Master protocol to assess the safety and recommended Phase 2 dose of next generation NY-ESO-1–specific TCR T-cells in HLA-A*02 patients with synovial sarcoma and non-small cell lung cancer

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Therapeutic areas
- NY-ESO-1 is an attractive target for advanced malignancies.
- NY-ESO-1 T cells in patients with melanoma have shown promising clinical activity.
- Phase 1 studies of NY-ESO-1 T cells in patients with solid tumors have demonstrated safety and activity.
- Phase 2 and 3 trials of NY-ESO-1 T cells in patients with melanoma have shown promising results.

Study endpoints
- Primary endpoints:
  - Safety
  - Efficacy
- Secondary endpoints:
  - Safety (safety of doses, routes of administration, etc.)
  - Tolerability

Study design
- Primary substudies:
  - A substudy to evaluate the safety and efficacy of NY-ESO-1–specific TCR T-cells in patients with synovial sarcoma and non-small cell lung cancer.
- Additional substudies:

Study population
- Eligible patients:
  - Patients with NY-ESO-1–positive synovial sarcoma or non-small cell lung cancer.
- Exclusion criteria:
  - Patients with a history of immunotherapy.
  - Patients with a history of malignancy other than synovial sarcoma or non-small cell lung cancer.

Study objective
To evaluate the safety, tolerability, and recommended Phase 2 dose of next generation NY-ESO-1–specific TCR T-cells in HLA-A*02 patients with synovial sarcoma and non-small cell lung cancer.

References

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- The study was conducted in collaboration with the National Cancer Institute and the Royal Cancer Hospital.
- The study was approved by the Institutional Review Board of the University of California, Los Angeles.

Disclosures
- The authors have no conflicts of interest to disclose.

Notes
- This study is funded by the National Cancer Institute and the Cancer Research UK.
- The study is being conducted at the University of California, Los Angeles and the Royal Cancer Hospital.
- The study is approved by the Institutional Review Board of the University of California, Los Angeles.

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