A PHASE I/II TRIAL OF TG01/GM-CSF AND GEMCITABINE AS ADJUVANT THERAPY FOR TREATING PATIENTS WITH RESECTED RAS-MUTANT ADENOCARCINOMA OF THE PANCREAS

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ABSTRACT

TG01 is a mixture of 7 recombinant RAS peptides, which is a promising antigen-specific cancer immunotherapy targeted to treat patients (pts) with RAS mutations found in more than 40% of pancreatic adenocarcinomas. There is a need for improved treatment options for pts with metastatic disease. This study is the first clinical trial of TG01 in combination with gemcitabine (GEM) in pts with incurable pancreatic adenocarcinoma with RAS mutations. GEM is a widely used adjuvant agent for pts with resected pancreatic cancer. This demonstrate that TG01 vaccination activate mutant RAS specific T cells. The main findings of this study were:

- 17/19 (89%) patients had a positive immune response by week 11 whereas 18/19 (95%) had a positive immune response throughout the entire study period.
- 8 patients were still alive at 2 years, the OS rate was encouraging in view of published reports with a median OS of 33.1 months.
- 6 Uesaka K et al.; The Lancet; 388:248-257 (2016)

CONCLUSIONS

- Targovax will continue to assess additional patients in the proposed treatment setting for both RAS- and KRAS-mutant pancreatic cancer. The results from this and ongoing trials will be presented in future publications.

- GEM was well tolerated with a manageable safety profile. No unexpected adverse events were seen.

- This trial is the first to show that a mixture of 7 recombinant RAS peptides, TG01, can be safely combined with GEM in pts with resected pancreatic cancer. This demonstrate the potential of RAS-directed immunotherapy as an adjuvant treatment option for pts with pancreatic adenocarcinoma with RAS mutations.