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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

Mechanism of Action of Oregovomab

Oregovomab is an investigational monoclonal antibody that has been studied in clinical trials as an immunotherapy for patients with ovarian cancer whose tumor cells express the tumor-associated antigen, CA-125 (MUC16). The active component of oregovomab is the modified murine monoclonal antibody (MAb) B43.13, an IgG1κ subclass immunoglobulin that binds with high affinity to CA-125. Its interaction with circulating and tissue-associated CA-125 modifies the immune response to the tumor antigen and is the basis for treatment activity.

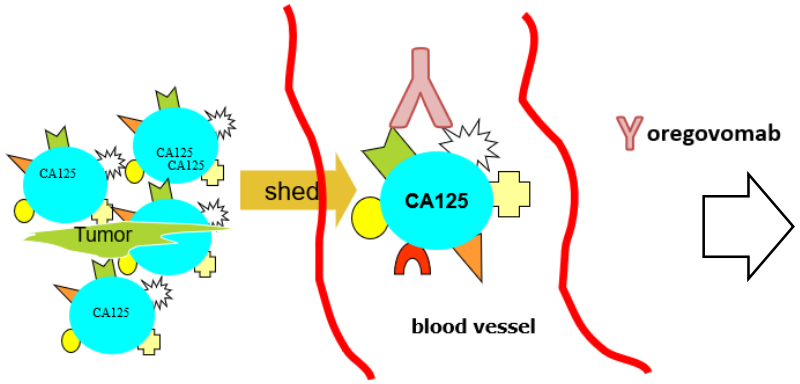
Indirect immunization involves transient repeated exposure to a lower dose of specific antibody, avoiding gross antibody excess, and allows immune-stimulatory antigen processing in the tumor microenvironment and additional systemic sites. Induced cellular immunity targeting tumor antigen is believed to be the primary mechanism of indirect treatment effect.

Current evidence supports that this binding in vivo renders the target antigen CA125 more immunogenic or "neoantigen-like" through altered and enhanced antigen processing and presentation to specific T cells. This induces antigen-antibody uptake and processing using the immunoglobulin Fcγ binding via the mannose receptor, FcγR1, and CCR5, a binding pattern in the human unique to murine IgG1 resulting in cross-presentation of CA125 peptides and initiation of local specific immune responses with an IFN-γ signature. These properties initiate demonstrable humoral and cellular responses in patients with CA125-positive cancer that are otherwise in a state of relative immune tolerance to their disease.

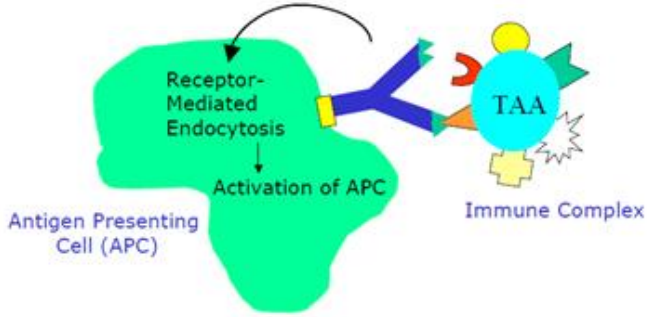
The activity is particularly enhanced when oregovomab is given in combination with selected chemotherapy in a precisely defined sequence and schedule in patients with Stage III or IV epithelial ovarian, tubal, or primary peritoneal cancer in the front-line setting, after optimal debulking surgery (residual disease less than 1cm).

Mechanism of Action of Oregovomab

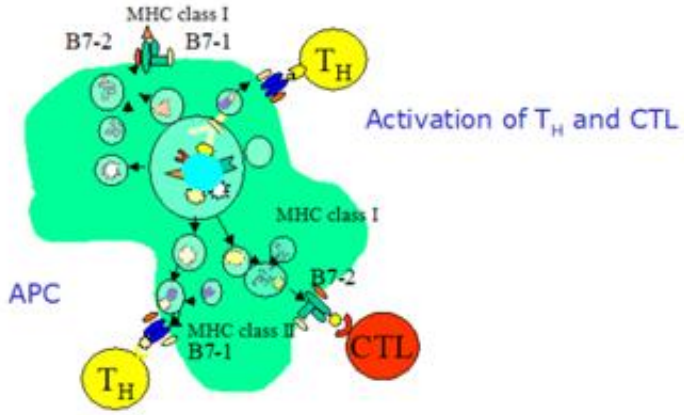
Immune complexes of oregovomab and CA125



