Aravive Reports Third Quarter 2021 Financial Results and Provides Corporate Updates

October 28, 2021

- Dosed first patient in batiraxcept (formerly AVB-500) Phase 1b clinical trial in pancreatic adenocarcinoma
- Orphan drug designation granted by European Commission to batiraxcept in platinum resistant ovarian cancer
- New preliminary data from batiraxcept Phase 1b clinical trial in clear cell renal cell carcinoma to be presented at 2021 Society for Immunotherapy of Cancer Annual Meeting

HOUSTON, Oct. 28, 2021 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers, today announced recent corporate updates and financial results for the third quarter ended September 30, 2021.

“During the third quarter, we expanded our clinical oncology pipeline with the initiation of a Phase 1b trial of batiraxcept (AVB-500) for the treatment of pancreatic adenocarcinoma,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “Aravive is now advancing three clinical trials for life threatening cancers with unmet medical needs. We look forward to presenting new preliminary data from our Phase 1b trial of batiraxcept in clear cell renal cell carcinoma at the upcoming Society for Immunotherapy of Cancer Annual Meeting in November. We remain optimistic about the broad potential of batiraxcept to improve the lives of people living with cancer.”

Recent Corporate Highlights

- **Batiraxcept (AVB-500) in Platinum Resistant Ovarian Cancer (PROC):** As a result of the evolving pandemic and other factors, the pace of enrollment in the registrational Phase 3 clinical trial of batiraxcept in PROC has been slower than originally anticipated. Aravive now expects to conduct the interim analysis in mid-2022. The interim analysis is being conducted to determine whether randomization will continue with all patients, regardless of prior bevacizumab treatment, or only with patients medically ineligible to receive bevacizumab or who chose not to receive bevacizumab. The final analysis of the primary endpoint preserves the opportunity to evaluate the efficacy in patients who received bevacizumab prior to study entry, as well as those patients who never received bevacizumab. This provides an additional opportunity to be successful in both patient populations, regardless of the results of the interim analysis. The global, randomized, double-blind, placebo-controlled adaptive trial is designed to evaluate efficacy and safety of batiraxcept at a dose of 15 mg/kg in combination with paclitaxel versus paclitaxel alone.

  In October, the European Commission granted orphan drug designation to batiraxcept for the treatment of PROC. Orphan drug designation is granted for medicines being developed for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 people in the European Union.

- **Batiraxcept in Clear Cell Renal Cell Carcinoma (ccRCC):** Aravive plans to present new preliminary data from the Phase 1b portion of its Phase 1b/2 clinical trial of batiraxcept in ccRCC at the Society for Immunotherapy of Cancer Annual Meeting on November 13, 2021. The Company previously announced positive initial safety, pharmacokinetic and pharmacodynamic results from three patients dosed with 15 mg/kg of batiraxcept in combination with cabozantinib in the Phase 1b portion of the trial. Aravive expects to complete enrollment in the Phase 1b portion of the trial and initiate the Phase 2 portion of the trial in the fourth quarter of 2021.

- **Batiraxcept in Pancreatic Adenocarcinoma:** In August 2021, Aravive dosed the first patient in the Phase 1b portion of its Phase 1b/2 trial of batiraxcept in combination with gemcitabine and nab-paclitaxel as a first-line treatment in patients with advanced or metastatic pancreatic adenocarcinoma. The Phase 1b portion of the clinical trial will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of batiraxcept in combination with gemcitabine and nab-paclitaxel. The Company expects to complete enrollment in the Phase 1b portion of the trial in the first half of 2022 and initiate the Phase 2 portion of the trial in the second half of 2022.

- **Achieved Second Development Milestone with 3D Medicines:** In July 2021, Aravive achieved a $3.0 million development milestone based on the Center for Drug Evaluation of the China National Medical Products Administration approval of the Investigational New Drug application submitted by 3D Medicines Inc. to participate in Aravive’s registrational Phase 3 clinical trial of batiraxcept in PROC. The Company received the $3.0 million development milestone payment in the third quarter of 2021. Under the terms of the collaboration and license agreement with 3D Medicines, Aravive is eligible to receive up to an aggregate of $207 million in development and commercial milestone payments and royalties.

Third Quarter 2021 Financial Results
Revenue for the three and nine months ended September 30, 2021 were $2.4 million and $6.5 million, respectively, compared to $0 for both periods in 2020. Revenue for the three and nine months ended September 30, 2021 was derived solely from the Company's collaboration and license agreement with 3D Medicines and represents a portion of initial signing and milestone payments received from 3D Medicines that is recognized at the time of the receipt and a portion of the payments that is deferred and recognized over the PROC trial period.

Total operating expenses for the three and nine months ended September 30, 2021 were $14.0 million and $33.4 million, respectively, compared to $10.7 million and $26.7 million for the same periods in 2020.

Total operating expenses for the three and nine months ended September 30, 2021 included non-cash stock-based compensation expense of $0.6 million and $1.7 million, respectively, compared to $0.4 million and $1.6 million for the same periods in 2020. In addition, during the nine months ended September 30, 2020, there were non-recurring non-cash charges for impairment of the Company's right-of-use asset and leasehold improvements of $5.8 million.

For the three and nine months ended September 30, 2021, Aravive reported a net loss of $11.1 million and $26.2 million, or $0.53 per share and $1.33 per share, respectively, compared to a net loss of $10.7 million and $26.5 million, or $0.66 per share and $1.69 per share, for the same periods in 2020.

