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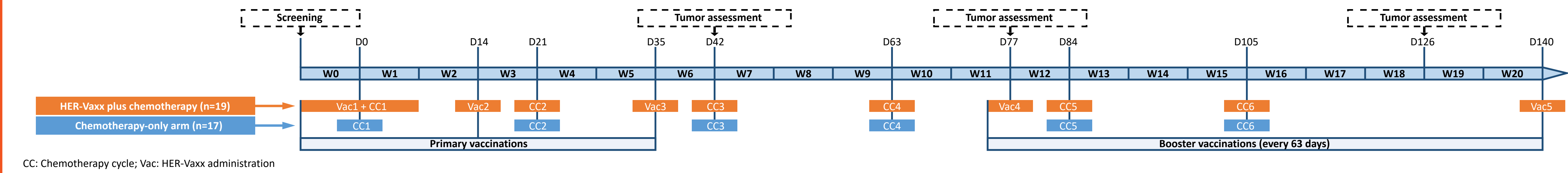
## Introduction

- HER2 is overexpressed in various cancers, including 10%-30% of breast and gastric cancers
- HER-Vaxx is a B cell peptide-based anti-HER2 vaccine (IMU-131) comprising three peptides representing B cell epitopes on HER2 extracellular domains, including the binding site of trastuzumab (Herceptin®)
- In a Phase I trial, vaccination with the single peptides induced humoral and cellular immune responses, as well as an excellent safety profile in patients with metastatic breast cancer
- For clinical efficacy, in a Phase Ib/II trial (NCT02795988), with randomization in Phase II, HER-Vaxx was shown to be safe and induced vaccine-specific humoral and cellular responses associated with prolonged progression-free survival in patients with HER2-overexpressing gastric/gastro-esophageal junction cancer (GC)

## Aims

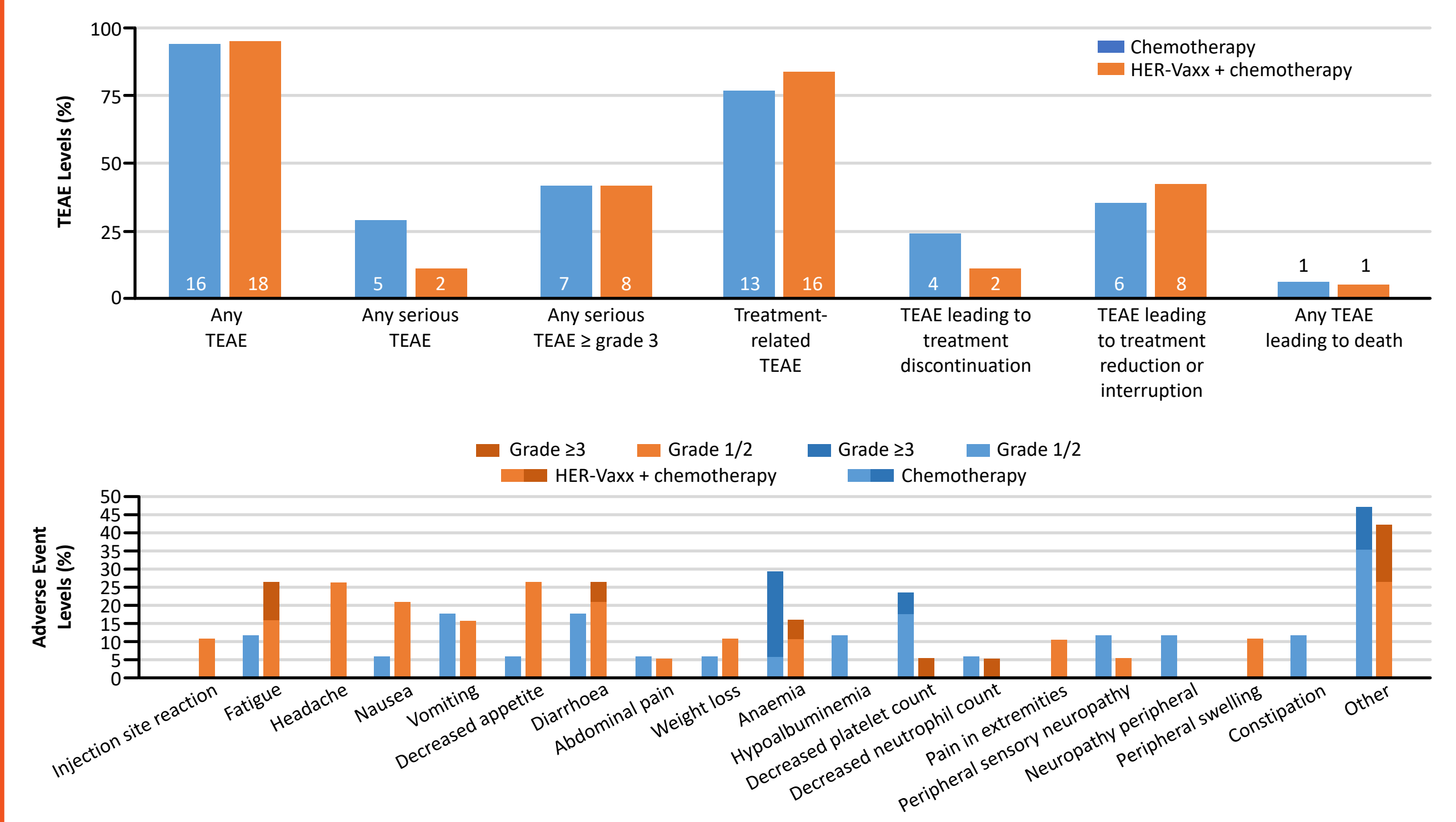
- The presented randomized phase II open-label, multi-center study in patients with metastatic/advanced HER2 overexpressing GC aimed to evaluate:
- Safety
  - Clinical efficacy (overall survival, progression-free survival) of HER-Vaxx plus chemotherapy compared to chemotherapy alone,
  - HER-Vaxx-induced antibodies and their functionality and correlation with the clinical responses.

