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**Nereus Pharmaceuticals Presents Positive Interim Data from the ADVANCE study, A  
Randomized Phase 2 Clinical Trial of Plinabulin (NPI-2358) in Non-Small Cell Lung  
Cancer at the 2009 EORTC-NCI-AACR Conference**

SAN DIEGO, Calif., November 23, 2009 – Nereus Pharmaceuticals, Inc., a pioneer in drug discovery from marine microbial sources, today announced positive interim results from a randomized Phase 2 clinical trial evaluating the vascular disrupting agent (VDA) plinabulin (NPI-2358) in combination with standard chemotherapy (docetaxel) in patients with advanced non-small cell lung cancer (NSCLC). This data is consistent with the favorable outcomes seen in the Phase 1 portion of the study, which assessed the safety, pharmacokinetics and efficacy of the combination.

The ADVANCE (Assessment of Docetaxel and Vascular Disruption in Non-Small Cell Lung Cancer) trial is investigating plinabulin in combination with docetaxel compared to docetaxel alone in patients with advanced NSCLC who previously failed at least one prior chemotherapy regimen. Overall survival is the primary endpoint of the trial, and progression free survival and tumor response rates are being evaluated as secondary endpoints. Approximately 150 patients are expected to participate in the study at clinical trial sites in the U.S., Australia, India, and South America, of which 110 have been enrolled.

The interim results were presented in a poster at the 2009 EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics meeting in Boston, Massachusetts by the lead author Dr. Rebecca Heist, M.D., M.P.H., Assistant Professor in Medicine, Massachusetts General Hospital Cancer Center. The data indicated that the combination of plinabulin and docetaxel is tolerable, and suggested that the plinabulin combination improves tumor response rate by demonstrating that out of 57 evaluable patients an estimated 26 percent of those treated with plinabulin and docetaxel had a greater than or equal to 30 percent shrinkage of tumors (standard response criteria) compared to 3 percent of those treated with docetaxel alone.

“The positive preclinical and early clinical data continues to translate well in the clinic in non-small cell lung cancer, where patients could benefit from a new treatment that improves the outcomes of current chemotherapy regimens. Vascular disrupting agents could represent a significant advance in cancer treatment, particularly in NSCLC where indications have been positive for use of VDAs with standard of care cytotoxic and vascular targeted agents, as well as for use in patient subsets with particular unmet needs such as those with squamous cell carcinoma,” said Kobi Sethna, President and CEO, Nereus Pharmaceuticals, Inc.

### **About Vascular Disrupting Agents (VDA)**

Vascular disrupting agents are a newer class of agents that selectively attack tumor vasculature like anti-angiogenesis agents, but differ in molecular mechanism and affect established tumor blood vessels. Data have suggested these agents have different effect and side effect profiles and can work well with anti-angiogenesis agents as well as other anti-cancer agents. Positive clinical trial results have been reported for VDAs in NSCLC and other cancers, generating significant interest in this class of anti-cancer agents.

Preclinical and clinical data suggest that VDAs may be complementary or synergistic with chemotherapeutics and anti-angiogenesis agents due to the different targets and mechanisms of action. In addition, the non-overlapping side effect profile of VDAs compared to most other anti-cancer treatments makes them ideal candidates to employ in new combination therapies. Models combining plinabulin with docetaxel have produced particularly positive results in both efficacy and tolerability.

### **About Plinabulin (NPI-2358)**

Plinabulin is a VDA of novel structure currently in clinical development by Nereus for the treatment of cancer. Plinabulin is one of over 200 synthetic analogues that were prepared following the discovery of the compound Halimide isolated from a marine fungus. Plinabulin has a dual effect on tumors: it selectively attacks existing tumor blood vessels leading to hemorrhagic tumor necrosis without affecting normal vasculature, and it has a direct apoptotic effect on tumor cells. In preclinical models of cancer, including lung, breast, sarcoma, colon and

prostate, plinabulin demonstrated potent and selective anti-tumor effects in combination with docetaxel and other oncology therapies, as well as single-agent efficacy in a number of models. Plinabulin prevents the polymerization of tubulin monomers without altering the dynamic function of formed microtubules. As demonstrated in preclinical testing, this results in a highly specific nanomolar cytotoxicity while producing a favorable profile relative to the cardiotoxic and neuropathic side effects seen in first-generation VDAs. Results from Phase 1 studies indicated plinabulin has favorable safety, pharmacokinetic and pharmacodynamic profiles, and preclinical data demonstrated significant improvements in efficacy when added to standard cancer therapies. The ADVANCE study represents the first randomized assessment of plinabulin, and Nereus expects to initiate additional studies in other cancers within the year.

#### **About Nereus Pharmaceuticals, Inc.**

Nereus Pharmaceuticals pursues novel sources of chemical diversity to discover and develop new therapeutics. Using its unmatched expertise in marine microbiology to identify unique biologically active compounds, Nereus has two oncology drug candidates in clinical trials. Plinabulin (NPI-2358), a novel vascular disrupting agent, is being evaluated in patients with solid tumors and lymphomas. The second-generation proteasome inhibitor NPI-0052 is being evaluated in patients with solid tumors, lymphomas, leukemias and multiple myeloma. The Company's discovery portfolio includes potential drug candidates for cancer, infectious diseases and inflammation. For more information, visit [www.nereuspharm.com](http://www.nereuspharm.com).

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