Patients with Platinum-Resistant Recurrent Epithelial Ovarian Cancer

November 12, 2019

Investigator-sponsored study being conducted in clinical collaboration with Aravive and AstraZeneca

HOUSTON and WILMINGTON, Del., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV) and AstraZeneca (NYSE: AZN) today announced that an investigator-sponsored Phase 1/2 clinical trial of AVB-500, a GAS6/AXL inhibitor, in combination with durvalumab, a PD-L1 inhibitor, in patients with platinum-resistant, recurrent epithelial ovarian cancer has initiated and is recruiting patients. The clinical trial is jointly funded by Aravive and AstraZeneca.

“GAS6/AXL signaling plays a key role in immune evasion, suggesting that inhibition of this pathway has the potential to augment the anti-tumor effects of an anti-PD-L1 agent to achieve better outcomes for patients,” said Gail McIntyre, Ph.D., chief scientific officer of Aravive. “Consequently, we believe there is a strong mechanistic and clinical rationale for exploring the potential of AVB-500 in combination with a checkpoint inhibitor in the treatment of ovarian cancer.”

This open-label trial will begin with a Phase 1b safety lead-in phase to determine the recommended Phase 2 dose (RP2D) for the combination of AVB-500 and durvalumab. In the Phase 2 portion, eligible subjects will participate in a 6-week monotherapy cycle randomized to either AVB-500 or durvalumab before receiving the combination therapy at the RP2D. Patients will receive treatment until progression or unacceptable toxicity with combination therapy. The study is listed on clinicaltrials.gov NCT04019288.

“There is a significant need for effective treatments that don't add to the treatment burden for women with ovarian cancer,” said Laura Bonifacio, Pharm.D., Ph.D., vice president of clinical operations at Aravive.

About Ovarian Cancer
Each year in the United States, more than 22,000 women develop ovarian cancer and there are approximately 14,240 attributed deaths annually, making ovarian cancer the deadliest of gynecologic malignancies.

About AVB-500
AVB-500 (previously AVB-S6-500) 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. A Phase 1 clinical trial in healthy volunteers (NCT03401528) investigating the safety, pharmacokinetics, and pharmacodynamics of AVB-500 met the safety and tolerability endpoints and demonstrated clinical proof-of-mechanism for AVB-500 in neutralizing GAS6. Based on AVB-500’s favorable safety profile, coupled with its 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 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 belief that there is a strong mechanistic and clinical rationale for exploring the potential of AVB-500 in combination with a checkpoint inhibitor in the treatment of ovarian cancer, the suggestion that inhibition of the GAS6-AXL pathway has the potential to augment the anti-tumor effects of an anti-PD-L1 agent to achieve better outcomes for patients, 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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