Aravive Biologics Achieves Proof-of-Mechanism for Novel GAS6-AXL Pathway Inhibitor, AVB-S6-500, in Ongoing Phase 1 Trial

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Aravive Biologics, Inc. announced today that the company has demonstrated clinical proof-of-mechanism for AVB-S6-500 in neutralizing GAS6, based on analysis of the single ascending dose portion of the ongoing Phase I study (32 subjects).

The objective of this study is to evaluate the safety, pharmacokinetics and pharmacodynamics for AVB-S6-500, as well as to demonstrate proof-of-mechanism based on the dose-dependent decrease in measurable, circulating free GAS6 in serum.

The Phase 1 study is being conducted in healthy volunteers in two phases: single-ascending dose and repeat-dose phases. At all doses tested in the single-ascending dose portion, AVB-S6-500 demonstrated pharmacological activity and suppressed serum GAS6 levels. Single doses of AVB-S6-500 were well-tolerated. Aravive expects to complete the repeat-dose portion of the study during the second quarter and will present full results of the trial at a major medical meeting later in 2018.

As a decoy molecule, AVB-S6-500 has been shown to neutralize GAS6 activity by binding to that molecule with very high affinity. In doing so, the molecule selectively inhibits triggering of the GAS6-AXL signaling pathway. “We believe this mechanism of action represents a novel approach to inhibiting tumor growth and metastasis, as well as addressing tumor immune evasion and resistance to other anticancer agents,” said Gail McIntyre Ph.D., DABT, Senior Vice President of R&D at Aravive. “We are very pleased to have successfully achieved clinical proof-of-mechanism for AVB-S6-500 by showing a dose-related reduction of circulating free GAS6, a measurement that we anticipate will be a valuable biomarker of drug activity for future clinical studies.”

“Showing proof of mechanism for this first-in-class drug candidate is a significant milestone, as it is an important step towards removing the risk of the drug’s activity with respect to its intended action in humans,” said Laura Bonifacio, Pharm. D., Ph.D., Vice President, Clinical Programs. “This result positions us well for our upcoming Ph1b/Ph2 studies of AVB-S6-500 in ovarian cancer patients where we will evaluate the effect of lowering GAS-6 in the treatment of cancer.”

Elevated GAS6 levels have been associated with poor prognosis in cancer. 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, immuno-oncology 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, Inc.
Aravive Biologics is a privately held biopharmaceutical company developing novel, highly selective therapies designed to treat serious cancers and certain fibrotic diseases. The company’s lead program is focused on the GAS6-AXL pathway. Aravive Biologics has generated strong preclinical data for its lead drug candidate in a variety of cancer models. The company is based in Houston, Texas, and receives support from the Cancer Prevention & Research Institute of Texas (CPRIT). For more information, please visit our website at http://www.aravive.com.