Immune complexes efficiently taken up by Antigen Presenting Cells

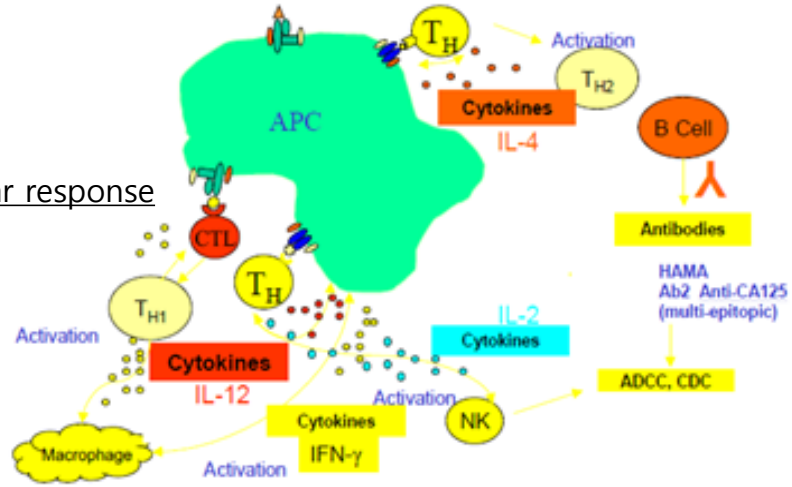


Antigen presentation via MHC II as well as MHC I (cross-presentation)



