

To whom it may concern

NanoCarrier Co., Ltd  
Ichiro Nakatomi, Ph.D., President & CEO  
(Code No.: 4571 Tokyo Stock Exchange Mothers)  
Toshiki Kaura, head of President's Office  
TEL: +81-3-3548-0217

## **Commencement of Clinical Phase II of Nanoplatin<sup>®</sup> (NC-6004)**

NanoCarrier has been conducting Phase I/II study of the combination therapy with Nanoplatin<sup>®</sup> (NC-6004) and Gemcitabine in patients with locally advanced or metastatic pancreatic cancer in Taiwan and Singapore in collaboration with Orient Europharma (Taiwan). A part of Phase I has been finished and the recommended dose of NC-6004 in combination with Gemcitabine was determined to be 90 mg/m<sup>2</sup>. A part of phase II for the efficacy and safety assessment has been commenced, and the first patient was administered the study drugs in Singapore (National Cancer Singapore).

NC-6004<sup>1,2)</sup>, a cisplatin-incorporated micellar formulation, has been developed by NanoCarrier for the treatment of pancreatic cancer in combination with Gemcitabine. In a part of Phase I, the reduction of cisplatin-related toxicity and the increase in safety have been confirmed. Furthermore, administration period was 17 cycles (approx. 1 year) at most in the combination therapy with NC-6004 and Gemcitabine compared with average 4-5 cycles for Gemcitabine only, suggesting the possibility for increased efficacy and the extension of progression-free survival (PFS)<sup>\*1</sup>. In the second-half of the FY2012, Phase II clinical study mentioned above is planned to commence in Japan after IND application and approval<sup>\*2</sup>.

### Effect on financial forecast in FY2012

FY2012 will not be affected by this issue.

### <References>

- 1) Review for phase I study of NC-6004, a cisplatin-incorporated polymeric micelle, in United Kingdom  
Drug Delivery System Vol. 24 (2009), No.1 p45-53
- 2) A Phase I clinical study of cisplatin-incorporated polymeric micelles (NC-6004) in patients with solid tumours  
British Journal of Cancer (2011) 104, 593 – 598

### <term explanation>

- \* 1 Progression-free survival (PFS)  
Survival period of patients without disease progression.
- \* 2 IND(Investigational New Drug) application and approval.  
Application of clinical trial execution materials to authorities and approval of clinical trial execution plan by institutional review board.