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To Whom It May Concern

NanoCarrier Co., Ltd.
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NC-6300 Administration Commenced in Expansion Cohort of Patients with Angiosarcoma

NanoCarrier is pleased to announce that the development of NC-6300, one of our pipeline products, has reached a new phase in the U.S., and administration to participating patients has commenced.

[Summary of the expansion cohort trial]

Target indication	: Angiosarcoma*
Development region	: The U.S. (Duke Cancer Center and Sarcoma Oncology Center)
Planned number of subjects	: 10 patients
Primary endpoint	: Efficacy and safety of NC-6300 monotherapy (150 mg/m^2, every 3 weeks) in patients with angiosarcoma
Study duration	: Approx. 2 years (topline results are planned be obtained in the third quarter of FY2020)

NC-6300 has been designated as an orphan drug in the U.S. and NanoCarrier has been pursuing developmental strategies toward early approval. Epirubicin, an anticancer agent encapsulated in NC-6300, is gaining attention because of its cytotoxic effect as well as its action of inducing the immunogenic cell death. Besides, it is reported that immune-oncology is quite influential to angiosarcoma among several subtypes of soft tissue sarcoma. Therefore, taking into consideration the NC-6300's mechanism of action, NanoCarrier selected angiosarcoma as the target indication of NC-6300. As announced previously, in the US phase I study, two out of two enrolled patients with angiosarcoma achieved partial response (PR), and its performance in the expansion cohort of patients with angiosarcoma is eagerly anticipated.

Please note that this case will have no impact on the business results for the fiscal year ending March 2020.

* Angiosarcoma is a subtype of soft tissue sarcoma, in which more than 50 subtypes have been reported, a malignant tumor originating in vascular endothelium. Considering that sarcoma accounts for 1% of all malignant tumors, angiosarcoma is an extremely rare malignant tumor reported in 2 to 3% of soft tissue sarcoma. Although anthracyclines or paclitaxel are used as treatment for angiosarcoma, standard treatment has not yet been established, and more efficacious and tolerable therapeutic drugs are awaited.

NC-6300 development strategies

As announced on December 12, 2018, NC-6300 achieved the primary endpoint in the phase I clinical study and NanoCarrier was preparing for the next phase. Previously, NanoCarrier planned to use NC-6300 in combination with olaratumab, a new drug got accelerated approval in the U.S. for the treatment of soft tissue sarcomas, expecting a synergetic effect with micellar nanoparticles. However, in January 2019, Eli Lilly and Company, the supplier of olaratumab, released the results of the phase III clinical study of olaratumab in which the endpoint was not met, and announced in April 2019 that they were preparing to withdraw olaratumab from the market. In association with this, NanoCarrier has elaborated on study design based on various findings through meetings with soft tissue sarcoma experts and the FDA. As a result, NanoCarrier has decided to move forward with the expansion study to confirm the efficacy and safety of NC-6300 monotherapy in patients with angiosarcoma, aiming to ensure probability of approval.

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