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**SOPHERION THERAPEUTICS LLC ANNOUNCES PUBLICATION OF PHASE I/II MYOCET® (NONPEGYLATED LIPOSOMAL DOXORUBICIN) DATA IN ADVANCED BREAST CANCER PATIENTS**

Princeton, N.J. February 5, 2009 – Sopherion Therapeutics, LLC, a biopharmaceutical company focused on the development and commercialization of anti-cancer therapies, today announced the publication of data from a phase I/II study of nonpegylated liposomal doxorubicin (Myocet®) in the January 1 issue of *Clinical Cancer Research*. The study was supported by a grant from Roche and was conducted by the Spanish Breast Cancer Cooperative Group (SOLTI).

The study results suggest that Myocet®, in combination with the approved trastuzumab (Herceptin®) plus paclitaxel (Taxol) treatment regimen, yielded an unusually high clinical response rate in patients with HER-2 overexpressing breast cancer. The 3-drug combination was well tolerated. There were no cases of treatment-related symptomatic congestive heart failure. This is noteworthy because cardiotoxicity is a common and therapy-limiting adverse event of the anthracycline class of anti-cancer agents and because Herceptin® has its own, well recognized, potential for cardiac toxicity.

Myocet is a liposomal delivery system for doxorubicin designed to reduce the risk of cardiotoxicity associated with doxorubicin while preserving its antitumor efficacy. It is currently in Phase III development in the United States for the treatment of advanced breast cancer.

“These clinical results are encouraging because they suggest that use of a nonpegylated liposomal anthracycline, such as Myocet, may provide important therapeutic benefits, while diminishing cardiac toxicity,” said Ronald H. Goldfarb, Ph.D., President and CEO of Sopherion Therapeutics. “Moreover, the incidence of hand foot syndrome, a rate limiting toxicity of other liposomal anthracyclines, is rare with nonpegylated liposomal anthracyclines. We look forward to reporting additional data from ongoing Myocet clinical trials, which further test this concept in patients with advanced breast cancer.”

**Study Background**

This multicenter, open-label phase I/II study was designed to determine the recommended dose, cardiac safety and antitumor activity of nonpegylated liposomal doxorubicin, paclitaxel and trastuzumab in patients with HER-2-overexpressing locally advanced nonoperable breast cancer (LABC) or metastatic breast cancer (MBC).

Sixty-nine adult patients from Spain participated, 15 in the dose escalating part and 54 at the recommended phase II dose. Women with measurable, previously untreated, HER-2-overexpressing LABC and MBC – and a baseline left ventricular ejection fraction (LVEF) > 50 percent – received weekly trastuzumab in combination with escalating doses of weekly paclitaxel and nonpegylated liposomal doxorubicin every three weeks for six cycles. Overall response rate was defined as the total of

complete response plus partial response. LVEF was monitored every 3 weeks for the first 18 weeks and every eight weeks thereafter.

### **Study Results**

No case of symptomatic treatment-related cardiac failure was reported. A total of 12 patients (17%) developed asymptomatic minimal and reversible declines in LVEF. In eight of these patients, LVEF recovered to  $\geq 50\%$  after a median time of nine weeks (range, 3-38 weeks). In the remaining patients, LVEF ranged from 44% to 49%.

The combination therapy was highly active and well-tolerated. The overall response rate, at the recommended phase II dose, was 98.1%: 29 patients achieved a complete response (53.7%) and 24 patients had a partial response (44.4%). This response rate ranks among the highest reported in HER-2-overexpressing breast cancer patients. The median time to progression was not reached in patients with locally advanced nonoperable breast cancer, while it exceeded 21 months in those with metastatic disease. The most common adverse events included alopecia (85.1%), mucosal inflammation (57.4%), asthenia (51.8%) and nausea (50%). Only two patients went off study due to “dermatitis”.

### **About Myocet™ (Nonpegylated Liposomal Doxorubicin)**

Myocet is a liposome-encapsulated doxorubicin-citrate complex. By encapsulating doxorubicin in a liposome – a manufactured, microscopic, vesicle consisting of discreet aqueous compartments surrounded by membranes composed of naturally occurring fats – its distribution in the body is altered in such a way as to reduce doxorubicin’s toxicity. Extensive clinical studies of Myocet in women with breast cancer have shown that the cardiac toxicity of doxorubicin can be significantly reduced, while the efficacy of the drug is maintained. This delivery system does not encompass pegylation and yields very little hand foot syndrome.

The results of the SOLTI study further supports an ongoing registration trial in patients with metastatic HER-2-overexpressing breast cancer, sponsored by Sopherion Therapeutics, LLC. This is a pivotal Phase III trial of Myocet™, paclitaxel and trastuzumab vs. paclitaxel and trastuzumab that uses progression-free survival as the primary efficacy endpoint, with careful monitoring for cardiac safety.

### **About Sopherion Therapeutics, LLC**

Sopherion Therapeutics, LLC, is a privately-held biotechnology company based in Princeton, New Jersey. The Company is focused on developing novel anti-cancer therapies for patients suffering with advanced cancer, particularly metastatic disease. Sopherion is dedicated to the acquisition, discovery, development and commercialization of novel anti-cancer therapies with unique therapeutic activities that address unmet medical needs in and extend human life. In 2004, Sopherion entered into an exclusive licensing agreement with Zeneus Pharma Ltd. (now Cephalon, Inc.) for the future commercialization of Myocet in North America. For more information, visit [www.sopherion.com](http://www.sopherion.com).

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