



Aravive Announces Complete Enrollment in the Global Registrational Phase 3 AXLerate-OC Trial for Platinum-Resistant Ovarian Cancer

January 4, 2023

- Topline data expected mid-2023
- Potential Biologics License Application (BLA) submission end of 2023

HOUSTON, Jan. 04, 2023 (GLOBE NEWSWIRE) -- Aravive, Inc. (Nasdaq: ARAV, the "Company"), a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, today announced the achievement of full enrollment in the registrational Phase 3 trial of batiraxcept plus paclitaxel for platinum-resistant ovarian cancer (PROC). The global, randomized, double-blind, placebo-controlled Phase 3 AXLerate-OC trial is evaluating efficacy and tolerability of 15 mg/kg batiraxcept in combination with weekly paclitaxel versus placebo in combination with weekly paclitaxel. The trial was planned to enroll approximately 350 patients with platinum resistant, high grade serous ovarian cancer who received 1-4 prior lines of therapy at approximately 165 sites in the U.S. and Europe.

"Completing enrollment of this pivotal study brings us closer to the day when batiraxcept potentially is available to patients," said Scott Dove, Ph.D., Chief Operating Officer of Aravive. "Public reporting of topline data remains on track for mid-2023 and, if successful, are expected to support a Biologics License Application for PROC at the end of 2023. I would like to thank the patients enrolled in the trial, the clinical investigators, our CRO partners, and the Aravive team who worked tirelessly to advance the trial to this stage."

"The majority of patients with ovarian cancer will develop platinum resistance and have residual side effects from previous treatments," said Katherine Fuh, MD, PhD, John A. Kerner Chair in Gynecologic Oncology, Associate Professor, Department of OB/GYN, Director of Basic and Translational Research, Division of Gynecologic Oncology, University of California, San Francisco. "There is a need to develop effective novel agents with little to no side effects. As overall response rates for current treatments in platinum-resistant ovarian cancer range from 4% to 30%, we anticipate that batiraxcept and paclitaxel could be an option for our patients."

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 batiraxcept at a dose of 15 mg/kg in combination with paclitaxel. The trial is expected to enroll approximately 350 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. 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 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, thereby inhibiting metastasis and tumor growth, and restoring sensitivity to anti-cancer agents. Batiraxcept has been granted Fast Track Designation by the U.S. Food and Drug Administration for both the platinum-resistant ovarian cancer and clear cell renal cell cancer programs and Orphan Drug Designation by the European Commission in platinum-resistant recurrent ovarian cancer. 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.

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 the achievement of full enrollment in the registrational Phase 3 trial of batiraxcept plus paclitaxel for platinum-resistant ovarian cancer, the timing for reporting topline Phase 3 PROC data and the proposed BLA submission for PROC at the end of 2023. 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 potential of batiraxcept as a treatment for advanced or metastatic clear cell renal cell carcinoma (ccRCC), the ability to provide data when anticipated; the Company's dependence upon batiraxcept; batiraxcept's ability to have favorable results in clinical trials; 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, June 30, 2022 and September 30, 2022, respectively, recent Current Reports on Form 8-K and subsequent filings with the Securities and Exchange Commission. 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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