

HERIZON: A PHASE 2 STUDY OF HER-VAXX (IMU-131), A HER-2-TARGETING PEPTIDE VACCINE PLUS SOC CHEMOTHERAPY IN PATIENTS WITH HER-2+ ADVANCED STOMACH CANCER — CORRELATION OF THE ANTIBODY RESPONSES AND CLINICAL OUTCOME

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Introduction

- HER-2/neu, a member of the epidermal growth factor receptor (EGFR) family, is overexpressed in 6%-30% of gastric cancers.
- HER-Vaxx is a B cell peptide-based anti-HER-2/neu vaccine (IMU-131) comprising trastuzumab's binding site^{1,2}.
- In the phase 1b HERIZON trial (NCT02795988), HER-Vaxx has been shown to be safe and to prolong progression-free survival in patients with HER-2/neu-overexpressing gastric/gastro-esophageal junction cancer (GC)³.
- Results from a phase 2 study showed that treatment with HER-Vaxx lead to a clinical meaningful increase in overall survival when added to standard of care chemotherapy⁴.

Aim

The randomized phase 2 open-label, multi center study included patients with metastatic HER-2 overexpressing GC naïve to HER-2/neu therapy, aimed to evaluate:

- Clinical efficacy of HER-Vaxx plus chemotherapy compared to chemotherapy alone based on overall survival (OS)
- Progression free survival (PFS), time to progression (TTP), disease control rate (DCR), objective response rate (ORR), duration of response (DOR)
- Antibody response to HER-Vaxx

Method

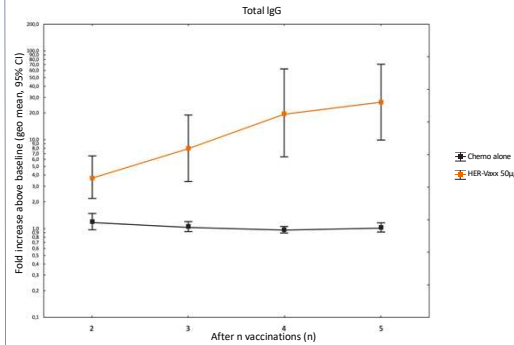
- Patients were randomized to HER-Vaxx plus chemo (n=19) or chemotherapy alone (n=17).
- HER-Vaxx (50µg) was administered on days 0, 14, 35, 77, 140 and q.63 days.
- Levels of serum HER-2/neu-specific IgG and IgG1 were assessed by ELISA. Clinical response was assessed by RECIST 1.1.

References

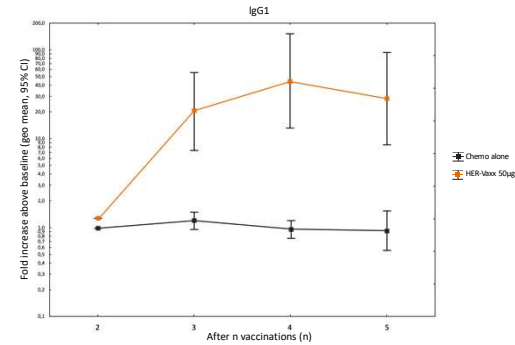
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Results

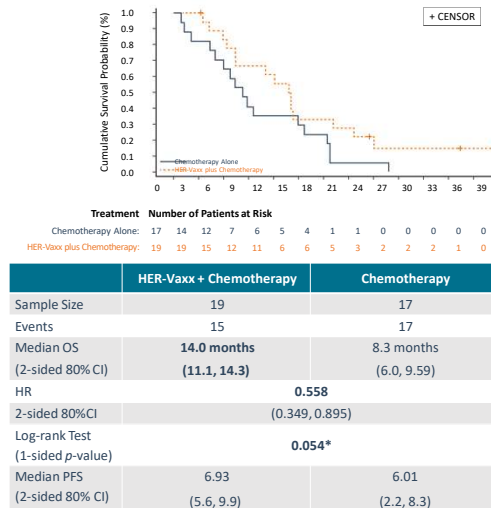
HER-Vaxx induced significant levels of HER-2/neu-specific IgG antibodies



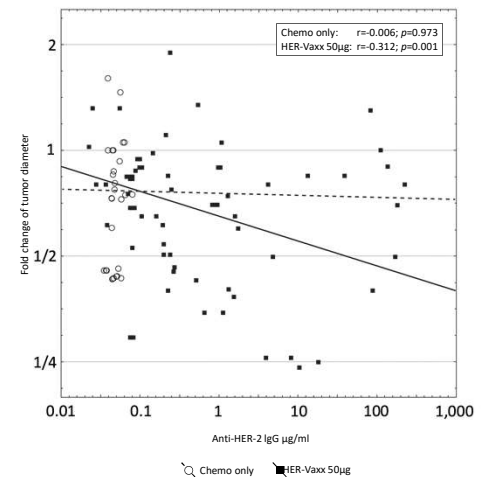
HER-Vaxx induced significant levels of HER-2/neu-specific IgG1 antibodies



A significant increase in overall survival induced by HER-Vaxx



HER-Vaxx-induced IgGs correlated with tumor reduction



Conclusions

- HER-Vaxx treatment produced robust anti-HER-2-IgG and IgG1 antibody response ($p < 0.001$)
- HER-Vaxx-based vaccination of patients with HER-2 overexpressing GC-induced anti-HER-2-IgG and IgG1 subclass antibody responses ($p < 0.001$)
- Compared to chemotherapy alone, the vaccination resulted in a statistically significant overall survival benefit.
- The present data further validate the proof of concept for a first-in-class B-cell immunotherapy based on HER-2/neu peptides.

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