Aravive Reports Second Quarter 2021 Financial Results and Provides Corporate Updates

August 5, 2021

- Positive initial results from AVB-500 Phase 1b portion of Phase 1b/2 clinical trial in clear cell renal cell carcinoma; expect to initiate Phase 2 trial in second half of 2021
- On track to initiate the AVB-500 Phase 1b/2 clinical trial in pancreatic adenocarcinoma in second half of 2021
- Achieved development milestones from 3D Medicines
- Board of Directors strengthened and expanded with three new members with extensive experience in the biopharmaceutical industry

HOUSTON, Aug. 05, 2021 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases, today announced recent corporate updates and financial results for the second quarter ended June 30, 2021.

“Aravive continued to make strong progress in advancing the development of AVB-500 in the second quarter of 2021,” said Gail McIntyre, Ph.D., DABT, Chief Executive Officer of Aravive. “We are very encouraged by the positive preliminary pharmacokinetic/pharmacodynamic results from the patients dosed at 15 mg/kg in the first portion of the Phase 1b trial of AVB-500 in clear cell renal cell carcinoma, and we plan to initiate the Phase 2 trial in the second half of 2021. Additionally, we are on track to initiate the Phase 1b/2 trial evaluating AVB-500 as a first-line treatment for pancreatic adenocarcinoma, another area of high, unmet medical need, in the second half of 2021.”

Recent Corporate Highlights

- **AVB-500 in Platinum Resistant Ovarian Cancer (PROC):** In April 2021, Aravive announced that the first patient was dosed in its registrational Phase 3 trial of AVB-500 in PROC. The global, randomized, double-blind, placebo-controlled adaptive trial is designed to evaluate efficacy and safety of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel versus paclitaxel alone. The Company expects to conduct the interim analysis in the first quarter of 2022.

- **AVB-500 in Clear Cell Renal Cell Carcinoma (ccRCC):** In June 2021, Aravive announced positive initial safety, pharmacokinetic and pharmacodynamic results from the Phase 1b portion of its Phase 1b/2 trial in patients dosed with 15 mg/kg of AVB-500 in combination with cabozantinib who have ccRCC (advanced stage kidney cancer). The data in three evaluable patients showed that AVB-500 was well tolerated with no adverse findings. Based on the pharmacokinetics, pharmacodynamics, and safety data at 15 mg/kg of AVB-500, and approval by the Data and Safety Monitoring Board (DSMB), the Company has expanded the dosing of 15 mg/kg of AVB-500 to at least three additional patients to determine the potential of initiating the Phase 2 portion with this dose. The Company will also continue to investigate higher doses of AVB-500 in the Phase 1b trial to obtain additional safety, pharmacokinetics, and pharmacodynamics information. Aravive expects to complete enrollment in the Phase 1b portion of the Phase 1b/2 trial and initiate the Phase 2 trial in the second half of 2021.

- **Achieved One Development Milestone with 3D Medicines in Q2 and One Milestone in July 2021 Totaling $9 million in Milestone Payments:** In July 2021, Aravive achieved a $3.0 million development milestone based on the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) approval of the Investigational New Drug (IND) application submitted by 3D Medicines Inc. to participate in Aravive’s international AVB-500 Phase 3 PROC clinical trial. The Company also received a $6.0 million milestone payment in June 2021 related to the first patient dosed by Aravive in the AVB-500 Phase 3 registrational clinical trial for PROC in the United States. 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, including the $9 million already achieved.

- **Expanded and Strengthened Board of Directors:** Aravive appointed three highly experienced biopharmaceutical industry executives, John A. Hohneker, M.D., Sigurd C. Kirk, and Peter T.C. Ho, M.D., Ph.D., to its Board of Directors. Dr. Hohneker serves on the Compensation Committee of the Board, and Mr. Kirk serves on the Audit Committee.

Second Quarter 2021 Financial Results

Revenue for the three and six months ended June 30, 2021 were $3.8 million and $4.0 million, respectively, compared to $0 for both periods in 2020. Revenue for the three and six months ended June 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 six months ended June 30, 2021 were $11.2 million and $19.5 million, respectively, compared to $5.7 million and $16.0 million for the same periods in 2020.

Total operating expenses for the three and six months ended June 30, 2021 included non-cash stock-based compensation expense of $0.5 million and $1.0 million, respectively, compared to $0.5 million and $1.2 million for the same periods in 2020. In addition, during the six months ended June 30, 2020, there were non-recurring non-cash charges for impairment of the Company's right-of-use asset and leasehold improvements of $2.9 million.

For the three and six months ended June 30, 2021, Aravive reported a net loss of $7.1 million and $15.1 million, or $0.35 per share and $0.78 per share, respectively, compared to a net loss of $5.0 million and $15.8 million, or $0.32 per share and $1.02 per share, for the same periods in 2020.

Cash Position
As of June 30, 2021, cash and cash equivalents were $75.4 million, compared to $60.5 million as of December 31, 2020. The Company expects that its current cash and cash equivalents will be sufficient to fund its operating plans into the second half of 2022.

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 preclinical models. In doing so, AVB-500 selectively inhibits the GAS6-AXL signaling pathway, which is upregulated in multiple cancer types including ovarian 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. AVB-500 is currently being evaluated in clinical trials and has been granted Fast Track Designation by the U.S. Food and Drug Administration in platinum resistant recurrent ovarian cancer. Analysis of all safety data to date showed that AVB-500 has been generally well tolerated with no dose-limiting toxicities or unexpected safety signals.