Humoral response

Cellular response

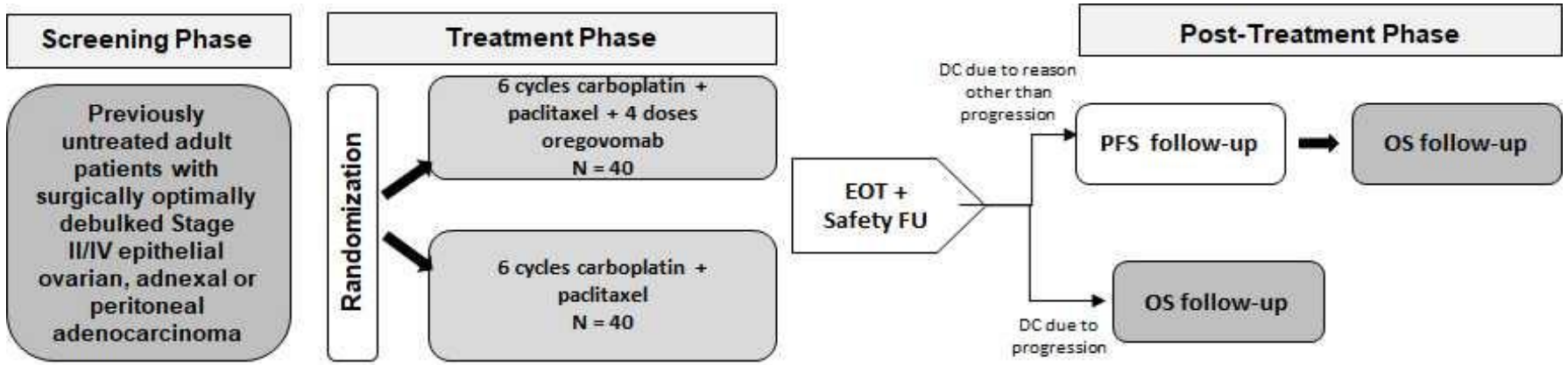


Phase 2 study

Overall Study Design and Plan: Description

QPT-ORE-002 was a Phase 2, randomized, multisite study with 2 treatment arms assessing first-line chemoimmunotherapy (carboplatin-paclitaxel-oregovomab) versus chemotherapy (carboplatin and paclitaxel) in patients with advanced epithelial ovarian, adnexal, or peritoneal carcinoma. Arm 1 received, sequentially on the same day, carboplatin area under the curve (AUC) 6 administered intravenously (IV) every 3 weeks for 6 cycles, paclitaxel 175 mg/m2IV over 3 hours every 3 weeks for 6 cycles, and oregovomab 2 mg infused IV over 20 minutes administered during the first, third, and fifth cycles, and as a monotherapy 12 weeks after the fifth cycle. Treatment Arm 2 received, sequentially, carboplatin AUC 6 administered IV every 3 weeks for 6 cycles, followed by paclitaxel 175 mg/m2IV over 3 hours every 3 weeks for 6 cycles. The follow-up period began at study treatment termination (Cycle 5 plus 13 weeks). Follow-up surveys for time to clinical relapse and survival (as well as any second-line therapy, cause of death, new progression, high-grade toxicities, etc.) were to be conducted every 3 months for the first 2 years and then every 6 months for the third year.

Phase 2 Study Design



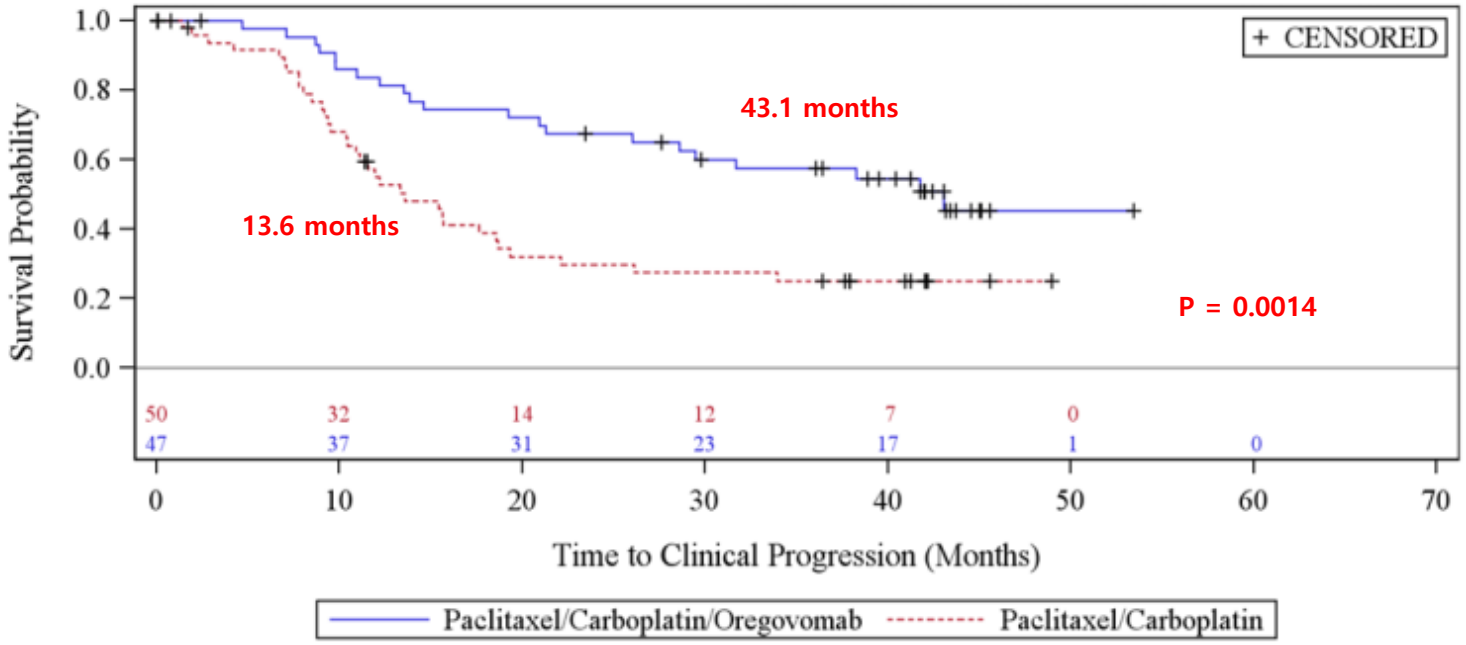
Abbreviations: DC = discontinued; EOT = end of treatment; FU = follow-up; OS = overall survival; PFS = progression-free survival.

