

Final results of the Phase II trial of HER-Vaxx, a B-cell peptide-based vaccine plus standard care of chemotherapy, in patients with HER2-overexpressing advanced gastric cancer - (HERIZON)

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Introduction

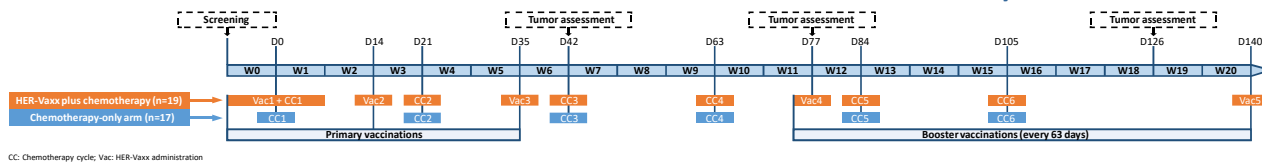
- HER2, a member of the epidermal growth factor receptor (EGFR) family, is overexpressed in 6%-30% of gastric cancers
- HER-Vaxx is a B cell peptide-based anti-HER2 vaccine (IMU-131) comprising the binding site of trastuzumab (Herceptin®)
- HER-Vaxx was shown (Phase Ib, NCT02795988) to be safe and to prolong progression-free survival in patients with HER2-overexpressing gastric/gastro-esophageal junction cancer (GC)

The Study's Aim

This randomized phase II open-label, multi-center study in patients with metastatic/advanced HER2 overexpressing GC aimed to evaluate:

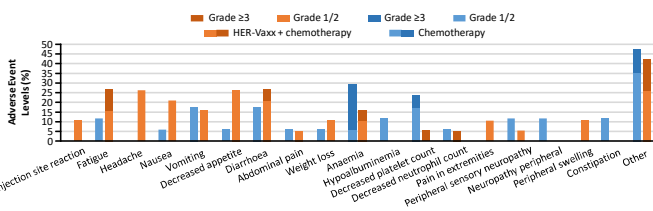
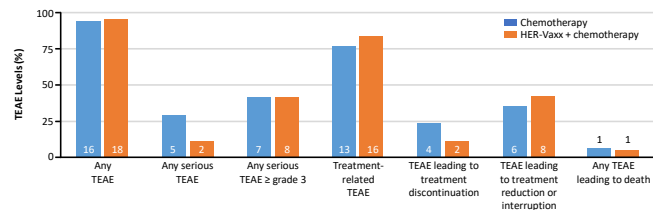
- 1) Safety
- 2) Clinical efficacy (overall survival, progression-free survival) of HER-Vaxx plus chemotherapy compared to chemotherapy alone,
- 3) HER-Vaxx-induced antibodies and their functionality and correlation with the clinical responses.

The Study's Plan and Results



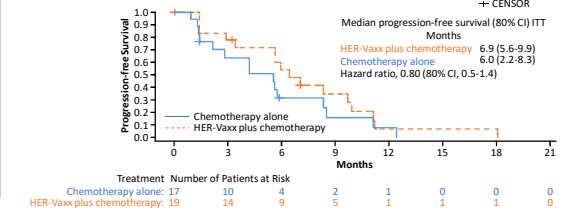
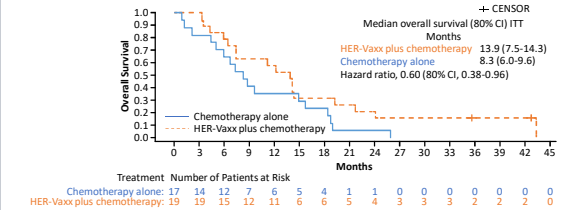
Safety

- No additive vaccine-associated toxicity



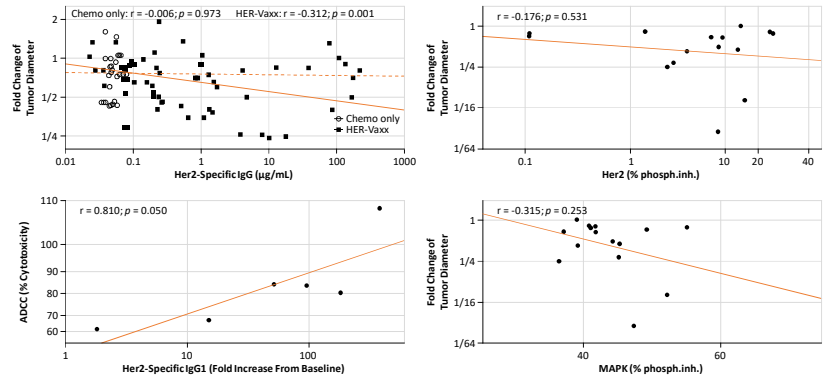
Clinical Response

- HER-Vaxx was associated with 40% OS benefit and 20% PFS benefit



HER-Vaxx-induced Antibodies – Functionality and Mechanism of Action

- HER-Vaxx induced HER2-specific total IgG and IgG1 antibodies, significantly:
- Correlating with tumor reduction and mediation of ADCC
- Inhibiting the intracellular phosphorylation of HER2-signalling pathways



These results show the safety and immunogenicity of the novel B-cell epitope vaccine, HER-Vaxx, in patients with HER2-overexpressing GC and provide proof of concept for a first-in-class HER2 B-cell, peptide-based immunotherapy.

Tobias et al, *Clin. Cancer Res.* 2024, 30 (18): 4044–4054

References

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