Aravive Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Updates

March 16, 2021

- Initiated a registrational trial of AVB-500 in Platinum Resistant Ovarian Cancer in 1Q 2021
- First patient dosed in Phase 1b/2 trial of AVB-500 in Clear Cell Renal Cell Carcinoma in 1Q 2021; On-track to report topline data in 2H 2021
- Strengthened balance sheet with $21.0 million registered direct offering; Current cash and cash equivalents expected to fund operations into 2H 2022

HOUSTON, March 16, 2021 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing transformative therapeutics, today announced recent corporate updates and financial results for the fourth quarter and full year ended December 31, 2020.

“In the fourth quarter of 2020, we continued to make important progress on Aravive’s mission to improve the lives of people living with cancer,” said Gail McIntyre, Ph.D., Chief Executive Officer of Aravive. “We received guidance from the FDA on a registrational Phase 3 trial design for AVB-500 in platinum resistant ovarian cancer and have initiated the trial. We have dosed our first patient in a Phase 1b/2 trial evaluating AVB-500 in clear cell renal cell carcinoma and are on track to report topline data from the Phase 1b portion of the trial in the second half of 2021. On the corporate front, we established a strategic collaboration with 3D Medicines to develop and commercialize AVB-500 in Greater China and we recently strengthened our balance sheet with a registered direct offering with Eshelman Ventures. Our 2021 objectives are clear, and we are well positioned to achieve our development milestones for AVB-500 while creating value for patients and shareholders.”

Recent Corporate Highlights

- **AVB-500 in Platinum Resistant Ovarian Cancer (PROC):** Aravive received guidance from the FDA on a registrational Phase 3 trial design for AVB-500 in PROC and initiated the trial during the first quarter of 2021. The global, randomized, double-blind, placebo-controlled adaptive trial will evaluate the efficacy and tolerability of AVB-500 at a dose of 15 mg/kg in combination with paclitaxel vs paclitaxel monotherapy. The registrational, adaptive Phase 3 trial is expected to enroll 300-500 patients with high-grade serous ovarian cancer who have received 1-4 prior lines of therapy across sites in the U.S. and Europe.
- **AVB-500 in Clear Cell Renal Cell Carcinoma (ccRCC):** Aravive dosed its first patient in its Phase 1b/2 trial of AVB-500 in ccRCC during the first quarter of 2021. The Phase 1b portion of the 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 trial will enroll up to 45 patients and investigate the recommended AVB-500 dose identified during the Phase 1b portion of the trial in combination with cabozantinib versus cabozantinib alone. The Company expects to report topline data from the Phase 1b portion of the trial in the second half of 2021.
- **Strategic Collaboration with 3D Medicines for AVB-500 in Greater China:** Aravive established a collaboration and exclusive license agreement with 3D Medicines Inc. (3D Medicines) for the development and commercialization of AVB-500 across all oncology indications in mainland China, Hong Kong, Macau, and Taiwan (Greater China). The Company received a signing payment of $12 million and is eligible to receive up to $207 million in development and commercial milestone payments and tiered royalties ranging from the low double digits to mid-teens as a percentage of annual net sales of AVB-500 in Greater China.
- **Strengthened Balance Sheet:** In February 2021, Aravive raised $21.0 million from the sale of 2,875,000 shares of common stock to Eshelman Ventures, LLC at a price of $7.29 per share in a registered direct offering. Eshelman Ventures, LLC is an entity wholly owned by Fred Eshelman, Pharm.D., Chairman of Aravive’s Board of Directors.

Fourth Quarter and Full Year 2020 Financial Results

Revenue for the three and twelve months ended December 31, 2020 was $5.7 million for both periods, compared to $0 and $4.8 million for the same periods in 2019. Revenue for 2020 was derived solely from the Company’s collaboration and license agreement with 3D Medicines. Revenue for 2019 was derived solely from the Cancer Prevention Research Institute of Texas (CPRIT) grant.

Total operating expenses for the three and twelve months ended December 31, 2020 were $9.7 million and $36.5 million, respectively, compared to $5.2 million and $26.5 million for the same periods in 2019.

