A phase III, randomized, open-label, multicenter study of SHR-1210 (anti-PD-1 antibody) in combination with pemetrexed and carboplatin as first line therapy in subjects with advanced/metastatic non-squamous non-small cell lung cancer

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Background: SHR-1210 is a humanized anti–PD-1 antibody, with immunoglobulin gamma 4 (IgG4) as heavy chain and immunoglobulin kappa (IgK) as light chain expressed in the supernatant of a Chinese hamster ovary (CHO) stable cell line. Antitumor activity data for the ongoing clinical studies of SHR-1210 are currently being evaluated. SHR-1210 is currently being tested in 15 studies in advanced malignancies: 4 in advanced solid tumors, 3 in NSCLC, 2 in hepatocellular cancer (HCC; including 1 in HCC or gastric cancer [GC]), 2 in esophageal cancer (EC), 1 in melanoma, 1 in nasopharyngeal cancer (NPC), 1 in primary liver cancer (PLC), and 1 in classic Hodgkin lymphoma (cHL). Since 22 MAY 2017, 395 patients have been enrolled in this trial.

Trial design: In this trial, 412 patients will be randomly assigned in a 1:1 ratio, to receive either carboplatin–pemetrexed chemotherapy OR receive SHR-1210 combined with carboplatin–pemetrexed chemotherapy. Randomization will be stratified according to gender and smoking history. All the patients will receive carboplatin (area under the curve 5) plus pemetrexed (500 mg/m²), all administered as IV infusion on Day 1 of each 3-week cycle for 4 or 6 cycles of the investigator’s choice, followed by pemetrexed (500 mg/m²) every 3 weeks (Q3W) maintenance for the remainder of the study. Patients assigned to the SHR-1210 combined with chemotherapy arm, will additionally receive SHR-1210 (200mg) administered as IV infusion on Day 1 of each 3-week cycle, for up to 35 cycles. Patients assigned to the chemotherapy arm will have the opportunity to crossover to receive SHR-1210 (200mg) monotherapy every 3 weeks (Q3W) once they experience progression of disease (PD) defined by RECIST 1.1 and meet all crossover criteria.

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