

SINGAPORE  
2022

ESMO  
ASIA

# HERIZON:

A Phase 2 Study of HER-Vaxx (IMU-131),  
a HER2-targeting Peptide Vaccine, Plus Standard  
of Care Chemotherapy in Patients with HER2-  
Overexpressing Metastatic or Advanced Gastric/GEJ  
Adenocarcinoma— Overall Survival Analysis

**Marina Maglakelidze, MD**

Tbilisi, Georgia 04 December 2022

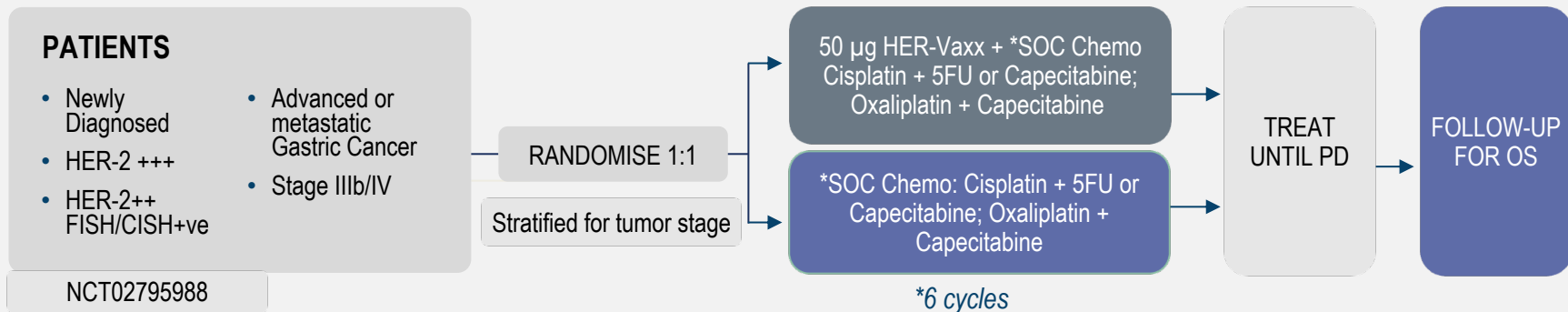


# DECLARATION OF INTERESTS

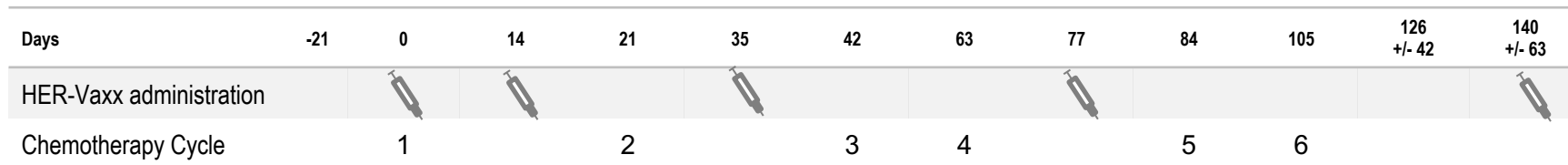
Marina Maglakelidze, MD

- Research funding paid to my institution by study sponsor, Imugene Limited, for role as site Principal Investigator in the HERIZON study

# HER-Vaxx (IMU-131): B-cell Immunotherapy Vaccine Against HER-2



First patient dosed March 2019/last patient enrolled January 2021



<b>PRIMARY ENDPOINT</b>	OS	<b>NO. OF PATIENTS</b>	36
<b>SECONDARY ENDPOINTS</b>	PFS, Safety, Immune Response	<b>SITE LOCATION</b>	Eastern Europe, India

# Baseline Demographics & Patient Characteristics

	HER-Vaxx plus Chemotherapy N=19 (%)	Chemotherapy N=17 (%)
Median Age [years] (range)	65 (48, 84)	68 (44, 79)
Male	10 (53)	13 (77)
ECOG performance grade, n (%)		
Grade 0	8 (42)	8 (47)
Grade 1/2	11 (58)	9 (53)
Initial tumor diagnosis type, n (%)		
Adenocarcinoma of gastroesophageal junction	2 (10)	2 (12)
Adenocarcinoma of the stomach	17 (90)	15 (88)
Tumor stage at screening, n (%)		
Stage IIIb	5 (26)	4 (24)
Stage V	14 (74)	13 (77)
Prior treatment n (%)		
Prior gastric cancer surgery	10 (53)	7 (41)
Prior gastric cancer drug therapy	4 (21)	2 (12)
Prior gastric cancer radiotherapy	1 (5)	0

