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. (NCT03667716)


COM701 ± nivolumab demonstrates preliminary suggestion of antitumor activity in a heavily pretreated population of patients with NSCLC with prior ICI treatment. Most of the patients (47 [57%]) received 2 or prior lines of ICI. All 4 patients with ICI and with 2 [2/4 [50%]] had ICI 2 months Median OS (median of 4 prior lines of therapy including multiple ICI in 57% of patients): COM701 + nivolumab (10 months) COM701 monotherapy (9 months) Historical data with LungMAP: post ICI NSCLC data - 1 prior line of ICI in metastatic setting, median OS 14.5 months (80% CI: 13.9 to 16.1) for ramucirumab + pembrolizumab 40 mg both study drugs IV Q4W 3/360, Q3W SD SD/Yes 4 Nivolumab x2, anti-GITR antibody (best response N/A)

METHODS

• We enrolled 7 patients with NSCLC:
  - 5 patients COM701 monotherapy
  - 1 patient during monotherapy dose escalation was treated with COM701 0.01 mg/kg IV Q3W
  - 2 patients were enrolled during combination (COM701 + nivolumab) dose escalation
  - 1 patient was treated with COM701 3 mg/kg + nivolumab 360 mg both study drugs IV Q4W
  - 1 patient was treated with COM701 10 mg/kg + nivolumab 480 mg both study drugs IV Q4W
  - Antitumor activity (per investigator) was evaluated per RECIST v1.1 with CT imaging C 6/W during follow up. Schedule of study treatment is fixed at any time point if progressive disease is suspected
  - Study treatment for 2yrs unless PD, toxicity, withdrawal of consent, disease progression
  - We have reported on preliminary safety/tolerability

ELIGIBILITY CRITERIA AND OBJECTIVES

Key Inclusion Criteria:
- Histologically confirmed locally advanced or metastatic solid malignancy and has exhausted all available standard treatment or is not a candidate for available standard therapy
- EGFR-1
- No limitation on the number of prior lines of therapy or prior PD-1/PD-L1 inhibitor

Key Exclusion Criteria:
- Active autoimmune disease requiring systemic treatment
- Prior receipt of anti-PVPIg inhibitor
- History of immune-related toxicities on prior immunotherapy treatment leading to discontinuation

Key Primary Objective:
- Safety and tolerability of COM701 monotherapy and the combination

Key Secondary Objective:
- Preliminary antitumor activity of COM701 monotherapy and the combination

Key Exploratory Objectives:
- Immunogenicity of COM701
- COM701-mediated pharmacodynamic effect in blood, immune-related changes (cytokines, immunophenotyping)

CONCLUSION

COM701 ± nivolumab demonstrates preliminary suggestion of antitumor activity in a heavily pretreated population of patients with NSCLC with prior ICI treatment. Most of the patients (47 [57%]) received 2 or prior lines of ICI. All 4 patients with ICI and with 2 [2/4 [50%]] had ICI 2 months Median OS (median of 4 prior lines of therapy including multiple ICI in 57% of patients): COM701 + nivolumab 40 mg both study drugs IV Q4W 3/360, Q3W SD SD/Yes 4 Nivolumab x2, anti-GITR antibody (best response N/A)