Aravive Reports First Quarter 2021 Financial Results and Announces Plans to Investigate AVB-500 in Clinical Trial as First-Line Treatment for Pancreatic Cancer

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- Aravive continues to expand development of AVB-500 in multiple indications and combination treatments with first-line treatment for pancreatic cancer
- First patient dosed in registrational Phase 3 trial of AVB-500 in platinum resistant ovarian cancer; on track to conduct interim analysis in first quarter 2022
- First patient dosed in Phase 1b/2 trial of AVB-500 in clear cell renal cell carcinoma; on track to report topline data in second half 2021

HOUSTON, May 06, 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 first quarter ended March 31, 2021.

“We are rapidly advancing development of AVB-500, while at the same time, expanding into additional oncology indications. We began dosing patients in our registrational Phase 3 trial in platinum resistant ovarian cancer and our Phase 1b/2 trial in clear cell renal cell carcinoma,” said Gail McIntyre, Ph.D., Chief Executive Officer of Aravive. “We plan to expand the development of AVB-500 as a first-line treatment of pancreatic cancer, another area of oncology where there is a high, unmet medical need. We look forward to initiating the Phase 1b portion of this clinical trial in the second half of 2021. We are optimistic about the broad potential of AVB-500 in the treatment of multiple cancers and multiple indications, as we advance and expand our pipeline.”

Recent Corporate Highlights

- **Aravive to Expand Development of AVB-500 with Plans to Investigate AVB-500 in a Clinical Trial as a First-Line Treatment for Pancreatic Cancer:** Aravive plans to expand development of AVB-500 in a Phase 1b/2 trial as a first-line treatment for pancreatic cancer. The expected design of the trial will evaluate AVB-500 in combination with gemcitabine and nab-paclitaxel (Abraxane®) in patients with advanced metastatic pancreatic cancer eligible to receive gemcitabine and nab-paclitaxel (Abraxane®) combination therapy. The Phase 1b portion of the clinical trial will assess safety, tolerability, and clinical activity of AVB-500 in combination with gemcitabine and nab-paclitaxel (Abraxane®). The randomized, controlled Phase 2 portion of the clinical trial will evaluate AVB-500 in combination with gemcitabine and nab-paclitaxel (Abraxane®) versus gemcitabine and nab-paclitaxel (Abraxane®) alone. The Company expects to initiate the Phase 1b portion of the clinical trial in the second half of 2021.

  It is estimated that there will be approximately 60,400 new cases of pancreatic cancer and 48,200 deaths from the disease in the U.S. in 2021. Pancreatic cancer typically has a poor prognosis and the five-year survival rate is approximately 11%. There is a clear, high, unmet medical need to improve patient survival with new effective treatments that are safe and well-tolerated. Pancreatic cancer is projected to become the second leading cause of cancer death in the U.S. by 2030.

- **AVB-500 in Platinum Resistant Ovarian Cancer (PROC):** In April 2021, Aravive dosed the first patient in its registrational Phase 3 trial of AVB-500 in PROC and simplified the trial’s statistical analysis plan. 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 primary endpoint is progression-free survival. 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 the U.S. and Europe. 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 chose not to receive bevacizumab. The Company is on track to conduct the interim analysis in the first quarter of 2022.

- **AVB-500 in Clear Cell Renal Cell Carcinoma (ccRCC):** In March 2021, Aravive dosed the first patient in its Phase 1b/2 trial of AVB-500 in ccRCC. The Phase 1b portion of the clinical trial is expected to enroll up to 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 will enroll up to 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 Company is on track to report topline data from the Phase 1b portion of the clinical trial in the second half of 2021.

- **Achieved First Clinical Milestone with 3D Medicines and Expected to Receive $6.0 Million Development Milestone Payment:** In April 2021, Aravive dosed the first patient in its Phase 3 trial of AVB-500 in platinum resistant ovarian cancer, and based upon this event, the Company successfully completed its first clinical milestone with 3D Medicines Inc. (3D Medicines). Aravive's collaboration and license agreement with 3D Medicines is for the development and commercialization of AVB-500 for oncology indications in Greater China. Under the terms of the agreement, Aravive is eligible to receive up to an aggregate of $207 million in development and commercial milestone payments and royalties.

First Quarter 2021 Financial Results
Revenue for the three months ended March 31, 2021 was $0.3 million, compared to $0 for the same period in 2020. Revenue for the first quarter of 2021 was derived solely from the Company's collaboration and license agreement with 3D Medicines.