# HER-Vaxx Added No Significant Toxicity to Chemotherapy

## Safety Overview

	HER-Vaxx + Chemotherapy N=19 (%)	Chemotherapy N=17 (%)
Any TEAE	18 (95)	16 (94)
Any serious TEAE	2 (11)	5 (29)
≥ Grade 3	8 (42)	7 (42)
Treatment-related TEAE	16 (84)	13 (77)
TEAE leading to treatment discontinuation	2 (11)	4 (24)
TEAE leading to treatment reduction or interruption	8 (42)	6 (35)
Any TEAE leading to death	1 (5)	1 (6)

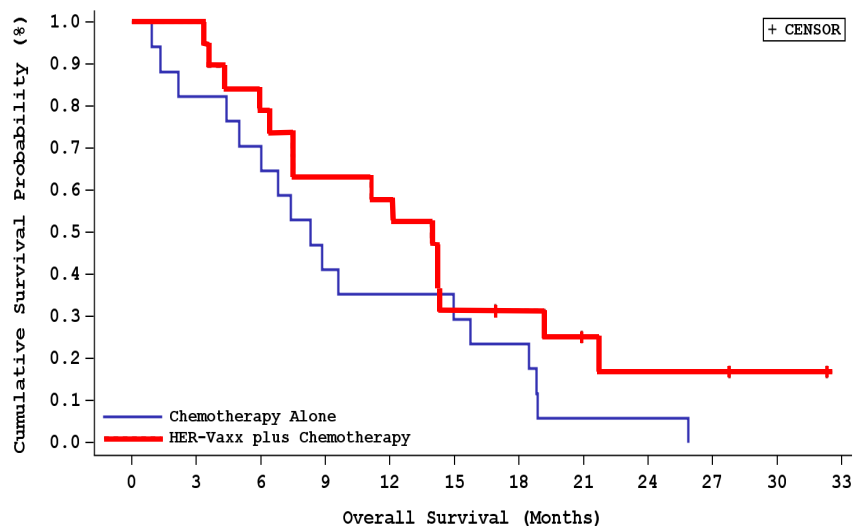
One patient in each arm experienced a grade 5 event:

- grade 5 Covid infection in the HER-Vaxx + Chemotherapy arm
- grade 5 respiratory failure in the Chemotherapy Alone arm.

## Adverse Event in ≥ 10% of Patients

	HER-Vaxx + Chemotherapy N=19 (%)		Chemotherapy N=17 (%)	
	Grade 1/2	Grade ≥ 3	Grade 1/2	Grade ≥ 3
Decreased appetite	5 (26)	0	1 (6)	0
Headache	5 (26)	0	0	0
Diarrhoea	4 (21)	1 (5)	3 (18)	0
Nausea	4 (21)	0	1 (6)	0
Fatigue	3 (16)	2 (11)	2 (12)	0
Vomiting	3 (16)	0	3 (18)	0
Anaemia	2 (11)	1 (5)	1 (6)	4 (24)
Injection site reaction	2 (11)	0	0	0
Pain in extremities	2 (11)	0	0	0
Peripheral swelling	2 (11)	0	0	0
Weight decreased	2 (11)	0	1 (6)	0
Platelet count decreased	0	1 (5)	3 (18)	1 (6)
Hypoalbuminemia	0	0	2 (12)	0
Peripheral Neuropathy	0	0	2 (12)	0

# Overall Survival Benefit with HER-Vaxx Added to Chemotherapy



Treatment Number of Patients at Risk

Treatment	0	3	6	9	12	15	18	21	24	27	30	33
Chemotherapy Alone:	17	14	12	7	6	5	4	1	1	0	0	0
HER-Vaxx plus Chemotherapy:	19	19	15	12	11	6	5	3	2	2	1	0