Cash Position
As of September 30, 2021, cash and cash equivalents were $67.5 million, compared to $60.5 million as of December 31, 2020. Based upon its current operating plan and balance sheet as of September 30, 2021, Aravive expects to have sufficient cash to be able to fund the base operating plan into the second half of 2022.

About Batiraxcept (Formerly AVB-500)
Batiraxcept is a therapeutic recombinant fusion protein that has been shown to neutralize GAS6 activity by binding to GAS6 with very high affinity in preclinical models. In doing so, batiraxcept selectively inhibits the GAS6-AXL signaling pathway, which is upregulated in multiple cancer types including ovarian, renal and pancreatic cancer. In preclinical studies, GAS6-AXL inhibition has shown anti-tumor activity 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 has been correlated with poor prognosis and decreased survival and has been implicated in therapeutic resistance to conventional chemotherapeutics and targeted therapies. Batiraxcept is currently being evaluated in multiple clinical trials and has been granted Fast Track designation by the U.S. Food and Drug Administration and orphan drug designation by the European Commission in platinum resistant recurrent ovarian cancer. Analysis of all safety data to date showed that batiraxcept has been generally well tolerated with no dose-limiting toxicities or unexpected safety signals.

About Aravive
Aravive, Inc. is a clinical-stage oncology company developing transformative, targeted therapeutics to treat life-threatening cancers. The Company is currently evaluating its lead therapeutic, batiraxcept (formerly AVB-500), in a registrational Phase 3 trial in platinum resistant ovarian cancer, a Phase 1b/2 trial in second line plus, clear cell renal cell carcinoma, and a Phase 1b/2 trial in first-line treatment of pancreatic adenocarcinoma. The Company 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 within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions and includes statements regarding the broad potential of batiraxcept to improve the lives of people living with cancer, conducting an interim analysis of the Phase 3 clinical trial of batiraxcept in PROC in mid-2022, completion of enrollment in the Phase 1b portion of the Phase1b/2 clinical trial in clear cell renal cell carcinoma and initiation of the Phase 2 portion of the trial in the fourth quarter of 2021, plans to present new preliminary data from the Phase 1b portion of its Phase 1b/2 clinical trial of batiraxcept in ccRCC at the Society for Immunotherapy of Cancer Annual Meeting in November, completion of enrollment in the Phase 1b portion of the Phase 1b/2 trial of batiraxcept in combination with gemcitabine and nab-paclitaxel as a first-line treatment in patients with advanced or metastatic pancreatic adenocarcinoma in the first half of 2022 and initiation of the Phase 2 portion of the trial in the second half of 2022, cash and cash equivalents being sufficient to fund operations into the second half of 2022 and the potential of batiraxcept to be combined with multiple anti-cancer therapies across several tumor types. 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 ability to conduct an interim analysis of its Phase 3 clinical trial of batiraxcept in PROC in mid-2022, complete enrollment in the Phase 1b portion of the Phase1b/2 clinical trial in clear cell renal cell carcinoma and initiate the Phase 2 portion of the trial in the fourth quarter of 2021, the ability to complete enrollment of the Phase 1b portion of the Phase 1b/2 pancreatic adenocarcinoma trial in the first half of 2022 and initiation of the Phase 2 portion of the trial in the second half of 2022, the ability to enroll the expected number of patients, the ability to combine batiraxcept with multiple anti-cancer therapies across several tumor types, the impact of COVID-19 on the Company's clinical strategy, clinical trials, supply chain and fundraising, the Company's ability to expand development into additional indications, the Company's dependence upon batiraxcept, batiraxcept's ability to have favorable results in clinical trials and ISTs, the clinical trials of batiraxcept having results that are as favorable as those of preclinical and clinical trials, 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 pandemic; the risk that batiraxcept 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 batiraxcept; if batiraxcept 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 its cash and cash equivalents being sufficient to fund its planned operations and its 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 for the fiscal year ended December 31, 2020, 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.

Aravive, Inc.

Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
Collaboration revenue	$ 2,412	$ —	$ 6,457	$ —
Total revenue	2,412	—	6,457	—
Operating expenses				
Research and development	11,343	5,070	25,347	11,085
General and administrative	2,643	2,715	8,102	9,866
Loss on impairment of long-lived assets	—	2,914	—	5,784
Total operating expenses	13,986	10,699	33,449	26,735
Loss from operations	(11,574)	(10,699)	(26,992)	(26,735)
Interest income	9	8	29	251
Other income (expense), net	479	31	768	(13)
Net loss	$ (11,086)	$ (10,660)	$ (26,195)	$ (26,497)
Net loss per share- basic and diluted	$ (0.53)	$ (0.66)	$ (1.33)	$ (1.69)
Weighted-average common shares used to compute basic and diluted net loss per share	20,763	16,055	19,758	15,658

Aravive, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2021	December 31, 2020
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 67,511	$ 60,541
Restricted cash	2,430	2,430
Other assets	4,458	1,781
Operating lease right-of-use assets	2,394	2,958
Total assets	$ **76,793**	$ **67,710**
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 6,574	$ 4,823
Deferred revenue	8,913	6,315
Operating lease obligation	6,970	8,517
Total liabilities	22,457	19,655
Total stockholders' equity	54,336	48,055
Total liabilities and stockholders' equity	$ **76,793**	$ **67,710**

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