AmpliMed Corporation Announces Promising 1-year Survival Data from Phase I/II Study of Amplimexon® in Metastatic Malignant Melanoma

AmpliMed today reported one year survival results from a Phase I/II trial of its lead drug candidate, Amplimexon® (imexon for injection) in combination with dacarbazine in patients with unresectable stage III or stage IV metastatic malignant melanoma. Results from the full cohort of patients in both the Phase I and Phase II shows a 11.7 month overall mean survival for the entire patient set and a 22 month overall mean survival in the subset of patients with normal LDH levels. This compares favorably to historical controls of 8 months and 10 months, respectively, for patients treated with dacarbazine alone. "The impact on overall survival demonstrated by Amplimexon in these trials is very promising and supports the need for a larger, randomized trial," said Ronald Garren, M.D. Chief Executive Officer of AmpliMed. "Amplimexon could represent a significant advance in the treatment of melanoma for which there have been no new treatments approved in the last decade."

Amplimexon is a small molecule drug that increases oxidative stress in tumor cells leading to mitochondrial damage and apoptosis. In preclinical in vitro and animal model studies it shows activity against human tumors including melanoma and is synergistic with alkylating agents including dacarbazine..Fifty (50) patients were treated with Amplimexon at MTD (maximum tolerated dose) during the Phase II portion of the trial, receiving 250 mg/m² of dacarbazine and 1,000 mg/m² of Amplimexon for 5 consecutive days every 3 weeks. Phase II was designed to preliminarily evaluate the efficacy of the Amplimexon/dacarbazine combination in metastatic malignant melanoma, in addition to safety. The criteria utilized for efficacy evaluation was RECIST. A total of 68 patients were enrolled at 13 U.S. centers in the Phase I and Phase II portions of the study.

Clinical Trial Results. The drug combination of Amplimexon and dacarbazine was well tolerated, with only 10.8 percent of patients showing myelosuppression and only 7 patients having serious adverse events likely related to the study drug. An objective response plus stable disease rate of 30.9 percent was observed for all treated patients (N = 68). The median overall survival of all patients was 11.7 months compared to approximately 8 months for dacarbazine treated historical controls. There was a minimum patient follow up of 1 year.Subsets of patients having a normal serum LDH or alternatively an elevated LDH were also analyzed for median overall survival. The median overall survival of the 31 patients in the Amplimexon/dacarbazine group with a normal LDH was 22.5 months compared to 10 months for a dacarbazine monotherapy historical control group having a
normal LDH. The median survival was 4.8 months for patients having an elevated LDH, no different than the historical control group receiving dacarbazine monotherapy. "In addition to the positive survival advantage observed for patients with less advanced disease, I am particularly impressed with the relatively infrequent side-effects of Amplimexon across the entire set of patients treated, even when administered with full dose standard chemotherapy" said Evan M. Hersh, M.D., Chief Medical Officer of Amplimed Corporation. "We look forward to evaluating Amplimexon in a larger, confirmatory trial and are excited by the potential this product candidate may offer to patients with malignant melanoma the most serious form of skin cancer."

About Metastatic Melanoma. Metastatic melanoma is the most deadly form of skin cancer, afflicting approximately 8,000 patients per year in the U.S. Based on statistics from the American Cancer Society, melanoma represents about 5% of all skin cancers, but causes almost 75% of all skin cancer related deaths. Whereas localized melanomas are largely curable by surgery, metastatic melanoma has a poor prognosis and there are few effective treatments. This results in an average survival time of 6.2 to 7.8 months in large multicenter studies. Two drugs are FDA-approved to treat metastatic melanoma: the alkylating agent dacarbazine, and the immunotherapy agent interleukin-2. Dacarbazine as a single agent has minimal activity and interleukin 2 is not widely used because of substantial toxicity. There have been no new treatments for metastatic melanoma approved by the FDA in over 10 years. In studies of dacarbazine as a single agent to treat malignant melanoma, median overall survival has ranged from 6-8 months.

About Amplimexon. Amplimexon is AmpliMed's parenteral formulation of imexon. Imexon is a cyanoaziridine compound which showed tantalizing evidence of activity in limited studies in lung cancer, melanoma and breast cancer that were documented in publications in the 1980s. The potential of imexon as a cancer drug was never fully explored, until 1994, when AmpliMed co-founding scientists Drs. Evan Hersh, David Alberts, Robert Dorr and William Remers initiated a program to decipher Amplimexon's novel mechanism of action. This led to the initiation in 2003 of a Phase I clinical study of the drug as a stand-alone therapy in late-stage cancer patients. Further preclinical research revealed that the combined use of Amplimexon and certain other chemotherapeutics resulted in a significant increase in efficacy compared to either drug alone. These findings are now being translated into a series of Phase I/II clinical studies of combination therapy in patients with various types of cancer.

About AmpliMed Corporation. AmpliMed Corporation was founded in 1989 with the support of the University of Arizona Technology Development Corporation and is focused on the clinical development of chemotherapeutic agents for cancer. AmpliMed's strategy is to develop anti-cancer drugs with novel mechanisms of action designed to overcome some of the limitations, such as myelosuppression (suppression of blood cell counts), multi-drug resistance (treatment-induced resistance to many cancer drugs) and cardiac toxicity, frequently associated with current cancer therapy. The company's lead product, Amplimexon (imexon for inj.), is in Phase II clinical trials. AmpliMed Corporation is based in Tucson, Arizona and is on the Web at http://www.amplimed.com/. Note that the data represented in this press release is provided as a snapshot of unaudited data, and thus final results may be marginally different after all auditing activities are concluded.
Important Notes:
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. This press release may contain certain statements of a forward-looking nature relating to future events or future business performance. Any such statements that refer to Algodon Wines & Luxury Development Group (Algodon Group) and its respective subsidiaries (“the Company”) estimated or anticipated future results or other non-historical facts are forward-looking and reflect the Company's current perspective of existing trends and information. These statements involve risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. The forward-looking statements speak only as of the date set forth above. The Company undertakes no obligation to update publicly any forward-looking statement, whether because of new information, future events or otherwise.

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