BACKGROUND

- More gradual tumor killing with less toxicity
- Treatment failure in 20% of patients on second line of treatment
- 60% of patients on third line of treatment

PRECLINICAL RATIONALE

- CAR-T cells with hypoglycosylated MUC1C are more capable of killing MUC1+ tumor cells
- MUC1C on CAR-T cells is more effective than MUC1

CLINICAL STUDY METHODS AND DESIGN

- Full dose escalation
- MTD, antitumor effect, safety
- Patients enrolled in groups of up to 15
- RP2D at ≤MTD
- ≤6 cycles q2W
- Up to 3 cycles
- All patients with ≥ 2 inhibitory checkpoint inhibitors

PHASE 1 DOSE-ESCALATION CLINICAL RESULTS

- 100 – 1000x CAR-T cells
- TILs
- Adverse events
- FAS
- CD16
- CD8
- CM

CONCLUSIONS

- 2x10^6 CAR-T cells
- 2x10^7 CAR-T cells
- 1x10^7 CAR-T cells
- Overall response
- Best response
- CR
- PR
- SD
- Toxicity

1. 2x10^6 CAR-T cells: No CAR-T cells killed tumors
2. 2x10^7 CAR-T cells: 100% of patients achieved tumor shrinkage
3. 1x10^7 CAR-T cells: 70% of patients achieved tumor shrinkage

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