Phase 2 Efficacy Evaluation

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

The TTCP was defined as the time from the date of randomization to the date of clinical progression. Patients whose disease had not progressed or who were lost to follow-up were censored on the date of last disease assessment (excluding death). In the ITT population, chemotherapy with the addition of oregovomab (Arm 1) significantly prolonged TTCP by 29.5 months when compared with treatment with chemotherapy alone (Arm 2); median TTCP was 43.1 months in the Arm 1 compared with 13.6 months in Arm 2. Based on the hazard ratio of 0.42 (95% CI: 0.24, 0.73), patients in Arm 1 had a 58% lower risk of clinical progression at any time during the study than patients in Arm 2 (p = 0.0014). At 36 months, the estimated Kaplan-Meier survival probability was 57% in Arm 1, compared to 25% in Arm 2.

Kaplan-Meier Survival Curve of Time to Clinical Progression Analysis (Intent-to-Treat Population)



Phase 2 Efficacy Evaluation

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

Parameter Statistic	Arm 1: 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 Observationsbn (%)	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)	
p-valued	0.0014	
Kaplan-Meier Survival Probability Estimates (95% CI)		
Month 6	0.98 (0.846-0.997)	0.92 (0.790-0.967)
Month 12	0.84 (0.689-0.919)	0.55 (0.397-0.679)
Month 18	0.74 (0.586-0.849)	0.39 (0.249-0.528)
Month 24	0.67 (0.513-0.793)	0.30 (0.173-0.434)
Month 30	0.60 (0.438-0.730)	0.28 (0.154-0.410)
Month 36	0.57 (0.411-0.707)	0.25 (0.137-0.385)

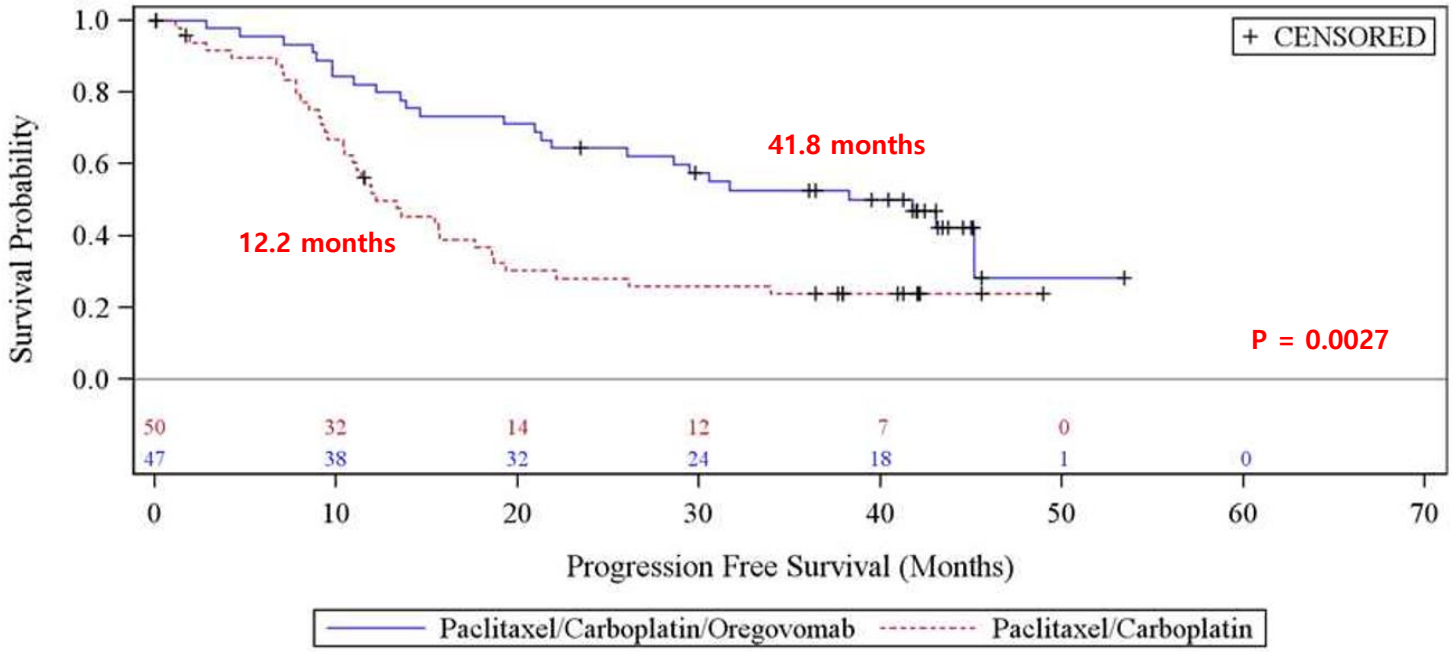
Abbreviations; CI = confidence interval; NE = not estimable.
a Time to clinical progression was defined as date of randomization to date of clinical progression.
b Patients whose disease had not progressed or who were lost to follow-up were censored on the date of last disease assessment.
c Hazard ratio (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)

