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COM701 ± Nivolumab – preliminary results of antitumor activity from a phase 1 study in patients with metastatic NSCLC who have received prior PD-1/PD-L1 inhibitor.

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Topic: Therapeutic development

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Background

Novel agents are urgently needed for the treatment [tx] of patients [pts] with metastatic NSCLC including post immune checkpoint inhibitors (ICI). COM701 [anti-PVRIG] is a novel 1st in class ICI. We hypothesized that COM701 ± nivolumab will demonstrate antitumor activity with a favorable safety and tolerability profile in pts with heavily pretreated NSCLC. Here, we present preliminary results on antitumor activity.

Methods

We enrolled 7 pts with NSCLC: 5 COM701 monotherapy [mtx] [4 - COM701 20 mg/kg IV Q4W mtx expansion, 1 pt COM701 0.01 mg/kg IV Q3W], 2 pts COM701 + nivolumab [COM701/nivolumab 3mg/kg/360 mg both IV Q3W, COM701/nivolumab 10 mg/kg/480 mg both IV Q4W]. Key study objectives were safety/tolerability and preliminary antitumor activity; OS was an exploratory endpoint. Key inclusion criteria: Age ≥ 18 yrs, histologically confirmed metastatic solid malignancy and has exhausted all standard tx. Key exclusion criteria: history of immune toxicities on prior ICI tx leading to discontinuation. Safety per CTCAE v4.03, investigator-assessed response per RECIST v1.1.

Results

Age >65 4/7 [57%], female 6/7 [86%], prior lines median [Min, Max] 4 [3, 6], all pts received prior ICI, 4/7 [57%] received ≥2 prior lines with ICI. Disease control rate [CR+PR+SD] 5/7 [71%], no CR or PR. Median [m] PFS [all pts] 84 days 95% CI [22, 231], mOS in all pts 9.5 months [mos] [95% CI, 2.7-11.6] – [COM701 mtx 9.5 mos [2.7, NE]; combination 10.1 mos [95% CI, 8.6, NE]. The most frequent AE was G1 nausea in 2 pts. Post ICI NSCLC data - 1 prior line of ICI in metastatic setting, mOS 14.5 mos for ramucirumab + pembrolizumab¹.

Conclusions

COM701 ± nivolumab has preliminary encouraging signal of antitumor activity in a heavily pretreated popn of pts with NSCLC with prior ICI txp comparable to historical data. A P1 study in post IO NSCLC evaluating COM902+COM701+PD-1 inhibitor, COM902+COM701+chemotherapy is planned. Datacut 07/17/2022.

1. Reckamp KL, et al Phase 2 Randomized Study of Ramucirumab and Pembrolizumab vs SOC in Advanced NSCLC Previously Treated With Immunotherapy-Lung-MAP S1800A. J Clin Oncol. 2022 Jul 20;40(21):2295-2306

Clinical trial identification

NCT03667716.

Editorial acknowledgement[Print](#)