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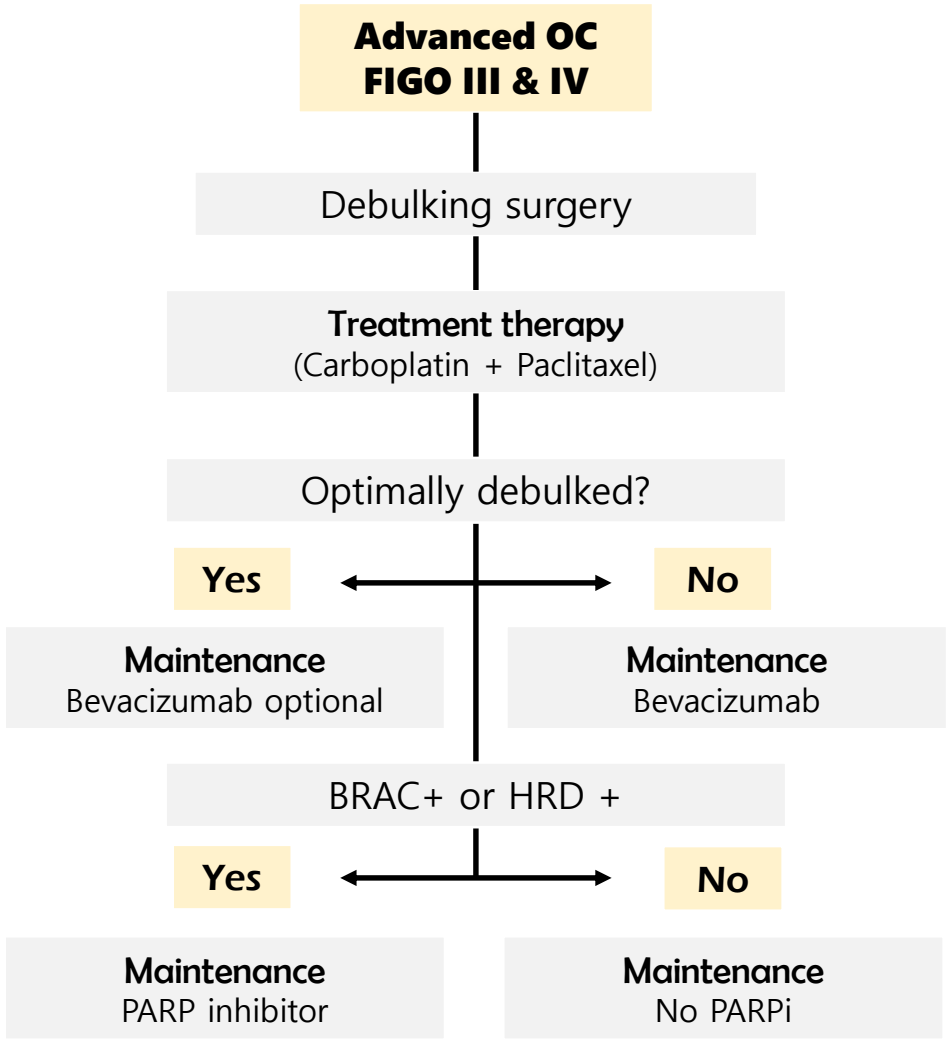
Oregovomab

- ✓ **First in class** immunotherapy for ovarian cancer (OC),
- ✓ No treatment therapy available, only maintenance therapy (bevacizumab, PARPi)
- ✓ Immune checkpoint inhibitors shown unsatisfactory results for OC
- ✓ **Front line** (carboplatin + paclitaxel + oregovomab) phase 3 underway
- ✓ Recurrent platinum resistant patient phase 2 underway
- ✓ PFS: treatment arm **42 months vs. 12 months** for control arm in placebo controlled multicenter phase 2 study
- ✓ 4 treatments of 2mg IV injection, extremely low toxicity
- ✓ Phase 3 patient enrollment started in Oct 2020, expect the interim analysis in 3Q23
- ✓ Orphan designation, Fast track
- ✓ EU peak revenue: the **base scenario is $1.0B** (upside of $1.4B and downside of $750M)
- ✓ EU, MENA, Emerging Markets available for partnering opportunity

Oregovomab TPP

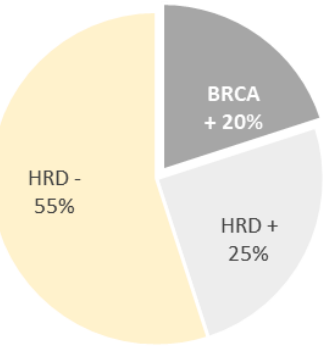
Categories	Definitions
Clinical Indication	FIGO Stage III & IV epithelial ovarian, fallopian tube, or peritoneal cancer following optimally debulked surgical resection
Modality	Murine monoclonal antibody IgG1-k mAb with high affinity (1.16X10^10/M) to CA125
Biological Activity	Oregovomab initiates tumor specific immunity by targeting CA125 in patients with CA125 positive cancers. The therapeutic intent is to induce clearance of CA-125 by antigen processing cells.
Efficacy	In the randomized phase 2 study (n=97), PFS and OS were significantly better (PFS: 42months vs. 12months)
Safety profile	Treatment-related toxicity clearly related to oregovomab has not been encountered in patients with ovarian cancer or patients in the completed or ongoing clinical studies.
Dosage schedule	Six (6) cycles of chemotherapy with oregovomab given at four (4) specific cycles (Cycle 1, Cycle 3, Cycle 5, and Cycle 5 plus 12 weeks)
Administration Route	Intravenous infusion over 20 ± 5 minutes
Formulation	Oregovomab solution is prepared by saline reconstitution of the lyophilized vial powder, which is added to a 50 mL saline infusion bag for IV administration.
Shelf-life and storage	Current shelf-life of DP is 36 months, storing 2-8°C

