To Whom It May Concern

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

NC-6004 Phase II study CTA in combination with immunecheck point inhibitor of Keytruda®

NanoCarrier has prepared study protocol of NC-6004 phase II study in combination with Keytruda® (Pembrolizumab, anti-PD-1 monoclonal antibody) for head and neck cancer. NanoCarrier submitted the study protocol as CTA (Clinical Trial Authorization) to some regulatory authorities in European countries.

[Outline of the Phase II clinical study]

Target indication:	Head and Neck Cancer
Conducted region:	US and Europe (expanding to Taiwan)
Study objective:	Phase IIa part
	Safety assessment of NC-6004 in combination with Keytruda®
	Determination of NC-6004 recommended dose in combination with Keytruda®
	Phase IIb part
	Efficacy assessment in combination with Keytruda®
Study duration:	Approximately 3 years from study initiation (planned)

This study expands combination therapy potency of NC-6004 in combination with immunecheck point inhibitor. NanoCarrier and our Taiwanese partner, OEP, are preparing the study protocol submission in Taiwan followed by US and EU. In worldwide, approximately 30 study sites will participate into the study.

Please note that this case will have no impact on the business results for the fiscal year ending March 2019.

*Immune checkpoint inhibitors

Tasuku Honjo, distinguished professor at Kyoto University, has won the 2018 Nobel Prize in physiology and medicine. Professor Honjo has discovered a protein named PD-1 which brakes immune activity. Immunecheck point inhibitor, which shows anti-cancer activity by removing such immune suppression by PD-1 pathway, has been spotlighted as novel immune-oncology therapy and has been developed actively in worldwide.

In Japan, four such drugs have been approved, namely, Nivolumab (product name: Opdivo®), Pembrolizumab (product name: Keytruda®), Atezolizumab (product name: Tecentriq®), Avelumab (product name: Bavencio®) and Durvalumab (product name: Imfinzi®).

* CTA (Clinical Trial Authorization)
Application documents that must be submitted to the regulatory authority in the EU when conducting a clinical trial.

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