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## **SOPHERION THERAPEUTICS RECEIVES FDA FAST TRACK DESIGNATION FOR MYOCET IN METASTATIC BREAST CANCER**

Princeton, N.J., January 7, 2010 – Sopherion Therapeutics, LLC, a biopharmaceutical company focused on the development and commercialization of anti-cancer therapies, announced today that it has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for nonpegylated liposomal doxorubicin (Myocet™) for first-line therapy of HER2 positive metastatic breast cancer. Treatment with Myocet™ has already shown a reduced level of cardiotoxicity as compared to traditional doxorubicin.

Fast Track Designation facilitates the development and expedites the review of drugs to treat serious and life-threatening diseases that pose an unmet medical need, providing important new treatments to patients earlier. The designation grants companies the ability to request that a New Drug Application (NDA) be filed on a rolling basis and provides the FDA with an opportunity for early review of components of the NDA. Sopherion announced it has completed enrollment of its pivotal Phase III trial earlier this year combining Myocet™, paclitaxel (Taxol) and trastuzumab (Herceptin™) vs the current standard of care (trastuzumab combined with paclitaxel) for the treatment of metastatic HER2 over-expressing breast cancer.

“Myocet has the potential of delivering the well-documented efficacy of doxorubicin to patients with an acceptable safety profile when compared to earlier products in this class” said Ronald H. Goldfarb, Ph.D., President and CEO of Sopherion Therapeutics. “There is significant medical need for new breast cancer treatments and we look forward to reporting results from our ongoing pivotal Phase III trial by the end of 2010.”

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

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 lipids – 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 significantly reduced cardiac toxicity as compared to conventional doxorubicin. This delivery system does not encompass pegylation.

### **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 from advanced cancer, particularly in the metastatic stage. 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. to develop and commercialize Myocet in North America. For more information, visit [www.sopherion.com](http://www.sopherion.com).