## The study's plan and Results

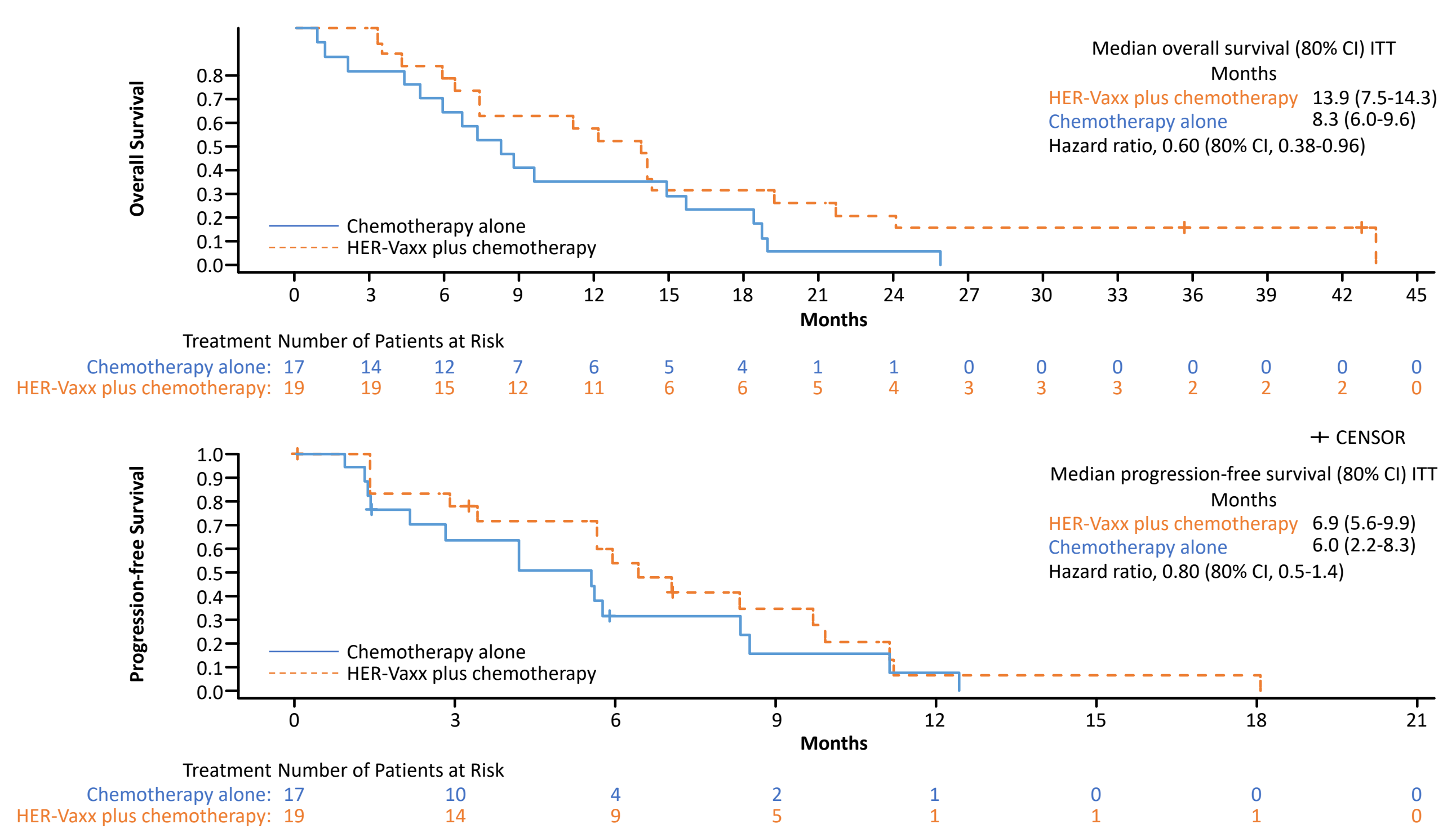


- The timepoints for the patients' initial screening and the assessment of their tumors are indicated by the arrow boxes.
- Clinical response was assessed by RECIST 1.1.
- Immunological assays were applied for the assessment and characterization of the HER-Vaxx-induced antibodies

