This innovative Master Protocol study design permits evaluation of
Mechanism of action CD8+ T-cell responses in vivo

This study design (IGNYTE-ESO) has a Master Protocol design consisting of a core protocol and allowing for multiple independent substudies to investigate the activity of NY-ESO-1–specific T cells in multiple tumor types; overall sample size is not fixed.

Target Expression Screening LHA-A*0201 and NY-ESO-1

The protocol may be amended to include additional substudies to investigate other NY-ESO-1+ or LAGE-1+ positive tumor types and other NY-ESO-1–specific T cells, potentially in combination with other agents.

Key inclusion criteria

• ≥18 years of age
• Measurable disease
• Positive for HLA-A*0201
• NY-ESO-1 antigen expression per REGEX v1.1 assessed by independent central review
• Adequate organ function
• ECOG performance status 0–1

Key exclusion criteria

• Central nervous system metastases
• Clinically significant systemic illness
• Prior gene therapy with integrating vector or NY-ESO-1–specific T cells, vectors, or targeting antibody
• Prior autologous disease or allogeneic hematopoietic stem-cell transplant

Exploratory Endpoints

• Correlation of NY-ESO-1 antigen expression with safety, clinical response, and phenotype of infiltrating T cells
• Relationship between antigen expression and antigen escape
• Potential immune response to GSK3377794 (Substudy 4)
• Impact on quality of life and daily functioning

PART 1 
Eligibility screening

PART 2 
Leukapheresis 
& Manufacture

PART 3 
Lymphodepletion, Treatment & Follow-up

PART 4 Long-term Follow-up (Study 208730)

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