Oregovomab First in Class, Front Line & Recurrent



First in class, front line treatment therapy

- ✓ First immunotherapy for ovarian cancer (OC)
- ✓ No other treatment therapy available
- ✓ ICIs shown unsatisfactory results for OC.
- ✓ 4 treatment of 2mg, extremely low toxicity
- ✓ Combination study with Bev, PARPi underway



Unmet need for recurrent patients

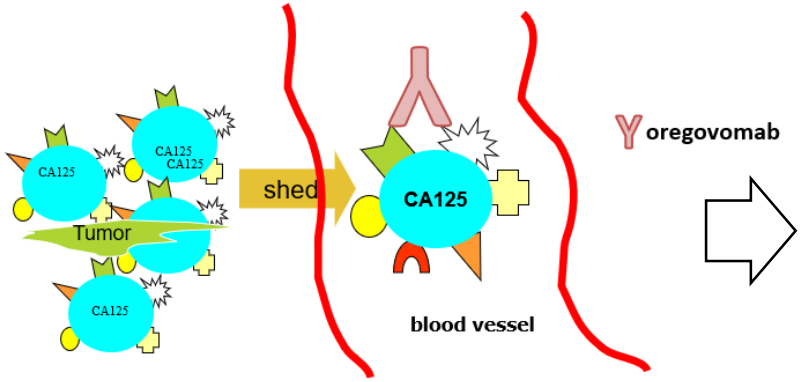
- ✓ Chemo still is the only treatment therapy available
- ✓ Huge unmet medical needs for platimun resistant patients
- ✓ PARPi for only BRCA + patients

Study	Population	Treatment	Maintenance	PFS (months)
FLORA-5	all comers	C + P	None	12
FLORA-5	all comers	C + P + oregovomab	None	42
NOVA	BRCA +	C + P	Bev + Niraparib	37
NOVA	HRD +	C + P	Bev + Niraparib	28
NOVA	HRD -	C + P	Bev + Niraparib	17
GOG-0218	all comers	C + P	None	12
GOG-0218	all comers	C + P + Bev	None	13
GOG-0218	all comers	C + P + Bev	Bevacizumab	18

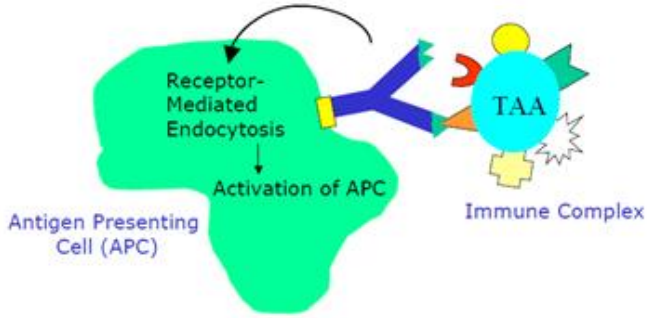
Mechanism of Action

Oregovomab is a murine IgG1-k mAb with high affinity (1.16 x 10^10/M) to CA125. The therapeutic intent is to induce clearance of CA-125 by antigen processing cells.

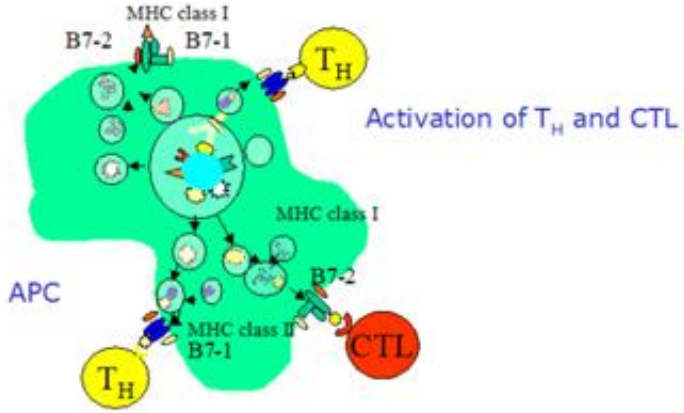
Immune complexes of oregovomab and CA125



Immune complexes efficiently taken up by Antigen Presenting Cells

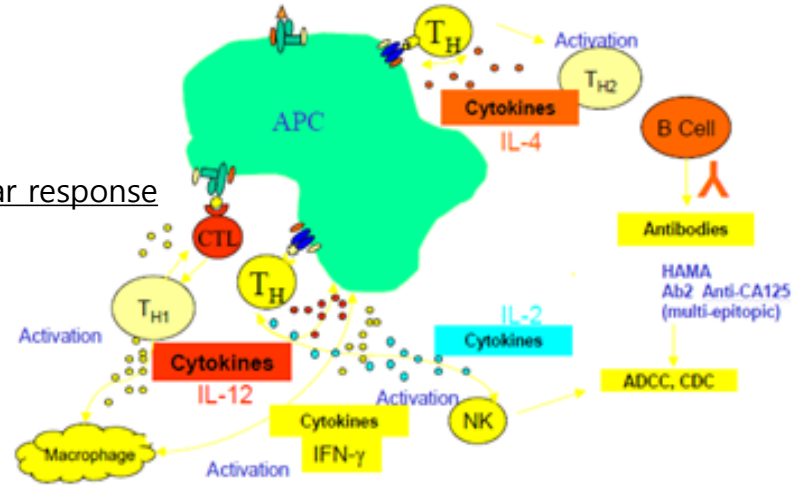


Antigen presentation via MHC II as well as MHC I (cross-presentation)



