



To Whom It May Concern

NanoCarrier Co., Ltd.
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NanoCarrier Presents Favorable Data from Phase IIa Portion of NC-6004 Phase II Clinical Study in Combination with Keytruda

NanoCarrier is pleased to announce that on October 24 to 25, at the 32nd EORTC-NCI-AACR Symposium, we presented favorable results of the NC-6004 Phase IIa clinical study for head and neck cancer in combination therapy of NC-6004 plus Keytruda, an immune checkpoint inhibitor.

Title: Phase IIa/IIb clinical trial of NC-6004 (Nanoparticle Cisplatin) plus

Pembrolizumab in patients with Head and Neck Cancer (HNSCC) who have

failed platinum or a platinum-containing regimen

Outline of the Phase IIa clinical study

- The maximum tolerated dose (MTD) of NC-6004 was not identified and the recommended dose (RD) of NC-6004 was concluded to be 135 mg/m<sup>2</sup>.
- Partial response (PR) was seen in 4 patients. The overall response rate (ORR) was 25% and the disease control rate was 87.5%.
- The median progression-free survival (mPFS) was 4.0 months for the overall population, and 5.2 months for 6 patients receiving 135 mg/m<sup>2</sup> of NC-6004 which is the RD in Phase IIb.
- The safety profile was favorable and dose limiting toxicity (DLT) was not observed. One patient (6.3%) experienced serious adverse events.

This clinical study 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. Based on these positive results for the Phase IIa part, NanoCarrier has great expectations for results in Phase IIb, in which NC-6004 plus Keytruda is compared with Keytruda alone. We are proceeding with preparations for the Phase IIb clinical study, and expecting patient recruitment within this year.

This will have no impact on the business results for the fiscal year ending March 2021. NanoCarrier will proceed with development to increase NC-6004 product value, employing combination therapies with immune checkpoint inhibitors, aiming at early licensing.