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Nereus Pharmaceuticals Initiates ADVANCE, A Randomized Phase 2 Clinical Trial of NPI-2358 in Non-Small Cell Lung Cancer

SAN DIEGO, Calif., March 23, 2009 – Nereus Pharmaceuticals, Inc., a pioneer in drug discovery from marine microbial sources, today announced that it is conducting a randomized Phase 2 clinical trial evaluating the vascular disrupting agent (VDA) NPI-2358 in combination with standard chemotherapy (docetaxel) in patients with non-small cell lung cancer (NSCLC). This study follows on positive outcomes in the Phase 1 study assessing the safety, pharmacokinetics and efficacy of the combination.

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 NPI-2358 with docetaxel have produced particularly positive results in both efficacy and tolerability.

The ADVANCE (Assessment of Docetaxel and Vascular Disruption in Non-Small Cell Lung Cancer) trial will assess NPI-2358 in combination with docetaxel compared to docetaxel alone in patients with NSCLC who previously failed at least one chemotherapy regimen. Overall survival will be the primary endpoint of the trial, and progression free survival and tumor response rates will be compared as secondary endpoints. Approximately 150 patients will participate in the trial at clinical trial sites in the U.S., Australia, India, and South America.

“This is an exciting time, as positive results for the combination of NPI-2358 and docetaxel appear to be translating well from the bench to the bedside. We will now be able to test the improvement in efficacy with the addition of NPI-2358 to the standard of care,” said Dr. Shirish

Gadgeel, M.D., Assistant Professor at the Barbara Ann Karmanos Cancer Institute in Detroit, Michigan where the first patient to enter this study was treated.

“The development program for NPI-2358 has consistently exceeded our expectations. The ADVANCE study provides a unique opportunity to assess the efficacy of NPI-2358 in a group of patients that could directly use a treatment that improves the outcomes of current chemotherapy regimens. Recent data suggest that VDAs could represent the next significant advance in cancer treatment, and we are eager to see whether previous results translate into a demonstrated benefit for the patients in this study,” said Matthew A. Spear, M.D, Chief Medical Officer, Nereus Pharmaceuticals, Inc.

Nereus is also evaluating NPI-2358 in other solid tumor indications and expects to initiate additional Phase 2 studies this year.

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.

About NPI-2358

NPI-2358 is a VDA of novel structure currently in clinical development by Nereus for the treatment of cancer. NPI-2358 is one of over 200 synthetic analogues that were prepared following the discovery of the compound Halimide isolated from a marine fungus. NPI-2358 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, NPI-2358 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.

NPI-2358 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 NPI-2358 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 NPI-2358, and Nereus expects to initiate additional studies in other cancers in 2009.

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. 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.

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