Total operating expenses for the three and twelve months ended December 31, 2020 included non-cash stock-based compensation expense of $0.4 million and $2.0 million, respectively, compared to $0.6 million and $3.4 million for the same periods in 2019. In addition, during the twelve months ended December 31, 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 twelve months ended December 31, 2020, Aravive reported a net loss of $4.0 million and $30.5 million, or $0.25 per share and $1.93 per share, respectively, compared to a net loss of $4.3 million and $18.2 million, or $0.35 per share and $1.57 per share, for the same periods in 2019.

Cash Position

As of December 31, 2020, cash and cash equivalents was $60.5 million, compared to $65.1 million as of December 31, 2019. 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 Aravive

Aravive, Inc. is a clinical-stage oncology company developing transformative therapeutics designed to halt the progression of life-threatening diseases. Aravive is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. Aravive's lead product candidate, AVB-500, is an ultra-high affinity decoy protein that targets the GAS6-AXL signaling pathway associated with tumor cell growth. Aravive successfully completed a Phase 1b trial of AVB-500 in platinum resistant ovarian cancer and has initiated a registrational Phase 3 trial of AVB-500 at a dose of 15 mg/kg. While the Phase 1b trial of AVB-500 in platinum resistant ovarian cancer was a safety trial and not powered to demonstrate efficacy, all 5 patients in the 15 mg/kg cohort experienced clinical benefit, with 1 complete response, 2 partial responses, and 2 stable disease. The Company is dosing patients in its Phase 1b/2 trial in clear cell renal cell carcinoma. 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, such statements regarding being on track to report topline data from the Phase 1b portion of the trial in the second half of 2021, the registrational, adaptive Phase 3 trial enrolling 300-500 patients with high-grade serous ovarian cancer who have received 1-4 prior lines of therapy across sites in the U.S. and Europe, the Phase 1b portion of the trial enrolling 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 and current cash being sufficient to fund its operating plans into the second half of 2022. 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: our ability to report topline data form our Phase 1b trial when anticipated, our ability to enroll the number of anticipated patients in each trial, our ability to show the potential for AVB-500 to treat clear cell renal cell carcinoma without adding toxicity, our ability to share updates on our studies as development of AVB-500 across a broad range of cancers advances, 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 ability to expand development into additional oncology indications, and the Company's reliance on its licensor of intellectual property and our cash runaway being sufficient to fund our operating plans into the second half of 2022 and our 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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Revenue				
Grant revenue	$ —	$ —	$ —	$ 4,753
Collaboration revenue	5,685	—	5,685	—
Total revenue	5,685	—	5,685	4,753
Operating expenses				
Research and development	6,535	2,511	17,620	12,836
General and administrative	3,199	2,652	13,065	13,691
Loss on impairment of long-lived assets	—	—	5,784	—
Total operating expenses	9,734	5,163	36,469	26,527
Loss from operations	(4,049)	(5,163)	(30,784)	(21,774)
Interest income	4	211	255	1,022
Other income (expense), net	(1)	624	(14)	2,534
Net loss	$ (4,046)	$ (4,328)	$ (30,543)	$ (18,218)
Net loss per share- basic and diluted	$ (0.25)	$ (0.35)	$ (1.93)	$ (1.57)
Weighted-average common shares used to compute net loss per share- basic and diluted	16,183	12,506	15,790	11,589

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

	December 31, 2020	December 31, 2019
Assets:		
Cash and cash equivalents	$ 60,541	$ 65,134
Restricted cash	2,430	2,423
Other assets	1,781	5,867
Operating lease right-of-use assets	2,958	8,697
Total assets	**$ 67,710**	**$ 82,121**
Liabilities and stockholders' equity:		
Accounts payable and other current liabilities	$ 4,823	$ 2,575
Deferred revenue	6,315	—
Operating lease obligation	8,517	10,233
Contingent liabilities	—	264
Total liabilities	19,655	13,072
Total stockholders' equity	48,055	69,049
Total liabilities and stockholders' equity	**$ 67,710**	**$ 82,121**

Contacts:
Investors:
Luke Heagle, W2O
lheagle@w2ogroup.com
(910) 726-1372

Media:
Sheryl Seapy, W2O
sseapy@w2ogroup.com
(949) 903-4750