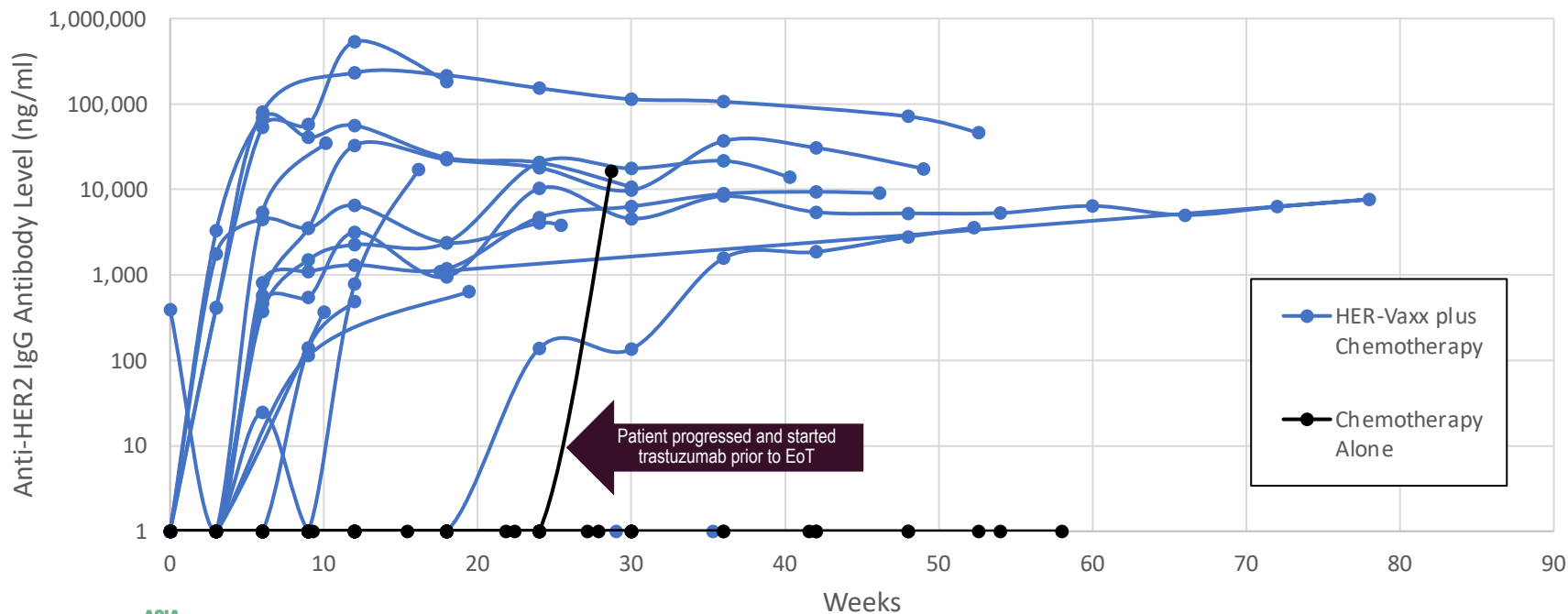
	HER-Vaxx + Chemotherapy	Chemotherapy
Sample Size	19	17
Events	15	17
Median OS (2-sided 80% CI)	<b>13.9 months</b> <b>(7.5, 14.3)</b>	8.3 months (6.0, 9.6)
Median Duration of Response	<b>30 weeks</b>	19 weeks
HR	<b>0.580</b>	
2-sided 80%CI	(0.362, 0.927)	
Log-rank Test (1-sided p-value) *	0.066 *	

\*Significant, 1-sided  $p < 0.10$

# HER-Vaxx Produced Elevated and Sustained Anti-HER2 IgG Antibodies

## HERIZON HER-2 ANTIBODY DEVELOPMENT PER PARTICIPANT

HER2-Specific IgG by Treatment Assignment and Study Visit - Logarithmic Scale



# Conclusions

- HER-Vaxx (IMU-131) + chemotherapy showed a statistically significant 42% overall survival benefit compared to chemotherapy alone (13.9 vs 8.3 months).
- Duration of response was longer in HER-Vaxx + chemotherapy arm over chemotherapy alone arm (30 vs 19 weeks).
- Vaccination with HER-Vaxx induced persistent HER-2 specific antibodies which correlated with clinical response as proof of concept for a first-in-class B-cell immunotherapy based on HER-2 peptides.
- No significant additive toxicity was seen when HER-Vaxx was administered in combination with chemotherapy.