Humoral response

Cellular response

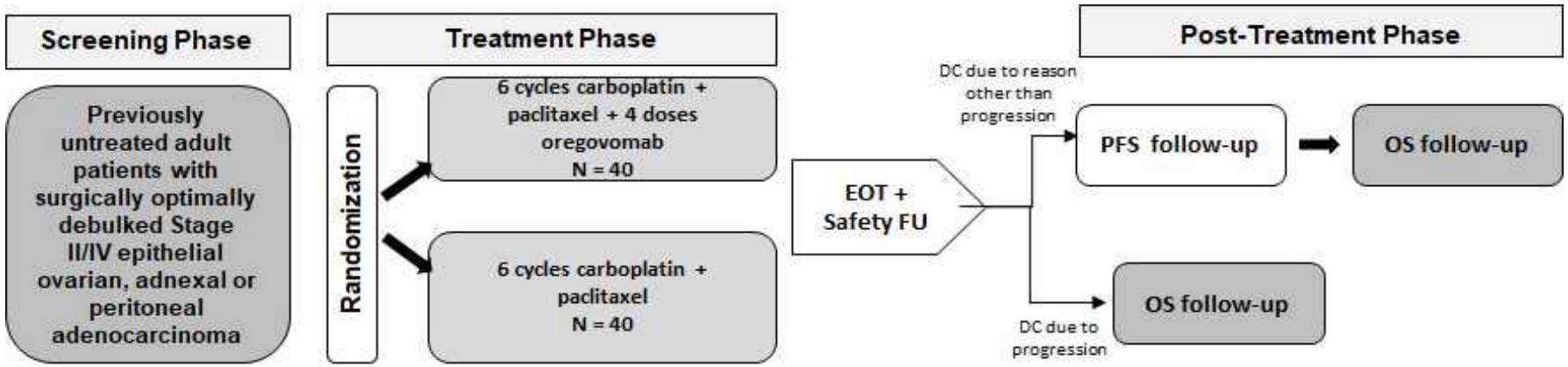


Phase 2 study

Overall Study Design and Plan: Description

- ✓ Phase 2 randomized trial with 8 centers in Italy and 4 centers in the US
- ✓ 97 patients enrolled. Initial treatment of newly diagnosed optimally debulked stage III/IV ovarian cancer expressing CA-125. Debulking equal to or less than 1cm. CA-125 levels at least 2x normal at baseline (50U/ml or greater)
- ✓ SOC chemotherapy (6 cycles IV carboplatin-paclitaxel) (Control) vs SOC chemotherapy plus oregovomab IT (CIT)
- ✓ In CIT group oregovomab administered cycle 1,3, 5 and cycle 5 plus 12 weeks. Initial analysis post completion of treatment phase. Final analysis after 3-year follow up

Phase 2 Study Design

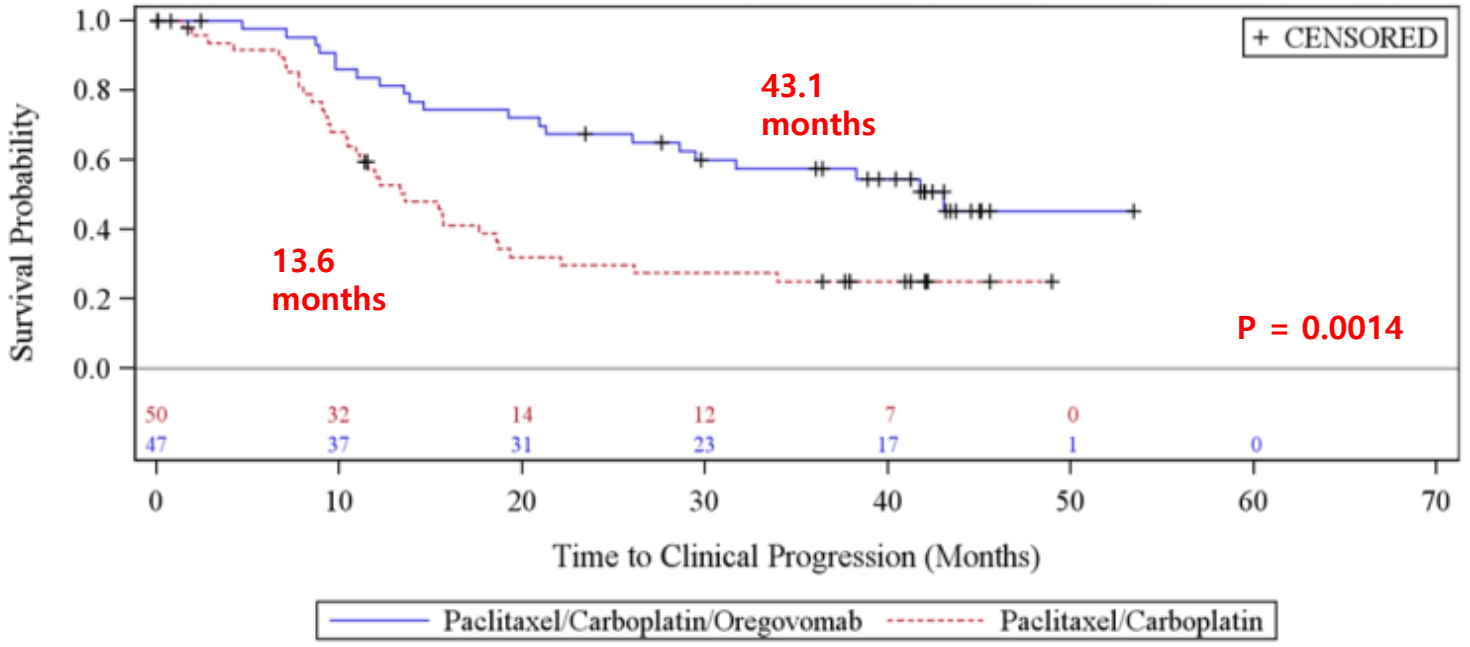


Abbreviations: DC = discontinued; EOT = end of treatment; FU = follow-up; OS = overall survival; PFS = progression-free survival.

