October 4, 2013

NanoCarrier Co., Ltd.
Ichiro Nakatomi, Ph.D., President & CEO
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Results of Asia Phase I/II Clinical Study of NC-6004Nanoplatin® Presented at Japanese Cancer Association Meeting

The Phase I/II clinical study of NC-6004 Nanoplatin® in patients with advanced pancreatic cancer has been completed in Taiwan and Singapore by NanoCarrier in collaboration with Orient Europharma Co., Ltd.(hereinafter referred to as OEP) in Taiwan. The Phase III protocol was submitted to the TFDA (Taiwan Food and Drug Administration) in June of this year, and the results of the Phase I/II clinical study were presented at the 72nd Annual Meeting of the Japanese Cancer Association (JCA) held in Yokohama on October 3-5, 2013 by Coordinating Investigator, Dr. Wu-Chou Su (National Cheng Kung University Hospital, Taiwan).

Session Date/Time:IS7-6 October 4, 2013 (Fri)13:00-15:30 Cancer nanomedicine
Title: Phase I/II study of NC-6004, a micellar formulation of cisplatin, with gemcitabine in patients with pancreatic cancer

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The objectives of this Phase I/II study were to determine the MTD (maximum tolerated dose), RD (recommended dose), safety and evidence of anti-tumor activity of NC-6004 in combination with Gemcitabine. A total of 24 patients with pancreatic cancer were treated with NC-6004 once every 3 weeks, and with Gemcitabine（1000 mg/m^2）twice every 3 weeks on Day 1 and 8.

【Summary of Phase I/II Clinical Study Results】

Due to the small number of enrolled patients, overall study results will not be clearly indicated until the Phase III clinical study is completed. The summary is described below:

Safety/Tolerability

The results showed possibility for clinical significance

- Lower frequency as well as severity of occurrence of Cisplatin-specific side effects such as kidney damage, gastrointestinal toxicity, neuropathy and hearing disorders
- Kidney damage can be reduced effectively without a high volume of hydration

Efficacy

- Efficacy was approximately the same compared to literature data of existing therapies (Abraxane+Gemcitabine)
- Phase I/II clinical trial OS median: 8.2 months, PFS median: 3.8 months

Convenience

- Possibility of lower doses to reduce side effects
- Potential for ambulatory treatment with reduced administration time

※Hydration: Adequate fluid infusion together with the administration of anti-cancer drugs to enhance urinary output and to reduce the renal toxicity of the drugs.

We are concurrently promoting the clinical development of NC-6004 in Japan (Phase I study for solid tumors) and in US (Phase Ib/II study for non-small cell lung cancer). We hope to contribute to society by providing anti-cancer drugs that are expected to improve the quality of life of patients.

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