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To Whom It May Concern

NanoCarrier Co., Ltd.  
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(Code No. 4571)

**NanoCarrier Starts Administering NC-6004 in the Phase IIb Clinical Study in Combination with  
Keytruda for Head and Neck Cancer**

NanoCarrier is pleased to announce that we have had the first patient dosed in the Phase IIb clinical study for head and neck cancer in combination therapy of NC-6004, our key pipeline, plus Keytruda. This is a comparative study with Keytruda monotherapy.

**[Outline of the Phase IIb clinical study]**

**Target indication:** Head and neck cancer

(Recurrent/metastatic head and neck squamous cell carcinoma  
previously treated with platinum agents)

**Planned number of subjects:** 124 (62 and 62)

**Primary endpoints:** Comparison of the median progression-free survival (PFS) between  
NC-6004 in combination with Keytruda and Keytruda alone

**Study duration:** Approximately 2 years

Phase IIa study showed the overall response rate (ORR) was 25%, and the median progression-free survival (mPFS) was 5.2 months for 135 mg/m<sup>2</sup> of NC-6004 which is the RD in Phase IIb. These results showed more favorable efficacy compared with the Keynote-040 Phase III clinical study of pembrolizumab (Keytruda), where the overall response rate was 14.6% and the mPFS was 2.1 months. This suggests that the comparative study being conducted in the Phase IIb clinical study would have certain potential to demonstrate the superiority of the combination therapy over the comparative control arm (Keytruda alone), and NanoCarrier has great expectations for this study.

This study will lead to an increase in the value of NC-6004 in the anticancer drug market as a combination therapy with immune checkpoint inhibitors, which are spotlighted in cancer treatment. Based on the results of the clinical trial, NanoCarrier is planning to license out NC-6004 in Europe and the United States in collaboration with Orient Europharma Co., Ltd. (OEP, Taiwan).

Development milestone payments that arose with OEP, the licensee in developing NC-6004 for head and neck cancer, has already been incorporated into the financial results of the fiscal year ending March 2021.