

December 24, 2015

To whom it may concern

NanoCarrier Co., Ltd.
Ichiro Nakatomi, Ph.D., President & CEO
(Code No. 4571 Tokyo Stock Exchange Mothers Section)

Commencement of Phase I Clinical Trial of NC-6004 for Patients with Head and Neck Cancer in Asia

Taiwan-based company Orient Europharma Co., Ltd. (hereinafter called “OEP”) notified to NanoCarrier Co., Ltd. that OEP submitted an investigational application plan to the Taiwan Food and Drug Administration (TFDA) on December 16 (local time) for the Phase I clinical trial of NC-6004 to be administered to patients with head and neck cancer.

Overview of Phase I

Indication: Distant metastatic and recurrent head and neck squamous cell carcinoma
Trial area: Taiwan
Trail content: (1) Verification of the safety and tolerability of NC-6004 when used in combination with 5-FU and cetuximab, and (2) determining the recommended dose of NC-6004
Trial period: Approximately two years from the start of trial (planned)

Head and neck cancer is a disease that still poses significant unmet needs for treatment in Asian countries including Japan. Squamous cell carcinoma, which accounts for approximately 90% of all types of head and neck cancer, is the sixth most common type of cancer in the world, with approximately 650,000 new cases being reported every year. The standard therapy around the world for head and neck cancer, in particular distant metastatic and recurrent head and neck squamous cell carcinoma, is a concomitant treatment with three anti-cancer agents: cisplatin, 5-FU, and cetuximab.

NC-6004, which is currently being developed by NanoCarrier, is a new drug delivery product that effectively generates the antitumor effect of cisplatin, while at the same time reducing side effects. In addition to head and neck cancer, clinical developments are under way in many parts of the world for pancreatic, lung, bladder, and bile duct cancer. Phase III trials for pancreatic cancer are now being conducted in Japan and other areas in Asia to steadily facilitate initiatives for practical application. NanoCarrier will continue to acquire approval for different types of indications around the world and work to expand the market size of the drug in hopes of enhancing the quality of life for as many patients as possible.

NanoCarrier expects that it will have a positive effect on its licensing efforts supported by enhanced product value while the aforementioned submission will not impact the financial results for the fiscal year ending March 31, 2016.

Contact: Tetsuhito Matsuyama
CFO and Head of CEO Office
TEL: +81-3-3241-0553
E-mail: info@nanocarrier.co.jp