Aravive Receives Third Development Milestone from 3D Medicines

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Milestone is Based on 3D Medicines' Initiation of the Phase 3 Clinical Trial for Platinum Resistant Ovarian Cancer in China

HOUSTON, Oct. 10, 2022 (GLOBE NEWSWIRE) -- Aravive Inc. (Nasdaq: ARAV), a late clinical-stage oncology company developing innovative therapeutics to treat life-threatening diseases, today announced that it received a $6 million development milestone payment from its licensee, 3D Medicines Inc. This milestone is based on the initiation of the global Phase 3 platinum resistant ovarian cancer (PROC) clinical trial in China for the development of Aravive's batiraxcept.

Gail McIntyre, Ph.D., DABT, Chief Executive Officer, said, "Our partnership with 3D Medicines continues with positive progress as they move forward with enrollment in the Phase 3 Trial for batiraxcept (3D-299) in China. Their enrollment of patients will support Aravive's potential marketing application for batiraxcept in the United States, as well as their potential marketing application in China. This is our third milestone achieved since entering our agreement with 3D Medicines in November 2020 and we look forward to continued advancement towards the potential approval of batiraxcept in both the United States and China. Our companies are dedicated and working together to improve patient survival and bring hope to women with advanced ovarian cancer."

Aravive's collaboration and license agreement with 3D Medicines Inc. is for the development and commercialization of batiraxcept 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 $6 million development milestone, the Company had previously received a $9 million in development milestones related to development of batiraxcept for platinum resistant ovarian cancer in the United States and China, as well as a $12 million upfront payment in 2020, totaling $27 million that has been achieved by Aravive from 3D Medicines.

About the Phase 3 PROC Trial

The global, randomized, double-blind, placebo-controlled trial (GOG-3059/ENGOT OV-66) is designed to evaluate efficacy and safety of batiraxcept 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 150 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. 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 late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease. Our lead product candidate, batiraxcept (formerly AVB-500), is an ultra-high affinity decoy protein that binds to GAS6, the sole ligand that activates AXL, inhibiting metastasis, tumor growth, and restoring sensitivity to anti-cancer agents. Batiraxcept has been granted Fast Track Designation by the U.S. FDA and Orphan Drug Designation by European Commission in PROC. Batiraxcept is in an active registrational Phase 3 trial in platinum resistant ovarian cancer (NCT04729608), a Phase 1b/2 trial in clear cell renal cell carcinoma (NCT04300140), and a Phase 1b/2 trial in pancreatic adenocarcinoma (NCT04983407). The Company is based in Houston, Texas and received a Product Development Award from the Cancer Prevention & Research Institute of Texas (CPRIT) in 2016. Additional information at www.aravive.com.

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 150 sites in North America and Europe, that the Company is eligible to receive up to an aggregate of $207 million in development and commercial milestone payments and royalties from 3D Medicines and the Company's ability to receive regulatory approval of batiraxcept. 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 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 oncology indications; the Company's dependence upon batiraxcept; batiraxcept's ability to have favorable results in clinical trials and investigator sponsored trials (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; and 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, 2021, the Company's Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2022 and June 30, 2022, respectively, 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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