Phase 2 Efficacy Evaluation

Time to Clinical Progression (Intent-to-Treat Population)

Parameter Statistic	Arm1: Paclitaxel/Carboplatin/Oregovomab (N = 47)	Arm 2: Paclitaxel/Carboplatin (N = 50)
Time to Clinical Progression, months		
75th Percentile (95% CI)	NE (NE, NE)	NE (17.6, NE)
Median (95% CI)	43.1 (26.1, NE)	13.6 (10.4, 18.7)
25th Percentile (95% CI)	14.6 (9.8, 29.5)	9.1 (7.0, 10.9)
Censored Observations (b), n (%)	26 (55.3)	16 (32.0)
Event Rate, Overall, n (%)	21 (44.7)	34 (68.0)
Hazard Ratio (95% CI)	0.42 (0.24, 0.73)	

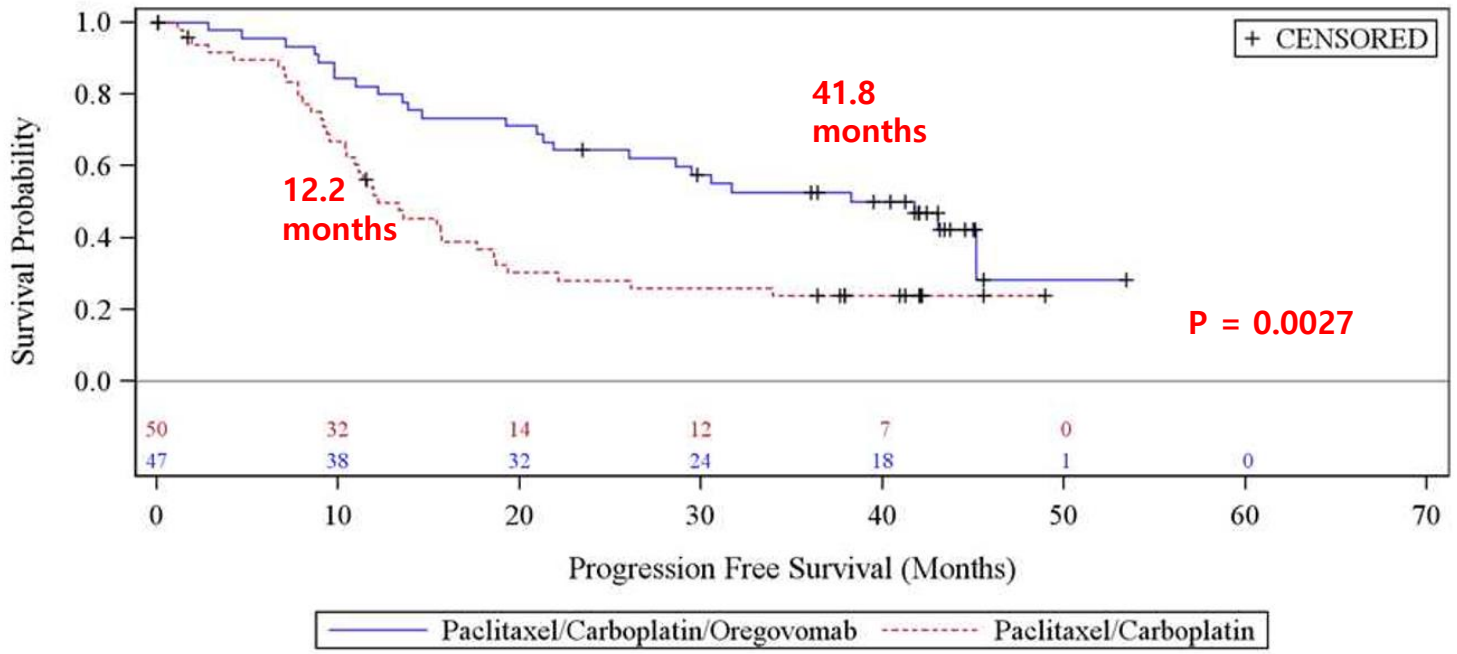


Abbreviations;
CI = confidence interval; **NE** = not estimable.
a Time to clinical progression was defined as date of randomization to date of clinical progression.
b Patients whose disease had not progressed or who were lost to follow-up were censored on the date of last disease assessment.
c Hazard ratio (95% CI): Cox proportional hazard model with treatment arm as covariate.
d p-value calculated using a 2-sided log-rank test.

Phase 2 Efficacy Evaluation

Progression-free survival (Intent-to-Treat Population)

Parameter Statistic	Arm1: Paclitaxel/Carboplatin/Oregovomab (N = 47)	Arm 2: Paclitaxel/Carboplatin (N = 50)
Time to Disease Progression or Death, months		
75th Percentile (95% CI)	NE (45.2, NE)	34.0 (17.6, NE)
Median (95% CI)	41.8 (21.8, NE)	12.2 (10.4, 18.6)
25th Percentile (95% CI)	14.6 (9.8, 26.1)	9.1 (6.7, 10.4)
Censored Observations,bn (%)	22 (46.8)	14 (28.0)
Event Rate, Overall, n (%)	25 (53.2)	36 (72.0)
Progressive Disease, n (%)	20 (42.6)	34 (68.0)
Death, n (%)	5 (10.6)	2 (4.0)
Hazard Ratioc(95% CI)	0.46 (0.28, 0.77)	