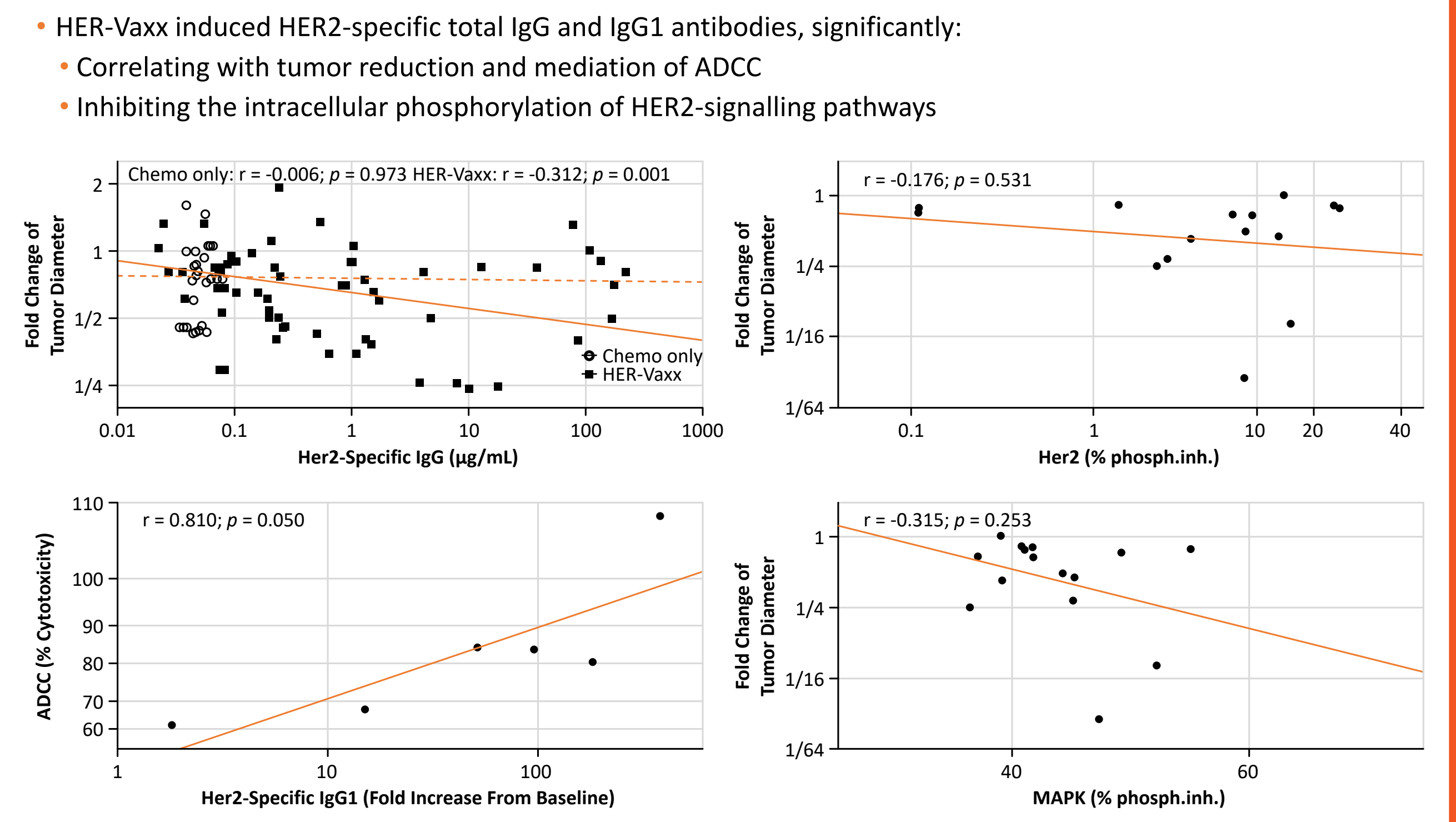
## Safety



## Clinical Response



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



The results of this Phase II trial, showing safety and immunogenicity of HER-Vaxx in patients with HER2-overexpressing GC (Tobias et al, Clin Cancer Res, 2024), suggests a potential pathway for HER2/HER-Vaxx-based vaccines as a treatment modality in HER2-overexpressing cancers.

## References

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- \* Maglakelidze, et.al. *ESMO Asia Poster*. 2022; \* Tobias, et al. *Ann. Oncol.*, 2023, 34, S4; \* Tobias, et al. *Ann. Oncol.*, 2023, 34: S864;
- \* Tobias, et al. *Clin. Cancer Res.*, 2024, 30: 4044-4054.

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