



June 9, 2015

To whom it may concern

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(Code No. 4571 Tokyo Stock Exchange Mothers Section)

IND Submission of for Phase I Clinical Trial of NC-6004 for in patients with Head and Neck Cancer in Japan

On June 9, 2015, NanoCarrier submitted an Investigational New Drug Application (IND Application)¹ to the Pharmaceuticals and Medical Devices Agency (PMDA), for the domestic Phase I clinical trial of NC-6004 in patients with head and neck cancer.

It remains significant unmet need of therapies for head and neck cancer in Asia, including Japan. The standard therapy is a chemoradio therapy when patients with head and neck cancer are not surgical treated. It is expected that the antitumor effect of such drug and radiation in combination therapy can be strengthened, and organs are remained by avoiding surgery. The representative anti-cancer drug used in chemotherapy is cisplatin. However, there is the need to reduce the amount of cisplatin administered in order to avoid side effects.

NanoCarrier has been developing NC-6004, a new drug delivery product that effectively deploys the antitumor effect of cisplatin, while also reducing side effects. In order to resolve some of the issues associated with cisplatin, NanoCarrier has submitted the trial on the combination of NC-6004 and radiotherapy. This trial will contribute to an increase in the product value of NC-6004, and an improvement in patients' quality of life.

Overview of the Phase I Clinical Trial

Indication: Head and neck squamous cell carcinoma²
Trial content: Verification of the safety and tolerability of NC-6004 when used in combination with radiotherapy and determination of the recommended dose of NC-6004
Trial period: Approximately two years from the start of the trial (planned)

NC-6004 is NanoCarrier's the most important pipeline. We have been developing this drug candidate in the combination with anti-cancer agent gemcitabine in many countries. In Asia, NanoCarrier is conducting a Phase III clinical trial together with our licensee Orient Europharma (Taiwan) for the indication of locally advanced or metastatic pancreatic cancer. NanoCarrier is also conducting a Phase Ib/II clinical trial in the U.S. for the indications of non-small cell lung cancer as well as a Phase I clinical trial for the indication of solid tumors in Japan.

NanoCarrier will continue to commit the development of its pipeline, in the belief that using micellar nanoparticle technology to increase efficacy and reduce side effects of anti-cancer drugs for the improvement of patients' quality of life.

This IND application will not affect the Company's results for the fiscal year ending March 31, 2016.

<Explanation of Terminology>

1. IND (Investigational New Drug) Application

The submission of documentation applying to conduct a clinical trial to a relevant regulatory body, and approval of the clinical trial plan.

2. Head and neck squamous cell carcinoma

Head and neck cancer is the general name for cancer occurring on the upper respiratory tract or digestive tract (lip, oral cavity and pharynx, larynx, nasal cavity and middle ear, paranasal sinuses, etc.). According to the national registry of the Japan Society for Head and Neck Cancer (2012), about 90% of head and neck cancers are squamous cell carcinomas. Head and neck squamous cell carcinoma is the sixth leading cancer by incidence worldwide, and about 650,000 new cases are reported every year.

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