Aravive Reports Positive Data Supporting Relationship Between AVB-500 Levels, Anti-Tumor Activity and Progression Free Survival in Women with Ovarian Cancer

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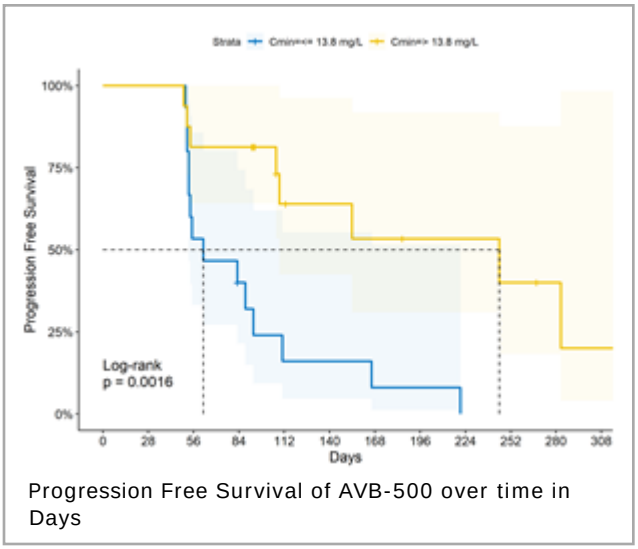
Statistically significant four-fold increase in progression free survival observed in women with high AVB-500 levels



Progression Free Survival of AVB-500 over time in Days

Aravive to Host Conference Call Today at 8 a.m. EST

HOUSTON, Nov. 20, 2019 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV) today announced new positive data from the ongoing Phase 1b portion of the Phase 1b/2 clinical trial of AVB-500 in platinum-resistant recurrent ovarian cancer patients. The data from the first 31 patients treated at the 10mg/kg dose are maturing and affirm earlier findings on the relationship between AVB-500 levels and anti-tumor response. In this data analysis, high serum drug levels of AVB-500 were strongly predictive of anti-tumor activity with statistically significant correlation to progression-free survival (PFS; p=0.0066). PFS is the primary endpoint for platinum-resistant ovarian cancer clinical trials.

At the 10 mg/kg dose, patients that met or exceeded the minimal efficacious concentration of AVB-500 demonstrated a greater than four-fold increase in median PFS over those with low exposure (8.1 vs. 1.8 months; p=0.0016) and approximately two-fold improvement in overall response rate (ORR; 29% vs. 14%), including one complete response (CR). Patients who achieved sufficient AVB-500 exposure also showed improvements in duration of response (from 7.6 to 3.9 months) and clinical benefit rate (82% vs. 43%), with reduced chance of progressing by 3.2-fold (from 57% to 18%).

“Platinum-resistant ovarian cancer is one of the most difficult diseases to treat, not only because of the poor prognosis, but because of the toxicities associated with chemotherapies,” said Katherine Fuh, M.D., Ph.D., Assistant Professor in Obstetrics and Gynecology, Washington University School of Medicine, and an investigator in the study. “The safety profile of AVB-500 along with the emerging data showing improvement in clinical benefit rate and progression-free survival, support the use of AVB-500 to change the treatment landscape for these patients.”

The open-label, Phase 1b portion of the Phase 1b/2 clinical trial of AVB-500 enrolled patients with platinum-resistant recurrent ovarian cancer in two cohorts, one investigating a combination of AVB-500 with pegylated liposomal doxorubicin (PLD) and the other a combination with paclitaxel (PAC). All patients were treated with 10mg/kg AVB-500 every other week. The company previously reported drug exposure-response relationship among the initial patients receiving 10 mg/kg.

The study identified a minimal efficacious concentration (MEC) (trough level greater than 13.8 mg/L) that is consistent with at least 95% target engagement based on independent pharmacokinetic (PK) modeling. At the 10 mg/kg dose, 17 of 31 patients in the study (approximately 50%) achieved the minimal efficacious concentration after the first dose of AVB-500.