Progression-free survival was defined as the time from date of randomization to the earlier date of confirmed progression or death. Patients whose disease had not progressed or who were lost to follow-up were censored on the date of last disease assessment. In the ITT population, treatment with the addition of oregovomab (Arm 1) significantly prolonged PFS by 29.6 months when compared with treatment with chemotherapy alone (Arm 2); median PFS was 41.8 months in the Arm 1 compared with 12.2 months in Arm 2. Based on the hazard ratio of 0.46 (95% CI: 0.28, 0.77), patients in Arm 1 had a 54% lower risk of disease progression or death at any time during the study than patients in Arm 2 (p = 0.0027). At 36 months, the estimated Kaplan-Meier survival probability was 53% in Arm 1, compared to 24% in Arm 2.

Kaplan-Meier Survival Curve of Progression-Free Survival Analysis (Intent-to-Treat Population)



Phase 2 Efficacy Evaluation

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

Parameter Statistic	Arm 1: 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)	
p-valued	0.0027	
Kaplan-Meier Survival Probability Estimates (95% CI)		
Month 6	0.96 (0.834-0.989)	0.90 (0.769-0.956)
Month 12	0.82 (0.676-0.907)	0.52 (0.370-0.650)
Month 18	0.73 (0.578-0.839)	0.37 (0.234-0.503)
Month 24	0.64 (0.487-0.765)	0.28 (0.162-0.413)
Month 30	0.58 (0.418-0.705)	0.26 (0.145-0.390)
Month 36	0.53 (0.372-0.661)	0.24 (0.128-0.367)

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.