Total operating expenses for the three months ended March 31, 2021 were $8.3 million, compared to $10.3 million for the same period in 2020.

Total operating expenses for the three months ended March 31, 2021 included non-cash stock-based compensation expense of $0.5 million, compared to $0.7 million for the same period in 2020. In addition, during the three months ended March 31, 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 months ended March 31, 2021, Aravive reported a net loss of $8.0 million, or $0.44 per share, compared to a net loss of $10.8 million, or $0.72 per share, for the same period in 2020.

Cash Position
As of March 31, 2021, cash and cash equivalents were $78.7 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 Pancreatic Cancer
Pancreatic cancer is the seventh leading cause of cancer death worldwide. There were approximately 495,800 new cases of pancreatic cancer and 466,000 deaths from the disease worldwide in 2020. It is estimated that there will be approximately 60,400 new cases of pancreatic cancer and 48,200 deaths from the disease in the U.S. in 2021. Pancreatic cancer typically has a poor prognosis and the five-year survival rate is approximately 11%. There is a clear, high, unmet medical need to improve patient survival with new effective treatments that are safe and well-tolerated. Pancreatic cancer is projected to become the third leading cause of cancer death worldwide by 2025 and the second leading cause of cancer death in the U.S. by 2030.

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 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 the U.S. and Europe. 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 sAXL/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 chose 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 Gynaecological Oncological Trial (ENGOT) groups in Europe. The Phase 3 trial is listed on clinicaltrials.gov NCT04729608.

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 clear cell renal cell carcinoma. Aravive plans to initiate a Phase 1b/2 trial evaluating AVB-500 in first-line treatment of pancreatic cancer 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 plans to expand development of AVB-500 in a Phase 1b/2 trial as a first-line treatment for pancreatic cancer, initiating the Phase 1b portion of the trial in the second half of 2021, the expected design of the Phase 1b/2 trial as a first-line treatment for pancreatic cancer evaluating AVB-500 in combination with gemcitabine and nab-paclitaxel (Abraxane®) in patients with advanced metastatic pancreatic cancer eligible to receive gemcitabine and nab-paclitaxel (Abraxane®) combination therapy, the broad potential of

AVB-500 in the treatment of multiple cancers and multiple indications, enrolling 300-400 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy at approximately 165 sites in the U.S. and Europe in the PROC Phase 3 trial, being on track to conduct an interim analysis in the PROC Phase 3 trial in the first quarter of 2022, the enrollment of up to 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 in the Phase 1b clear cell renal cell carcinoma clinical trial, being on track to report topline data from the Phase 1b portion of the clear cell renal cell carcinoma clinical trial in the second half of 2021 and receipt of a $6 million development milestone payment from 3D Medicines. 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 recruit for and enroll the expected number of patients into the Phase 3 trial of AVB-500 in PROC, its Phase 1b clear cell renal cell carcinoma clinical trial and its other trials as planned and its ability to report data as planned, 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 pancreatic cancer as a first-line treatment and other additional oncology 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 March 31,	
	2021	**2020**
Revenue		
Collaboration revenue	$ 256	$ —
Total revenue	256	—
Operating expenses		
Research and development	5,884	3,491
General and administrative	2,380	3,951
Loss on impairment of long-lived assets	—	2,870
Total operating expenses	8,264	10,312
Loss from operations	(8,008)	(10,312)
Interest income	9	217
Other income (expense), net	(5)	(701)
Net loss	$ (8,004)	$ (10,796)
Net loss per share- basic and diluted	$ (0.44)	$ (0.72)
Weighted-average common shares used to compute basic and diluted net loss per share	18,067	15,013

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

	March 31, 2021	**December 31, 2020**
	(unaudited)	
Assets:		
Cash and cash equivalents	$ 78,682	$ 60,541
Restricted cash	2,430	2,430
Other assets	3,385	1,781
Operating lease right-of-use assets	2,770	2,958
Total assets	**$ 87,267**	**$ 67,710**
Liabilities and stockholders' equity:		
Accounts payable and accrued liabilities	$ 4,252	$ 4,823
Deferred revenue	6,059	6,315
Operating lease obligation	8,240	8,517
Total liabilities	18,551	19,655

Total stockholders' equity	68,716	48,055
Total liabilities and stockholders' equity	**$ 87,267**	**$ 67,710**

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