A Phase Ia Study to Evaluate RO7198457, an Individualized Neoantigen-Specific Immunotherapy (iNeST), in Patients With Locally Advanced or Solid Tumors

**BACKGROUND**

- High tumor mutation burden correlates with clinical response to immune checkpoint blockade.
- Mutated neoantigens are recognized on foreign and endogenous T-cell responses through shared antigens.
- Most of these included neoantigens are not shared between patients, therefore, individualized reagent-specific reactivity is important for individualized approach.

**METHODS**

- **Patient Demographics and Disease Characteristics**
  - Table 1. Patient Demographics and Baseline Characteristics

**RESULTS**

- **Exposure and Disposition of Patients During Dose Escalation**
  - Table 3. Individual Signs and Symptoms of Systemic Reactions (CRS)/IRR/ILI in ≥10% of Patients

- **Adverse Events in Patients Treated With RO7198457**
  - Figure 5. AEs Reported in >10% of Patients Treated With RO7198457

- **Immune Monitoring of Peripheral Blood Detection T-Cell Responses Induced by RO7198457**
  - Figure 8. Kinetics and Phenotype of Neoantigen-Specific T-Cell Responses

- **Immune Monitoring of T-Cell Responses Induced by RO7198457**
  - Figure 7. Neoantigen-Specific T-Cell Responses Induced by RO7198457

**CONCLUSIONS**

- RO7198457 was generally well tolerated.
- One DLT of Grade 3 CRS occurred in the 100-μg dose cohort; the maximum tolerated dose was not reached.
- Systemic immune-related transient systemic reactions, manifesting as low-grade CRS, IRRs, and ILIs. Systemic reactions were generally manageable with the exception of ILIs occurring at higher doses.
- No clinical benefit was observed in the patients with CR or PR.
- One DLT of Grade 3 CRS occurred in a patient with glioblastoma.
- A Phase 3 study of RO7198457 in combination with checkpoint inhibitors is ongoing (NCT03632291).

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**REFERENCES**

- EMD Serono, Inc.

**DISCLOSURES**

- The study is sponsored by Genentech/Roche.
- No other disclosures were reported.