The baseline characteristics, demographics and safety parameters were comparable between patients who achieved the minimal efficacious concentration and those who fell below that threshold. The analysis shows that the clinical benefit at this dose level in the study can be primarily attributed to AVB-500 exposure.

The analysis of the best overall response by investigator determined RECIST v1.1 criteria data are summarized in the table below:

	High AVB-500	**Low AVB-500 Exposure***

	Exposure*	
Number of Patients (n)	17	14
Complete Response (CR)	1** (6%)	0
Partial Response (PR)	4 (24%)	2 (14%)
Overall Response (ORR, PR+CR)	5 (29%)	2 (14%)
Stable Disease (SD)	9 (53%)	4 (28%)
Progressive Disease (PD)	3 (18%)	8 (57%)
Clinical Benefit (SD+PR)	14 (82%)	6 (43%)
Median PFS (months)	8.1	1.8
Median DOR (months)	7.6	3.9
Number of patients still on study* **	8 (47%)	0

** High vs. Low is based on above or below MEC, respectively*
***Needs to be confirmed with repeat scan*
**** As of Oct. 31, 2019*

The company cautions that the data analyses were conducted on a small patient population (n=31).

Other notable findings:

- The patient with CR that is pending confirmation achieved the MEC of AVB-500 and was on paclitaxel. She had a baseline serum GAS6 level typical of the platinum-resistant ovarian cancer population and two-fold higher than that observed in healthy volunteers. She also exhibited poor prognostic factors, including two prior lines of therapy and platinum-free interval of less than three months.

- Among the patients who responded to AVB-500, four of seven remain responders and continue on study, and two patients remain on AVB-500 as a single agent. All four patients achieved the minimal efficacious AVB-500 concentration.

- Among the 13 patients whose best response was SD, four achieved the MEC of AVB-500 and remain on study. One SD patient, whose trough level was below the minimal efficacious concentration, did not progress but withdrew consent. Because the study is still ongoing and includes only patients above the MEC, duration of response and PFS may continue to evolve.

“The strong exposure-response relationship suggests that AVB-500 is adding to the clinical benefit experienced by patients on standard of care therapy,” said Gail McIntyre, Ph.D., chief scientific officer of Aravive. “The improvements in progression-free survival with AVB-500 bodes well for future studies where that will be the primary endpoint measured to support regulatory filing.”

These data confirm the company’s strategy to investigate higher doses in the current Phase 1b study, to determine if a greater proportion of patients can exceed the MEC. According to our modeling, a dose of 20 mg/kg should allow greater than 90% of the patients to achieve the MEC. It is anticipated 6 to 12 patients will be treated with 15mg/kg and an additional 12 patients will be treated with 20mg/kg. An independent safety monitoring group will review data from the 15mg/kg group prior to escalation to the 20mg/kg dose.

AVB-500 continues to be well-tolerated and there have been no serious and unexpected adverse reactions or dose-limiting toxicities to date.

Conference Call Information:
Aravive will host a live conference call and webcast at 8:00 a.m. ET today to discuss these clinical data. The conference call may be accessed by dialing (844) 281-9845 (domestic) and (314) 888-4254 (international) and referring to conference ID 2965263. A webcast of the conference call will be available in the Investors section of the Aravive website at https://ir.aravive.com/. The archived webcast will be available on Aravive’s website after the conference call.

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 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 strong exposure-response relationship suggesting that AVB-500 is adding to the clinical benefit experienced by patients on standard of care therapy, the safety profile of AVB-500 along with the improvement in clinical benefit rate and progression-free survival supporting the use of AVB-500 to change the treatment landscape for these patients, the improvements in progression-free survival with AVB-500 boding well for future pivotal studies where that will be the primary endpoint measured to support regulatory filing, a dose of 20 mg/kg should allow 90% or greater of the patients to achieve the desired high drug exposure levels, the existence of a dose response relationship with AVB-500, 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.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/e1c0c0cf-1964-49a0-bc8b-4ca5f3e2cc8d

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