To Whom It May Concern

NanoCarrier Co. Ltd.
Ichiro Nakatomi, President & CEO
(Code No. 4571 TSE Mothers)

Primary Endpoint Achieved in the U.S. NC-6300 Epirubicin Micelle Phase I Study

NanoCarrier has conducted a Phase I/II study of NC-6300 in the U.S. to evaluate the safety and tolerability of NC-6300 as well as to determine the recommended dose. NanoCarrier is pleased to announce that the primary endpoint has been achieved in the Phase I study of NC-6300*1 as part of the Phase I/II study in the U.S.

In Phase I part, NC-6300 was administered to 29 patients with solid tumors, including sarcoma, confirming its safety.

- The maximum tolerated dose (MTD) of NC-6300 was determined to be 185 mg/m².
  It was possible to administer a higher dose than popularly used clinical doses of epirubicin (for example, 60 mg/m² or 100 mg/m² for breast cancer).
- There were no adverse events specific to NC-6300. Although epirubicin-related adverse reactions such as nausea/vomiting and myelotoxicity were observed, both the incidence and severity tended to decrease.
- No clinically significant decrease in cardiac function was observed, even in patients with long-term administration.
- Partial Response (PR) was observed in two cases out of two enrolled patients with angiosarcoma, a type of soft tissue sarcoma.
- Long Stable Disease (SD) was observed in patients with malignant melanoma refractory to immune checkpoint inhibitor therapy.

In the near future, after meeting with experts on soft tissue sarcoma at world-renowned cancer centers, including Dana-Farber Cancer Institute and Memorial Sloan Kettering Cancer Center, NanoCarrier will confirm the development strategies with the U.S. Food and Drug Administration (FDA), such as priority review and the accelerated approval program to promote the transition of the study to Phase II. As previously announced, NanoCarrier is planning to develop NC-6300 for rare cancer of soft tissue sarcoma*2 in combination with antibody drug Olaratumab*3 in the Phase II part. NanoCarrier will be promoting a discussion with the U.S. FDA to promptly launch NC-6300.

Please note that this case will have no impact on the business results for the fiscal year ending March 2019.
*1 NC-6300 (epirubicin micelle)

NC-6300 is one of NanoCarrier’s pipeline products using our proprietary micellar nanoparticle technology. It is a pH-sensitive micelle compound that incorporates the anticancer drug epirubicin and selectively releases a large amount of epirubicin by sensing the intracellular environment after being absorbed into cancer cells. NanoCarrier promotes the development of this novel micellar compound under the concept of further reducing the impact on normal cells and enhancing the antitumor effect through a massive release of the anticancer drug inside the cells.

*2 Soft Tissue Sarcoma

Soft tissue sarcomas are a type of malignant solid tumor arising in soft tissue, such as fat, muscle and blood vessels. According to the U.S. National Cancer Institute, the number of new-onset adult patients with soft tissue sarcoma in the U.S. is estimated to be around 12,000 cases/year. Soft tissue sarcoma is globally recognized as a rare cancer.

*3 Olaratumab

Olaratumab is an antibody drug (brand name: Lartruvo) approved in the U.S. for soft tissue sarcoma in 2016, marketed by Eli Lilly and Company. It is a monoclonal antibody targeting platelet-derived growth factor receptor α (PDGFRα). It improves the stromal microenvironment of cancer tissue and effectively facilitates the delivery of concomitant anticancer drugs to the targeted cancer cells.

The information about ethical drugs (including development products) described in this press release is not for promoting/advertising the product, but only for disclosing information to investors. It does not guarantee commercialization of the product.

Contact: Tetsuhito Matsuyama
Director, CSFO and Head of CEO’s Office
Phone: +81-3-3241-0553