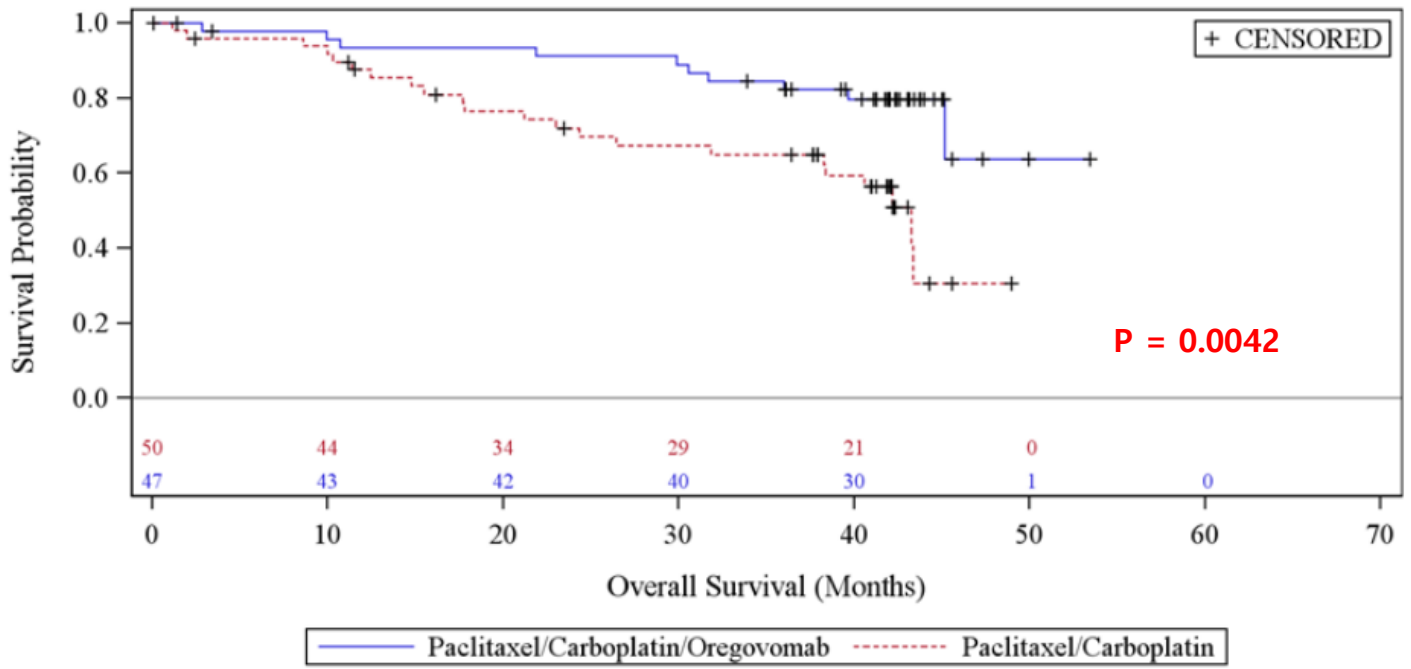


Abbreviations;
CI = confidence interval; **NE** = not estimable.
a Time to clinical progression was defined as date of randomization to date of clinical progression.
b Patients whose disease had not progressed or who were lost to follow-up were censored on the date of last disease assessment.
c Hazard ratio (95% CI): Cox proportional hazard model with treatment arm as covariate.
d p-value calculated using a 2-sided log-rank test.

Phase 2 Efficacy Evaluation

Overall Survival

Parameter Statistic	Arm1: Paclitaxel/Carboplatin/Oregovomab (N = 47)	Arm 2: Paclitaxel/Carboplatin (N = 50)
Overall Survival (months)		
75th Percentile (95% CI)	NE (NE, NE)	NE (43.2, NE)
Median (95% CI)	NE (45.2, NE)	43.2 (31.8, NE)
25th Percentile (95% CI)	45.2 (30.6, NE)	21.2 (11.4, 38.2)
Censored Observations,bn (%)	37 (78.7)	28 (56.0)
Deaths n (%)	10 (21.3)	22 (44.0)
Hazard Ratioc(95% CI)		0.35 (0.16, 0.74)



Abbreviations;
CI = confidence interval; **NE** = not estimable.
a Time to clinical progression was defined as date of randomization to date of clinical progression.
b Patients whose disease had not progressed or who were lost to follow-up were censored on the date of last disease assessment.
c Hazard ratio (95% CI): Cox proportional hazard model with treatment arm as covariate.
d p-value calculated using a 2-sided log-rank test.

Phase 2 Safety Evaluation

Study Treatment Exposure (Safety Population)

	Arm 1: Paclitaxel/Carboplatin Oregovomab (N=46)	Arm 2: Paclitaxel/Carboplatin (N=48)	Overall (N=94)
Number of cycle started			
Mean (SD)	5.5 (1.46)	5.3 (1.58)	5.4 (1.52)
Median	6	6	6
Minimum, maximum	1, 6	1, 6	1, 6
Number of patients (%) completing:			
1 cycle	3 (6.5)	3 (6.3)	6 (6.4)
2 cycles	1 (2.2)	2 (4.2)	3 (3.2)
3 cycles	2 (4.3)	4 (8.3)	6 (6.4)
4 cycles	0	0	
5 cycles	0	0	
6 cycles	40 (87.0)	39 (81.3)	79 (84.0)
Overall study treatment exposure (months) (a)			
Mean (SD)	5.45 (2.717)	3.31 (1.271)	4.36 (2.356)
Median	5.65	3.56	4.24
Minimum, maximum	0.0, 17.6	0.0, 5.4	0.0, 17.6
Number of oregovomab administrations (%)			
1	45 (97.8)		
2	42 (91.3)		
3	40 (87.0)		
4	37 (80.4)		

Abbreviations: SD = standard deviation.
a. Overall study treatment exposure = (last dose date of any study treatment - first dose date of any study treatment +1)/30.4375.

