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# LUD00-014: Phase I Study of recombinant vaccinia-NY-ESO-1 (rV-NY-ESO-1) and recombinant fowlpox-NY-ESO-1 (rF-NY-ESO-1) in patients with NY-ESO-1 or LAGE positive cancers

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## Objectives

To determine the toxicity and NY-ESO-1-specific immune responses induced by immunization with rV-NY-ESO-1 or rF-NY-ESO-1.

## Study design

Eligible patients (pts) for the first part of the study were HLA-A2+ with advanced NY-ESO-1/LAGE+ tumors assessed by RT-PCR or immunohistochemistry. For the second part, pts were enrolled irrespective of the HLA type. Four injections of rV-NY-ESO-1, $3.1 \times 10^7$ pfu i.d., or rF-NY-ESO-1, $7.41 \times 10^7$ pfu s.c., were administered four times at 4 week intervals in part 1. Pts enrolled to part 2 received 2 injections of rV-NY-ESO-1, $3.1 \times 10^7$ pfu i.d., followed by multiple injections of rF-NY-ESO-1, $7.41 \times 10^7$ at monthly intervals in case there was no evidence for progressive disease during vaccination. Toxicity was evaluated every 2 weeks. Delayed-type hypersensitivity (DTH) against HLA-A2 binding NY-ESO-1 peptides was assessed at baseline and after the last vaccination in HLA-A2+ pts. Immunogenicity was assessed by ELISPOT and tetramer analysis against HLA-A2 binding NY-ESO-1 peptides.

## Results

29 pts with different types of cancer were enrolled, 9 pts are ongoing, 11 completed at least 4 cycles of treatment, 9 were withdrawn for disease progression or at their own discretion. No remarkable toxicities occured. Positive post-vaccination DTH reactions against 2 HLA-A2 binding NY-ESO-1 peptides occurred in 6/6 pts tested. At baseline all HLA-A2+ pts of part 1 were NY-ESO-1 serum antibody- and CD8+ T-cell negative. In 2 pts a conversion of NY-ESO-1 serum antibody was observed after 3 vaccinations. In 9 pts for whom immune assay data are available, NY-ESO-1 specific CD8+ T-cell responses were induced during vaccination. After 4 injections maximum ELISPOTS ranged between 160–800 per 50,000 CD8+ T-cells in the 2 vaccinia pts and 100–500 in the 2 fowlpox pts as confirmed by tetramer assays. At 4 months 14 pts were found to have stable disease. 1 pt experienced a partial remission of subcutaneous and peritoneal melanoma metastases after 3 months of immunization. Assessments are underway for NY-ESO-1 specific T cell responses restricted by non-HLA-A2 and HLA class II alleles.

## Conclusion

Immunization with recombinant vaccinia- and fowlpox-NY-ESO-1 is safe and induces NY-ESO-1 specific immune responses.