About the AVB-500 Phase 3 PROC Trial
The global, randomized, double-blind, placebo-controlled adaptive trial (GOG-3059/ENGOT OV-66) is designed to evaluate efficacy and safety of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel. The trial is expected to enroll approximately 300-400 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy at approximately 165 sites in North America, Europe, and Asia. The primary endpoint for the trial is progression-free survival and the secondary endpoint is overall survival. Exploratory endpoints include objective response rate, duration of response, quality of life, clinical benefit rate, pharmacokinetic and pharmacodynamic profile, and AXL/GAS6 ratio. A prospectively defined interim analysis will determine whether randomization will continue with all patients, regardless of prior bevacizumab treatment, or only with patients medically ineligible to receive bevacizumab or who choose not to receive bevacizumab. This trial is being conducted in partnership with The GOG Foundation, Inc. (GOG-F), through the GOG Partners program in the USA, and in partnership with the European Network for Gynecological Oncological Trial (ENGOT) groups in Europe. The Phase 3 trial is listed on clinicaltrials.gov NCT04729608.

About the AVB-500 Phase 1b/2 ccRCC Trial
Aravive initiated its Phase 1b portion of the Phase 1b/2 trial of AVB-500 in ccRCC in March 2021. The Phase 1b portion of the clinical trial, a dose escalation study, is expected to enroll approximately 18 patients in three dosing arms (15 mg/kg, 20 mg/kg and 25 mg/kg) to evaluate tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of AVB-500 in combination with cabozantinib. The controlled, randomized, open-label Phase 2 portion of the clinical trial is expected to enroll approximately 45 patients and investigate the recommended AVB-500 dose identified during the Phase 1b portion of the clinical trial in combination with cabozantinib versus cabozantinib alone. The primary endpoint is progression-free survival. The trial will enroll patients with advanced ccRCC who have progressed on front-line treatment. The Phase 1b/2 trial is listed on clinicaltrials.gov NCT04300140.

About Aravive
Aravive, Inc. is a clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases. Aravive's lead therapeutic, AVB-500, is a first-in-class ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth, tumor metastasis, resistance to treatment and decreased survival. AVB-500 has the potential to be combined with multiple anti-cancer therapies across several tumor types, due to its novel mechanism of action and favorable safety profile. AVB-500 has been granted Fast Track Designation by the U.S. Food and Drug Administration in platinum resistant recurrent ovarian cancer. The Company is currently evaluating AVB-500 in a registrational Phase 3 trial in platinum resistant ovarian cancer and a Phase 1b/2 trial in second line plus, clear cell renal cell carcinoma. Aravive plans to initiate a Phase 1b/2 trial evaluating AVB-500 in first-line treatment of pancreatic adenocarcinoma in the second half of 2021. 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 initiation of a Phase 2 clinical trial in clear cell renal cell carcinoma in the second half of 2021, initiation of AVB-500 Phase 1b portion of Phase 1b/2 clinical trial in pancreatic adenocarcinoma in second half of 2021, conducting an interim analysis of its Phase 3 clinical trial of AVB-500 in PROC in the first quarter of 2022, completion of enrollment in the Phase 1b portion of the Phase1b/2 clinical trial in clear cell renal cell carcinoma in the second half of 2021, the expected enrollment of 300-400 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy at approximately 165 sites in North America, Europe, and Asia, the expected enrollment of approximately 18 patients in three dosing arms in the Phase1b portion of the Phase 1b/2 trial of AVB-500 in ccRCC, the expected enrollment of approximately 45 patients in the Phase 2 portion of the clinical trial of AVB-500 in ccRCC and the potential of AVB-500 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 initiate a Phase 2 clinical trial in clear cell renal cell carcinoma in the second half of 2021 and a Phase 1b/2 trial evaluating AVB-500 in first-line treatment of pancreatic adenocarcinoma in the second half of 2021, conduct an interim analysis of its Phase 3 clinical trial of AVB-500 in PROC in the first quarter of 2022, complete enrollment in the Phase 1b portion of the Phase1b/2 clinical trial in clear cell renal cell carcinoma in the second half of 2021, the ability to enroll the expected number of patients, the ability to combine AVB-500 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 AVB-500, AVB-500's ability to have favorable results in clinical trials and ISTs, the clinical trials of AVB-500 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 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 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 June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue				
Collaboration revenue	$ 3,789	$ —	$ 4,045	$ —
Total revenue	3,789	—	4,045	—
Operating expenses				
Research and development	8,120	2,522	14,004	6,014
General and administrative	3,080	3,201	5,460	7,151
Loss on impairment of long-lived assets	—	—	—	2,870
Total operating expenses	11,200	5,723	19,464	16,035
Loss from operations	(7,411)	(5,723)	(15,419)	(16,035)
Interest income	11	26	20	243
Other income (expense), net	295	656	290	(45)
Net loss	$ (7,105)	$ (5,041)	$ (15,109)	$ (15,837)
Net loss per share- basic and diluted	$ (0.35)	$ (0.32)	$ (0.78)	$ (1.02)
Weighted-average common shares used to compute basic and diluted net loss per share	20,414	15,902	19,247	15,457

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

	June 30, 2021	**December 31, 2020**
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 75,437	$ 60,541
Restricted cash	2,430	2,430
Other assets	4,781	1,781
Operating lease right-of-use assets	2,582	2,958
Total assets	$ **85,230**	$ **67,710**
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 5,216	$ 4,823
Deferred revenue	8,325	6,315
Operating lease obligation	7,631	8,517
Total liabilities	21,172	19,655
Total stockholders' equity	64,058	48,055
Total liabilities and stockholders' equity	$ **85,230**	$ **67,710**

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