Phase 2 Safety Evaluation

Summary of Treatment-Emergent Adverse Events

Patients with:	Arm 1:Paclitaxel/Carboplatin/Oregovomab (N=46) n (%)	Arm 2:Paclitaxel/Carboplatin (N=48) n (%)	Overall (N=94) n (%)
At least 1 TEAE	38 (82.6)	41 (85.4)	79 (84.0)
At least 1 related TEAE	8 (17.4)	10 (20.8)	18 (19.1)
At least 1 TEAE Grade≥3	24 (52.2)	29 (60.4)	53 (56.4)
At least 1 relatted TEAE Grade≥3	2 (4.3)	5 (10.4)	7 (7.4)
At least 1 serious TAAE	9 (19.6)	7 (14.6)	16 (17.0)
At least 1 related serious TEAE	0	0	0
At least 1 TEAE leading to study drug discontinuation	3 (6.5)	1 (2.1)	4 (4.3)
At least 1 TEAE leading to death	1 (2.2)	1 (2.1)	2 (2.1)

Abbreviations: TEAE = treatment-emergent adverse event

Treatment-Emergent Severe or Life-Threatening Events Occurring in≥2 Patients in Either Treatment Arm

MedDRA System Organ Class/ Preferred Term	Arm 1:Paclitaxel/Carboplatin/Oregovomab (N=46) n (%)	Arm 2: Paclitaxel/Carboplatin (N=48) n (%)	Overall (N=94)
Blood and lymphatic system disorders	19 (41.30)	21 (43.75)	40 (42.55)
Neutropenia	14 (30.43)	20 (41.67)	34 (36.17)
Leukopenia	4 (8.70)	6 (12.50)	10 (10.64)
Anaemia	5 (10.87)	2 (4.17)	7 (7.45)
Thrombocytopenia	2 (4.35)	2 (4.17)	4 (4.26)
Investigations	0	2 (4.17)	2 (2.13)
Granulocyte count decreased	0	2 (4.17)	2 (2.13)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities, version 19.0.

Phase 2 Safety Evaluation

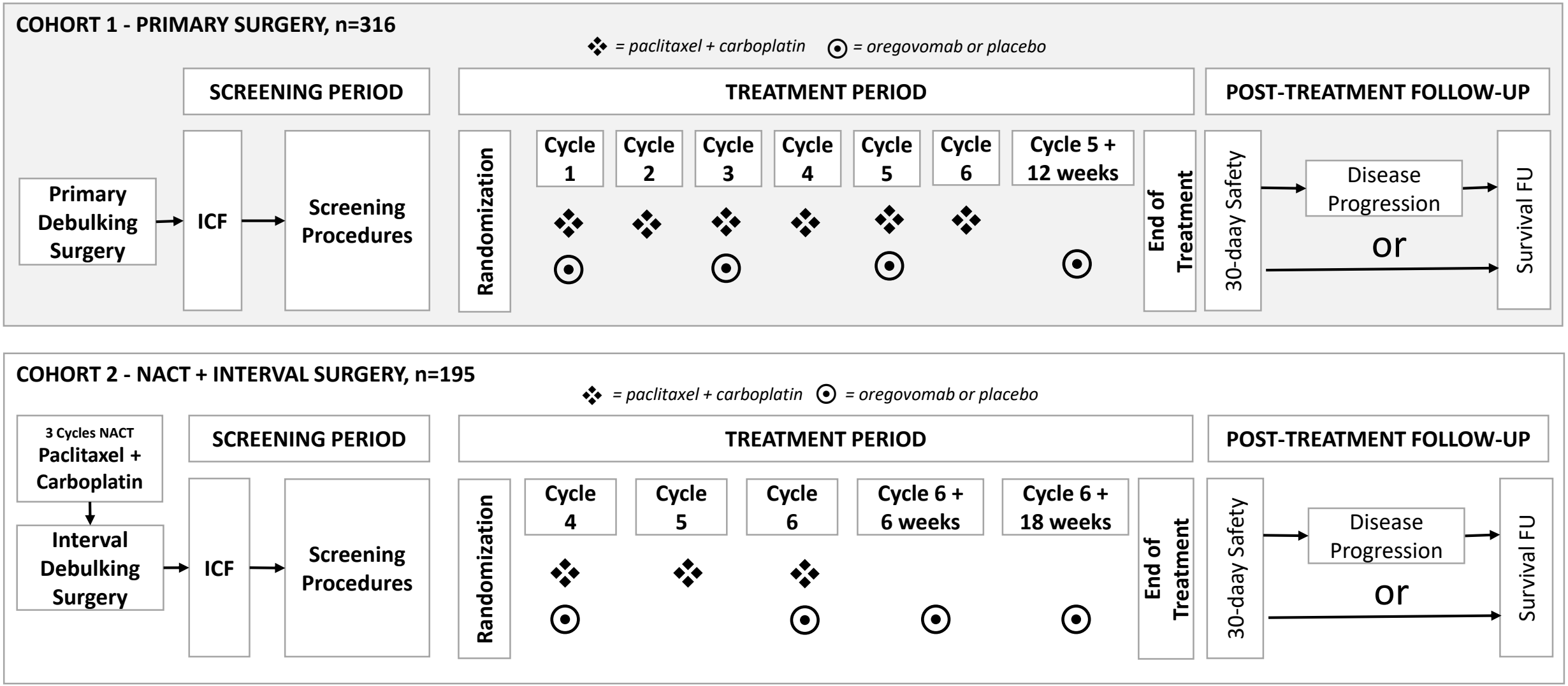
Treatment-Emergent Adverse Events Occuring in ≥ 5% of Patients Overall (Safety Population)

