U.S. FDA Grants Fast Track Designation to Aravive Biologics’ AVB-S6-500

August 20, 2018

HOUSTON, TEXAS (August 20, 2018): Aravive Biologics, Inc. announced today that the U.S. Food and Drug Administration has granted Fast Track Designation to AVB-S6-500 as a potential treatment for platinum-resistant recurrent ovarian cancer.

“Gaining Fast Track Designation is an important recognition of the potential that AVB-S6-500 has to offer to meet a critical unmet medical need for patients with recurrent ovarian cancer,” said Ray Tabibiazar, M.D., Executive Chairman of Aravive Biologics. “We look forward to initiating the Phase 1b portion of our planned Phase 1b/2 study combining AVB-S6-500 with standard-of-care therapies in patients with platinum-resistant ovarian cancer before the end of the year.”

The FDA’s Fast Track Designation is intended to facilitate development and expedite review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

“We are very pleased that the FDA has granted Fast Track status to AVB-S6-500,” said Gail McIntyre Ph.D., DABT, Senior Vice President of R&D at Aravive. “This important designation is based on the promising safety and activity observed to-date with AVB-S6-500, and we look forward to working closely with the FDA as we advance its development in ovarian cancer.”

About AVB-S6-500

AVB-S6-500 is a novel high-affinity, soluble Fc-fusion protein designed to block the activation of the GAS6-AXL signaling pathway by intercepting the binding of GAS6 to its receptor AXL. Research has shown GAS6-AXL signaling to be a key molecular pathway that promotes tumor growth and metastases, as well as immune evasion and resistance to other anticancer agents. AXL and GAS6 expression correlate with poor prognosis in cancer. Results of a Phase 1 study of AVB-S6-500 in healthy volunteers showed a favorable safety profile, with no reported serious or dose-limiting adverse events. Moreover, results of that trial showed a dose-related reduction of circulating free GAS6, a measurement that Aravive anticipates will be highly useful as a biomarker to better monitor the therapeutic responses and potentially to better select responder patient populations. A reduction in this biomarker has correlated to anti-tumor activity in preclinical animal studies. In preclinical studies, GAS6-AXL inhibition has shown activity, whether achieved by a single agent (including AVB-S6-500) or through combinations of a variety of anticancer therapies including radiation therapy, immunoncology agents, and drugs that affect DNA replication and repair. GAS6/AXL inhibition has also shown potential as a strategy for the treatment of certain fibrotic diseases.

About Aravive Biologics

Aravive Biologics is a clinical stage pharmaceutical company focused on developing novel, highly selective therapies designed to treat serious cancers and certain fibrotic diseases. The company’s primary therapeutic focus is the GAS6-AXL pathway, where AXL receptor signaling plays a critical role in multiple types of malignancies by promoting metastasis and cancer cell survival. Aravive Biologics has generated strong preclinical data for its lead drug candidate AVB-S6-500 in a variety of cancer models and recently completed a Phase 1 clinical study that established proof of mechanism at all doses tested in human subjects and suppressed serum GAS6 for at least one week. The company is based in Houston, Texas, and receives support from the Cancer Prevention & Research Institute of Texas (CPRIT). On June 3, 2018, Aravive entered into an Agreement and Plan of Merger and Reorganization with Versartis, Inc., and its wholly owned subsidiary Velo Merger Sub, Inc. For more information, please visit our website at http://www.aravive.com. Information contained on or accessed through our web site is not part of this press release.

Forward Looking Statement

This press release contains forward-looking statements. Forward-looking statements contained in this press release include, without limitation, statements regarding the timing of the initiation of the Phase 1b portion of the Phase 1b/2 clinical trial, inhibition of the GAS6-AXL pathway as a strategy for the treatment of certain fibrotic diseases, and dose-related reduction of circulating free GAS6 being a measurement that will be highly useful as a biomarker of drug activity in future clinical studies and the benefits to be derived from Fast Track Designation. These forward-looking statements are not guarantees of future performance and involve a number of unknown risks, assumptions, uncertainties and factors that are beyond our control, including, but not limited to, the potential of AVB-S6-500’s mechanism of action in additional clinical trials to represent a novel approach to inhibiting tumor growth and metastasis, as well as address tumor immune evasion and resistance to other anticancer agents, use of the GAS6 assay as a valuable biomarker of drug activity for future clinical studies, the potential of the inhibition of the GAS6-AXL signaling pathway to overcome tumor resistance and increase the efficacy of a variety of anticancer agents, the potential of GAS6-AXL inhibition as a strategy for the treatment of certain fibrotic diseases, the potential of AVB-S6-500 in a variety of solid tumors and acute myeloid leukemia, the ability of AVB-S6-500 to treat cancer, the ability of AVB-S6-500 to demonstrate safety and efficacy in future clinical trials, as well as clinical results that are consistent with prior in vitro results and Phase 1 clinical trial results, the ability to enroll patients and complete clinical trials on time and achieve desired results and benefits, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of our product candidates in the marketplace and the successful development, marketing or sale of products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate, our ability to establish and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our ability to retain our key scientists or management personnel and our ability to consummate the merger with Versartis, Inc.. All forward-looking statements are based on our expectations and assumptions as of the date of this press release. Actual results may differ materially from these forward-looking statements. Except as required by law, we expressly disclaim any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

Additional Information and Where to Find It
In connection with the proposed transaction pursuant to the terms of the Agreement and Plan of Merger and Reorganization, dated as of June 3, 2018, by and among Versartis, Inc., Velo Merger Sub, Inc. and Aravive Biologics, Versartis filed relevant materials with the Securities and Exchange Commission, or the SEC, including a registration statement on Form S-4 that contains a preliminary proxy statement/prospectus. Investors and shareholders will be able to obtain free copies of the proxy statement/prospectus and other documents filed by Versartis with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, Versartis and Aravive investors and shareholders will be able to obtain free copies of the definitive proxy statement/prospectus and other documents filed by Versartis with the SEC by contacting Versartis, Inc., 1020 Marsh Road, Menlo Park, California 94025, Attention: Corporate Secretary. Investors and stockholders are urged to read the definitive proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the merger.

Participants in the Solicitation

Versartis and Aravive Biologics, and each of their respective directors and executive officers and certain of their other members of management and employees, may be deemed to be participants in the solicitation of proxies in connection with the merger. Information about Versartis’s directors and executive officers is included in the registration statement on Form S-4 filed with the SEC on August 3, 2018 as well as Versartis’s Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 6, 2018, and the Form 10-K/A filed with the SEC on April 11, 2018. Additional information regarding these persons and their interests in the merger will be included in the definitive proxy statement/prospectus relating to the merger when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above. This communication is not intended to and does not constitute the solicitation of any vote in any jurisdiction pursuant to the merger or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law.

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