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).

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Abstract Number 130P

BACKGROUND

- Novel agents are urgently needed for the treatment of patients with metastatic NSCLC including post-immune checkpoint inhibitors
- COM701 is a novel,1st-in-class ICI that binds to PVRIG, leading to activation of T-and NK-cells
- 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 vs SOC 11.6 months (80% CI 9.9 to 13.0)[1]
- We hypothesized that COM701± nivolumab will demonstrate antitumor activity with a favorable safety and tolerability profile in patients with heavily pretreated NSCLC
- We have reported on preliminary safety and tolerability[2]
- We present preliminary results on antitumor activity and long term follow up

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
    - 4 patients enrolled during monotherapy dose expansion were treated with COM701 20 mg/kg IV Q4W [recommended dose for expansion]
  - 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 Q3W
    - 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 Q 6/8W depending on schedule of study treatment or at any time point progressive disease is suspected
- Study treatment for 2yrs unless PD, toxicity, withdrawal of consent, PI discretion
- We have reported on preliminary safety/tolerability[2]

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
- ECOG 0-1
- 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-PVRIG 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)

DEMOGRAPHICS

Characteristics	
Age, n(%) >65 years	4 (57)
Sex, n(%) Female	6 (86)
ECOG (0, 1), n(%)	
Prior PD-1/PD-L1	7 (100)
≥2 prior lines of ICI	4 (57)

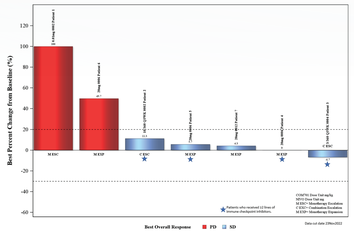
Data cut 23NOV2022

SUMMARY OF INVESTIGATOR ASSESSED RESPONSE (RECIST v1.1)

Parameter	All patients n = 7 (%)
ORR (CR+PR)	-
Disease control rate (CR+PR+SD)	5 (71)
Best response	
CR	-
PR	-
SD	5 (71)
PD	2 (29)

Data cut 23NOV2022

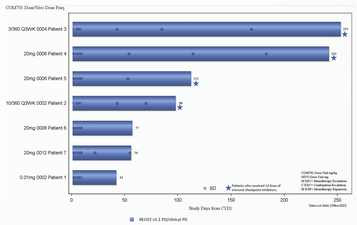
WATERFALL PLOT



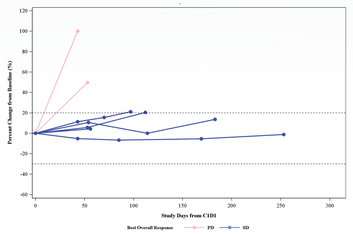
PATIENT DISPOSITION SUMMARY

	n = 20 (%)
Number of patient enrolled and treated - n(%)	7 (100)
Median (Min, Max) #Prior Lines	4 (3,6)
Discontinued study treatment - n(%)	7 (100)
Reasons for study treatment discontinuation (n) • Progressive disease per RECIST v1.1/clinical PD	7 (100)

SWIMMER PLOT



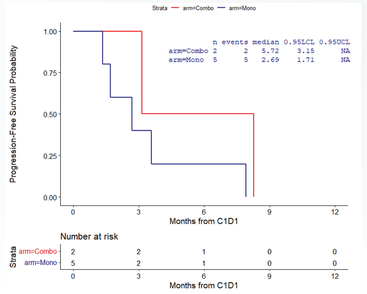
SPIDER PLOT



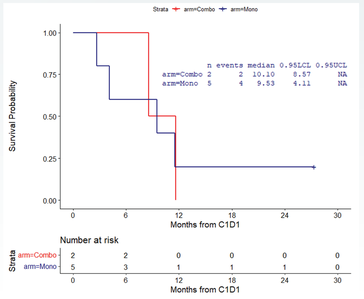
CLINICAL CHARACTERISTICS OF PATIENTS

Patient ID	Arm	Dose [COM701, mg/kg/Nivolumab, mg], schedule	Best time point Response assessment on this study	Response prior to study enrollment/ any prior ICI	Number prior lines	Prior ICI
1	Monotherapy dose escalation	0.01, Q3W	PD	PD/Yes	5	Pembrolizumab (best response, PD), pembro-chemo (best response PD)
4	Monotherapy expansion	20, Q4W	SD	SD/Yes	4	Ipilimumab+nivolumab, pembrolizumab; best response SD
5	Monotherapy expansion	20, Q4W	SD	SD/Yes	4	Nivolumab x2, best response SD
7	Monotherapy expansion	20, Q4W	SD	PD/Yes	5	Nivolumab (best response PD)
6	Monotherapy expansion	20, Q4W	PD	PR/Yes	4	Pembrolizumab (best response PR)
2	Combination dose escalation	10/480, Q4W	SD	SD/Yes	3	Pembro-chemo x2 (best response SD)
3	Combination dose escalation	3/360, Q3W	SD	-/Yes	6	Nivolumab x2, durvalumab + tremelimumab, anti-GITR antibody (best response N/A)

K-M Plot of PFS



K-M Plot of OS



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1. Reckamp KL, et al Phase 2 Randomized Study of Ramucirumab and Pembrolizumab vs SOC in Advanced NSCLCPreviously Treated With Immunotherapy-Lung-MAP S1800A. J Clin Oncol. 2022 Jul 20;40(21):2295-2306 **2.** Vaena, DA, Fleming GF et al. COM701 with or without nivolumab: Results of an ongoing phase 1 study of safety, tolerability and preliminary antitumor activity in patients with advanced solid malignancies (NCT03667716). J Clin Oncol 39, 2021 (suppl 15; abstr 2504).

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DISCLOSURES

R, Sullivan, MD reports no disclosures.

CONCLUSION

COM701 ± nivolumab demonstrates preliminary encouraging signal of antitumor activity in a heavily pretreated population of patients with NSCLC with prior ICI treatment. Most of the patients 4/7 [57%] received ≥2 prior lines of ICI All 4 patients with SD, with 2/4 [50%] with SD ≥6 months Median OS (median of 4 prior lines of therapy including multiple ICI in 57% of patients): COM701 + nivolumab (10 months) COM701 monotherapy (9.5 months) Historical data with LungMAP[2]: 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 vs SOC 11.6 months (80% CI 9.9 to 13.0) The combination warrants further investigation in a similar population