MedDRA System Organ Class / Preferred Term	Arm 1: Paclitaxel/Carboplatin Oregovomab (N=46) n (%)	Arm 2: Paclitaxel/Carboplatin (N=48) n (%)	Overall (N=94) n (%)
Blood and lymphatic system disorders	28 (60.87)	31 (64.58)	59 (62.77)
Neutropenia	21 (45.65)	25 (52.08)	46 (48.94)
Anaemia	18 (39.13)	16 (33.33)	34 (36.17)
Leukopenia	17 (36.96)	17 (35.42)	34 (36.17)
Thrombocytopenia	3 (6.52)	5 (10.42)	8 (8.51)
General disorders and administration site conditions	20 (43.48)	13 (27.08)	33 (35.11)
Asthenia	7 (15.22)	6 (12.50)	13 (13.83)
Fatigue	6 (13.04)	7 (14.58)	13 (13.83)
Gastrointestinal disorders	15 (32.61)	17 (35.42)	32 (34.04)
Nausea	9 (19.57)	7 (14.58)	16 (17.02)
Constipation	8 (17.39)	5 (10.42)	13 (13.83)
Diarrhoea	4 (8.70)	4 (8.33)	8 (8.51)
Vomiting	3 (6.52)	3 (6.25)	6 (6.38)
Nervous system disorders	15 (32.61)	16 (33.33)	31 (32.98)
Paraesthesia	8 (17.39)	9 (18.75)	17 (18.09)
Peripheral sensory neuropathy	4 (8.70)	3 (6.25)	7 (7.45)
Neuropathy peripheral	2 (4.35)	3 (6.25)	5 (5.32)
Musculoskeletal and connective tissue disorders	8 (17.39)	9 (18.75)	17 (18.09)
Arthralgia	1 (2.17)	5 (10.42)	6 (6.38)
Myalgia	2 (4.35)	3 (6.25)	5 (5.32)
Skin and subcutaneous tissue disorders	9 (19.57)	6 (12.50)	15 (15.96)
Alopecia	8 (17.39)	6 (12.50)	14 (14.89)

Abbreviations: MedDRA = Medical Dictionary for Regulatory Activities, version 19.0.