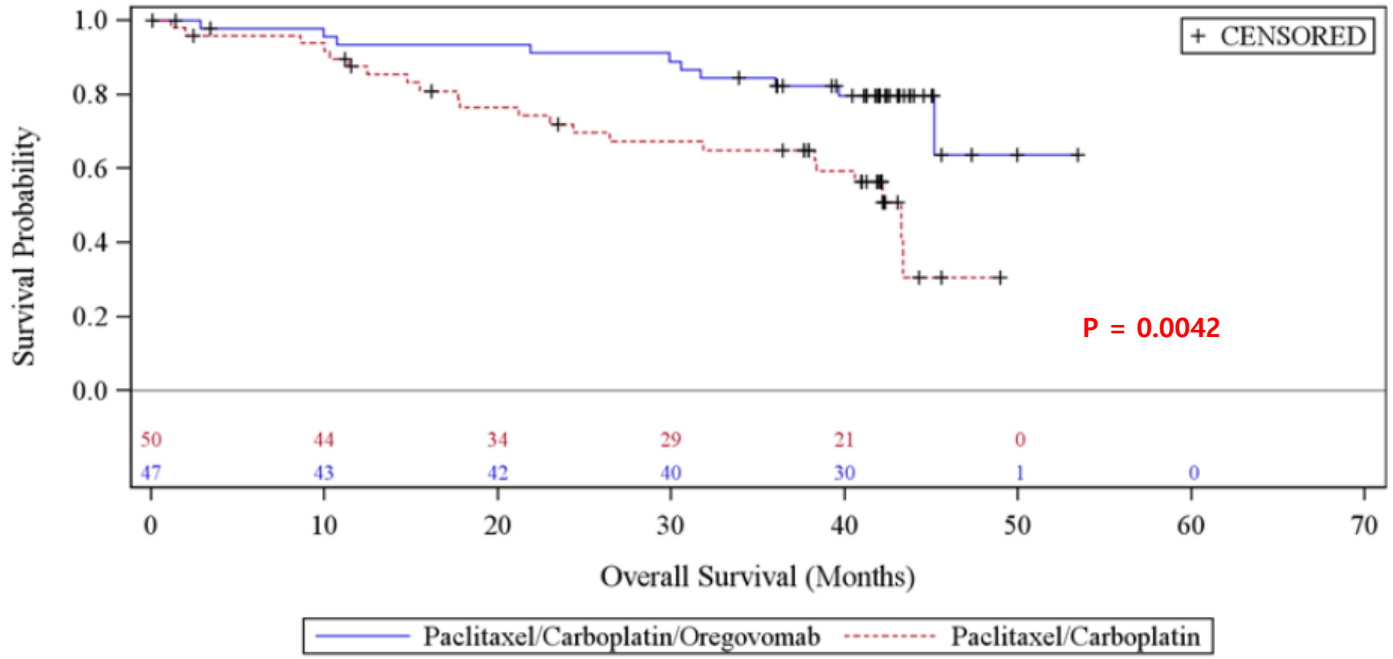
Phase 2 Efficacy Evaluation

Overall Survival

Overall survival was defined as the time from date of randomization until death. Patients who were still alive at the time of analysis or who dropped out before the study end were censored on the date they were last known to be alive.

In the ITT population, treatment with oregovomab (Arm 1) significantly prolonged OS when compared with treatment with chemotherapy alone (Arm 2). Based on the hazard ratio of 0.35 (95% CI: 0.16, 0.74), patients in the oregovomab treatment arm had a 65% lower risk of death at any time during the study than patients in the control arm (p = 0.0042). At 36 months, the estimated Kaplan-Meier survival probability was 84% in Arm 1, compared to 65% in Arm 2. The estimated survival probability at 12 months was 93% in Arm 1 compared with 88% in Arm 2 and at 24 months was 91% and 72%, respectively.

Kaplan-Meier Survival Curve of Overall Survival Analysis (Intent-to-Treat Population)



Phase 2 Efficacy Evaluation

Overall Survival (Intent-to-Treat Population)

Parameter Statistic	Arm 1: 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)	
p-valued	0.0042	
Kaplan-Meier Survival Probability Estimates (95% CI)		
Month 6	0.98 (0.856-0.997)	0.96 (0.847-0.990)
Month 12	0.93 (0.809-0.978)	0.88 (0.743-0.942)
Month 18	0.93 (0.809-0.978)	0.76 (0.615-0.862)
Month 24	0.91 (0.781-0.966)	0.72 (0.566-0.827)
Month 30	0.89 (0.754-0.952)	0.67 (0.517-0.789)
Month 36	0.84 (0.702-0.923)	0.65 (0.493-0.769)

Abbreviations: CI = confidence interval; NE = not estimable.
a. Overall survival was defined as time from date of randomization until death.
b. Patients who were still alive at the time of analysis or who dropped out before study end were censored on the date they were last known to be alive.
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

Extent of Exposure

In Arm 1, 87.0% of patients completed 6 cycles; 81.3% of patients in Arm 2 completed 6 cycles. The difference in months of study treatment exposure is due to the study design; patients in Arm 1 completed an additional 9 weeks of oregovomab monotherapy (single dose of oregovomab without chemotherapy at Cycle 5 + 12 weeks at the end of 6 cycles of chemotherapy. In Arm 1, 80.4% of patients received all 4 cycles of oregovomab.

Table 15: 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 adverse Events

The frequency, severity, and relatedness of TEAEs were similar across treatment arms. Overall, 79 patients (84.0%) had at least 1 TEAE. A total of 16 patients (17.0%) experienced a treatment-emergent SAE; 9 of these patients (19.6%) were in Arm 1, and 7 (14.6%) were in Arm 2. None of the SAEs were considered by the investigators to be related to study treatment; 8 patients (5 in Arm 1 and 3 in Arm 2) had SAEs the sponsor considered related or possibly related to study treatment (carboplatin, paclitaxel, and/or oregovomab). Three patients (6.5%) in Arm 1 and 1 patient (2.1%) in Arm 2 withdrew from the study due to a TEAE. One patient in each treatment arm had a TEAE leading to death.

Table 16. Summary of Treatment-Emergent Adverse Events (Safety Population)

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

Phase 2 Safety Evaluation

Display of Adverse Events

The frequency of TEAEs was generally similar between treatment arms. Blood and lymphatic system disorders were most common, with neutropenia occurring in 46 patients (48.9%) overall. A total of 34 patients (36.2%) each experienced anemia and leukopenia. Paresthesia was reported for a total of 17 patients (18.1 %) and nausea for 16 patients (17.0%).

