



Aravive Achieves Second Development Milestone from 3D Medicines

July 15, 2021

Milestone is Based on Approval of 3D Medicines' IND in China to Participate in Aravive's AVB-500 (3D-299) Phase 3 Clinical Trial for Platinum Resistant Ovarian Cancer

HOUSTON, July 15, 2021 (GLOBE NEWSWIRE) -- Aravive Inc. (Nasdaq: ARAV), a clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases, today announced that it achieved a \$3 million development milestone payment from its licensee, 3D Medicines Inc. This milestone is 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 platinum resistant ovarian cancer (PROC) clinical trial.

Gail McIntyre, Ph.D., DABT, Chief Executive Officer, said, "We have a strong partnership with 3D Medicines, and we are enthusiastic about the progress they have made with development of AVB-500 (3D-299) in China. Our companies are dedicated and working together to improve patient survival and bring hope to women with advanced ovarian cancer, and we plan to have patients from China included in our Phase 3 PROC trial along with patients from our approximately 165 sites in North America and Europe. This IND approval by the CDE in China is the second development milestone achieved by Aravive since we entered into our agreement with 3D Medicines in November 2020."

Aravive's collaboration and license agreement with 3D Medicines Inc. is for the development and commercialization of AVB-500 in 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. In addition to achieving this \$3 million development milestone, the company received a \$6 million development milestone payment in June 2021 related to the first patient dosed by Aravive in the AVB-500 Phase 3 registrational clinical trial for platinum resistant ovarian cancer in the United States, and a \$12 million upfront payment in 2020, totaling \$21 million that has been achieved by Aravive from 3D Medicines.

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 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 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 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 Gynaecological Oncological Trial (ENGOT) groups in Europe. The Phase 3 trial is listed on [clinicaltrials.gov](https://clinicaltrials.gov/NCT04729608) [NCT04729608](https://clinicaltrials.gov/NCT04729608).

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 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 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 have patients from China included in the Company's Phase 3 PROC trial along with patients from the Company's approximately 165 sites in North America and Europe, the potential of AVB-500 to be combined with multiple anti-cancer therapies across several tumor types, due to its novel mechanism of action and favorable safety profile and plans to initiate a Phase 1b/2 trial evaluating AVB-500 in first-line treatment of pancreatic cancer in the second half of 2021. 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 1b/2 trial evaluating AVB-500 in first-line treatment of pancreatic cancer in the second half of 2021, 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 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.

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