Phase 3 protocol

Two cohorts to be evaluated

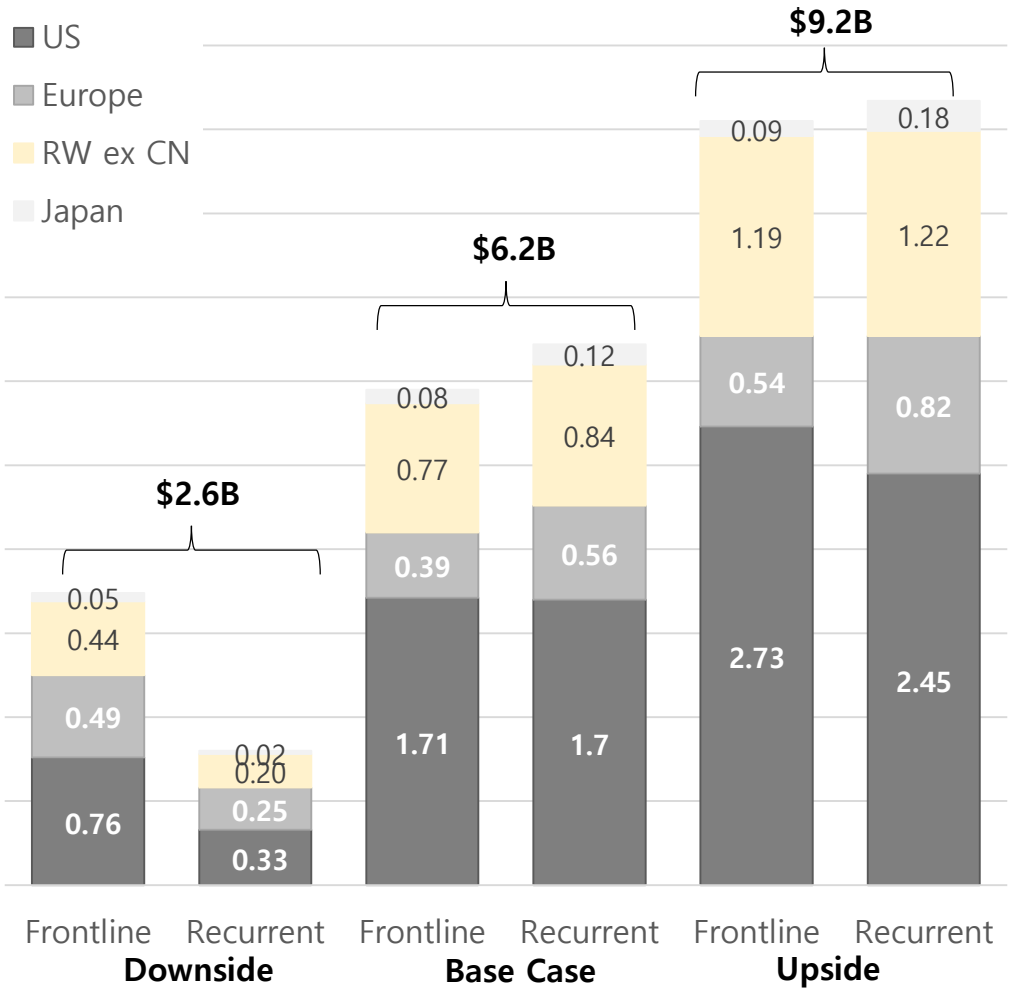


Commercial Assessment of Oregovomab *by Evaluate*

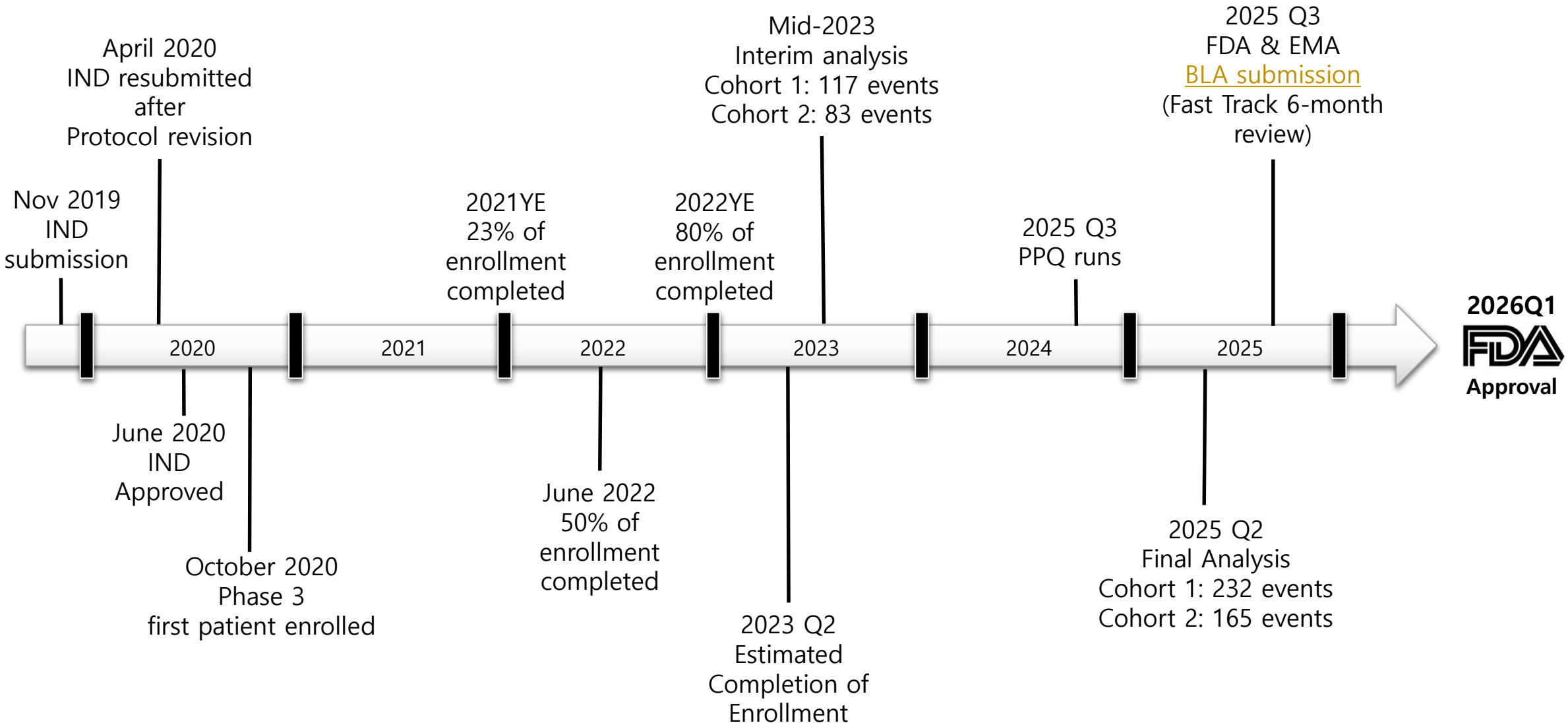
Key messages *by Evaluate*

- Insight gained via primary market research validated our market share assumptions on the frontline setting performed in 2020 based on secondary research. Evaluate suggest the use of primary research to augment assumptions in the recurrent setting once clinical data becomes available
- In the base case, our analysis results in a WW (ex CN) peak of $6.2B forecast in the peak year. This compares to $9.2B and $2.6B in the peak year for the upside and downside scenarios respectively
- The US is the market driving the largest potential sales with $3.4B forecast in the peak year in the base case. In the downside this is expected to be $1.1B with the upside at $5.2B. This is largely due to the price premium in the US
- This is closely followed by Europe as this contains the largest available patient population Oregovomab could capture. In the peak year the base scenario is $1.0B compared to an upside of $1.4B and downside of $750M
- Japan has the smallest forecast of the regions profiled with a base case forecast of $200M, with a downside of $70m and upside of $260M

Peak Year Sales by Region for each scenario ($B)



Development timeline Oregovomab



CanariaBio Pipeline

Study ID	NCT no.	Ovarian Cancer (Front Line)	Collaborator	Stage
QPT-ORE-005 (FLORA-5)	NCT04498117	Cohort1: Adjuvant Chemo + Oregovomab Cohort2: Neoadjuvant Chemo + Oregovomab	Gynecologic Oncology Group	Phase 3

Study ID	NCT no.	Ovarian Cancer (Recurrent)	Collaborator	Stage
KM-21(K-Master)	NCT04938583	Chemotherapy + Bevacizumab + Oregovomab	Korean Cancer Study Group (Roche)	Phase 2
APGOG OV6	NCT05407584	Cohort 1: Oregovomab + PLD Cohort 2: Oregovomab + Weekly paclitaxel	Yonsei Severance Hospital	Phase 2
QPT-ORE-004	NCT05335993	Niraparib + Oregovomab	GlaxoSmithKline	Phase 2

Study ID	NCT no.	Pancreatic Cancer	Collaborator	Stage
N/A	-	Chemotherapy + MAb-AR20.5 (anti-MUC1)		Completed Phase 1

Study ID	NCT no.	Breast Cancer	Collaborator	Stage
N/A	-	Ant-Her2/neu IgE Immunotherapy	UCLA	Preclinical