General disorders and administration site conditions were reported for 20 patients in Arm 1 (43.5%) and 13 patients (27.1%) in Arm 2. The difference in frequency of events in this SOC was due to TEAEs of chest discomfort, chest pain, death, febrile neutropenia, feeling hot, and hyperpyrexia each reported for 1 patient in Arm 1 versus no patients in Arm 2, and due to 2 patients in Arm 1 versus 1 patient in Arm 2 reporting flu-like illness.

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 2 Safety Evaluation

Severity of Adverse Events

Twenty-four patients (52.17%) in Arm 1 and 29 patients (60.42%) in Arm 2 had at least 1 TEAE Grade ≥3. A total of 19 patients (41.3%) in Arm 1 and 21 patients (43.8%) in Arm 2 had severe (Grade 3) or life-threatening (Grade 4) blood and lymphatic system disorders. In the investigations SOC, 2 patients in Arm 2 had Grade 4 events of granulocyte count decreased. For the majority of patients, events in other SOCs were mild.

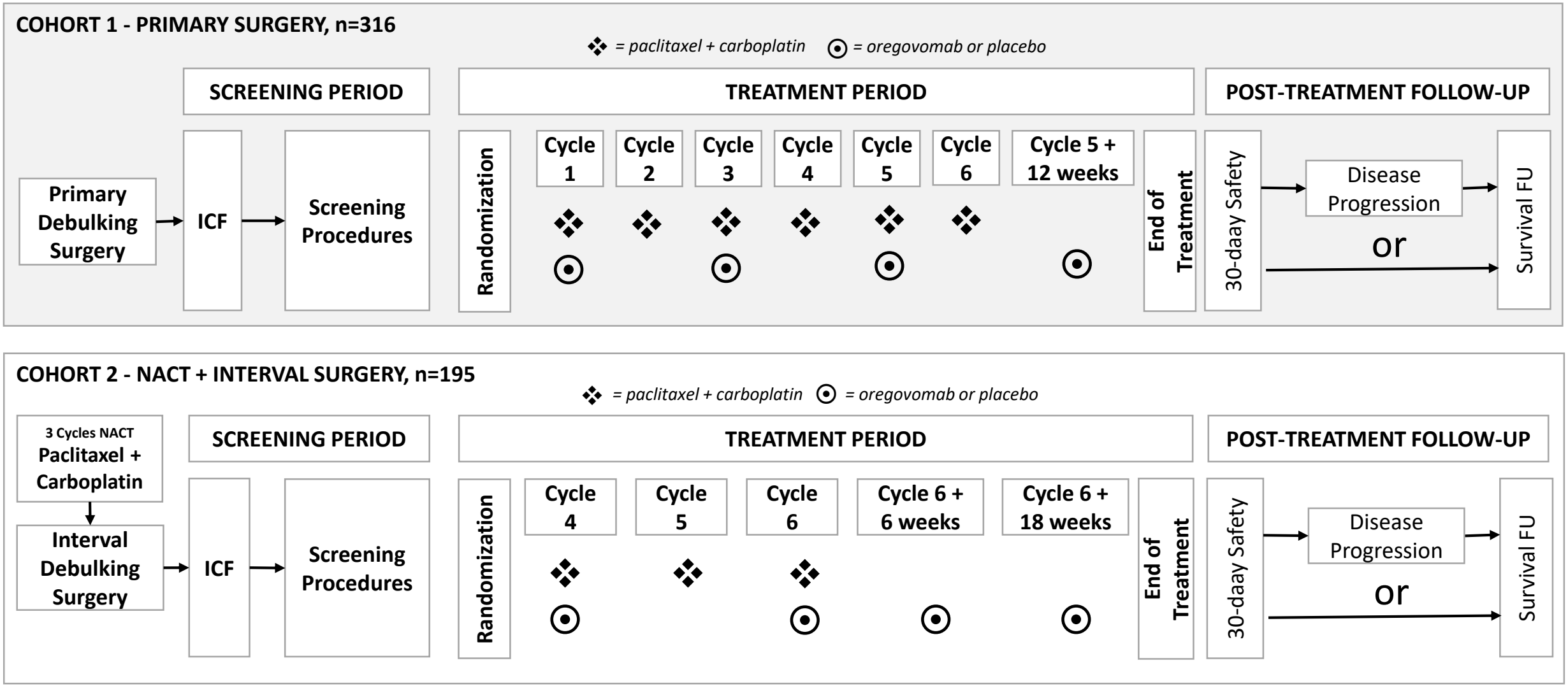
Treatment-Emergent Severe or Life-Threatening Events Occurring in≥2 Patients in Either Treatment Arm (Safety Population)

MedDRA System Organ Class/ Preferred Term	Arm 1: Paclitaxel/Carboplatin Oregovomab (N=46) n (%)	Arm 2: Paclitaxel/Carboplatin (N=48) n (%)	Overall (N=94)
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 3 protocol

Two cohorts to be evaluated

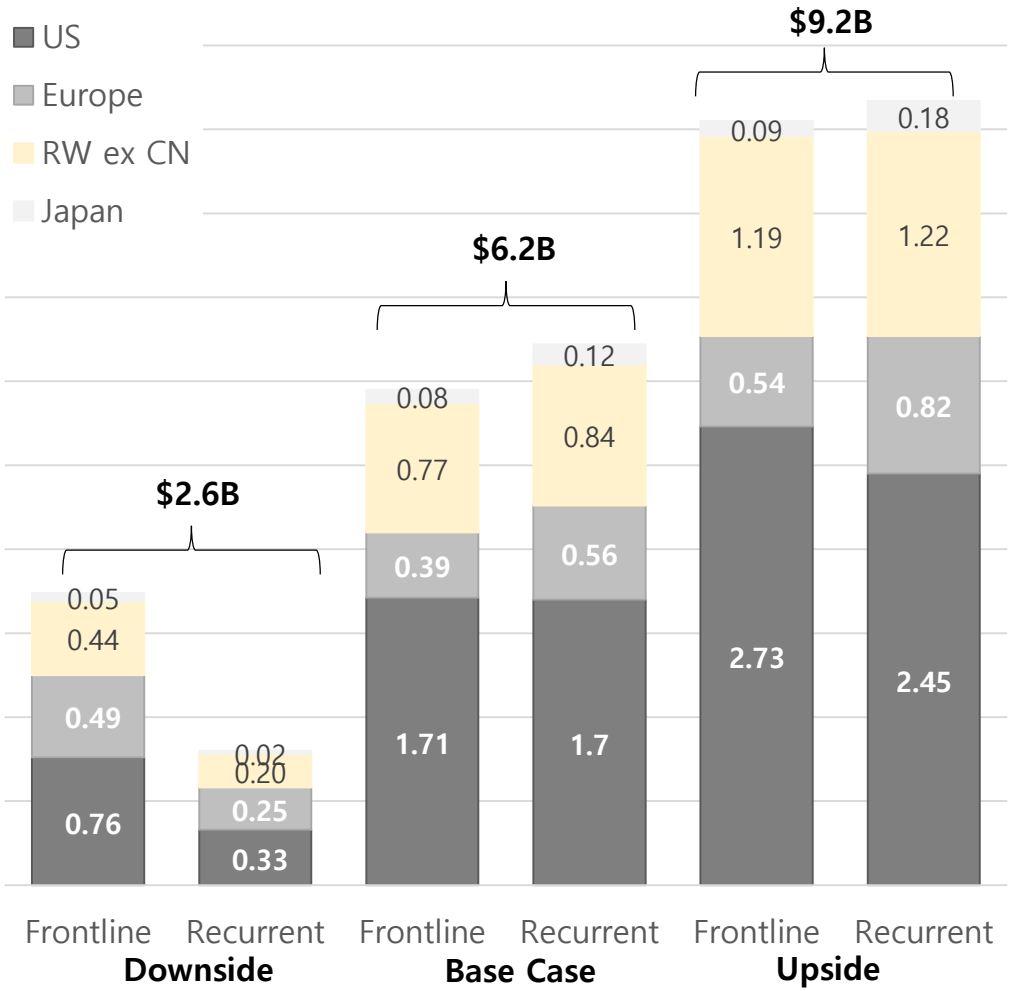


Commercial Assessment of Oregovomab *by Evaluate*

Key messages:

- 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