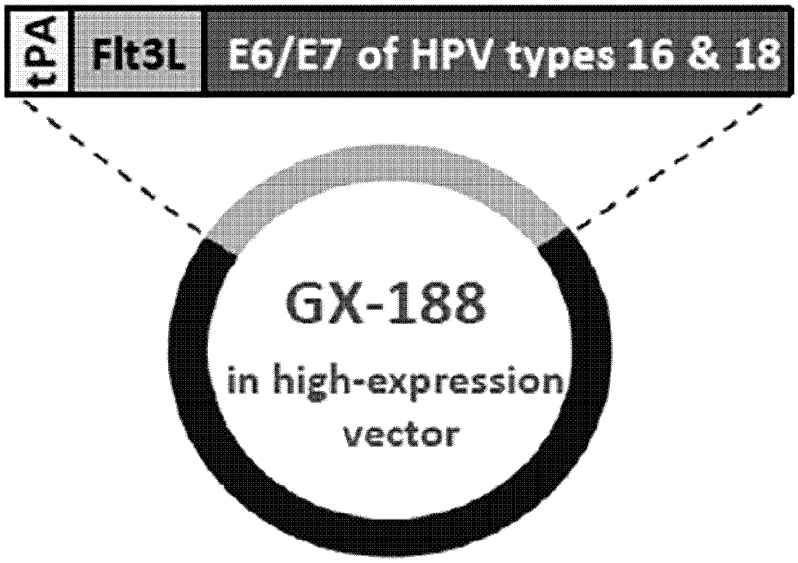
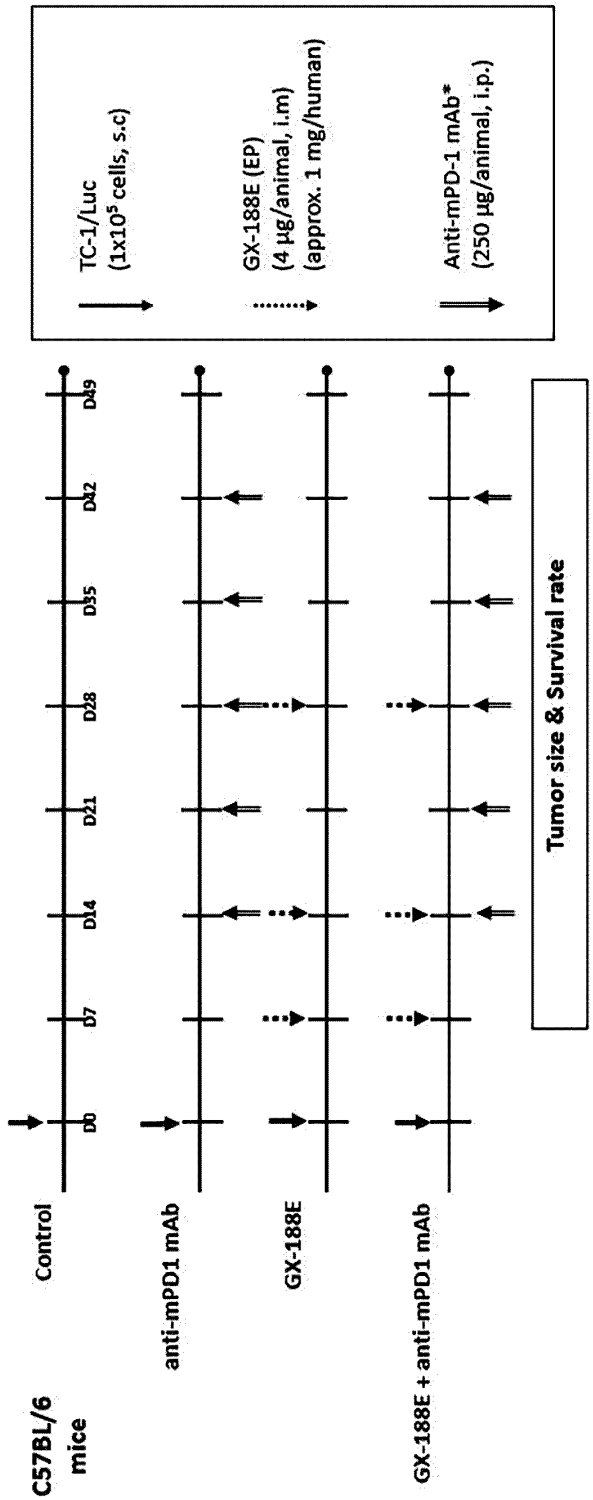
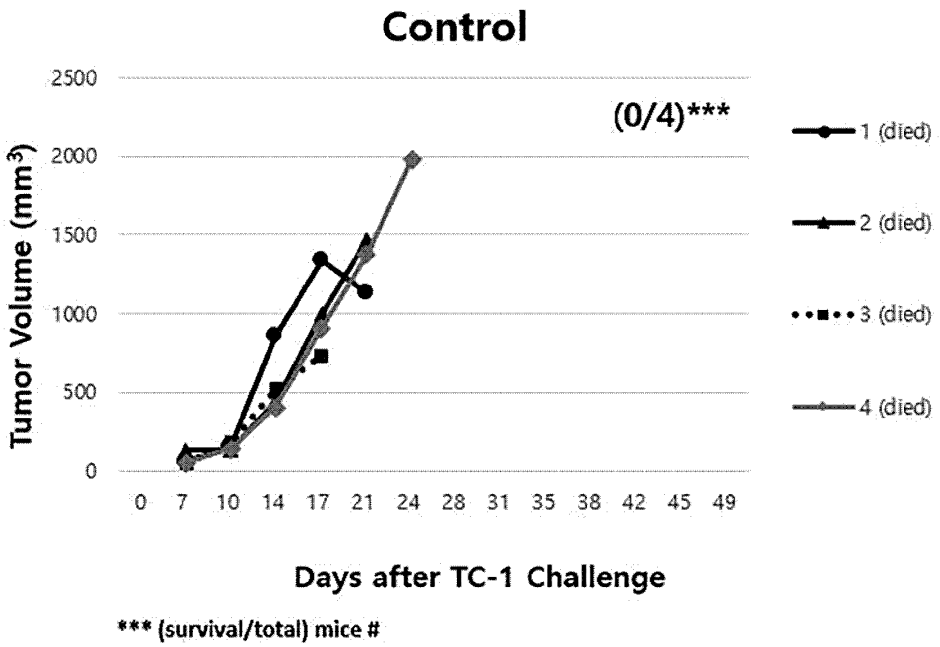
[Fig. 1]


tPA
Flt3L
E6/E7 of HPV types 16 & 18
GX-188
in high-expression vector

[Fig. 2a]

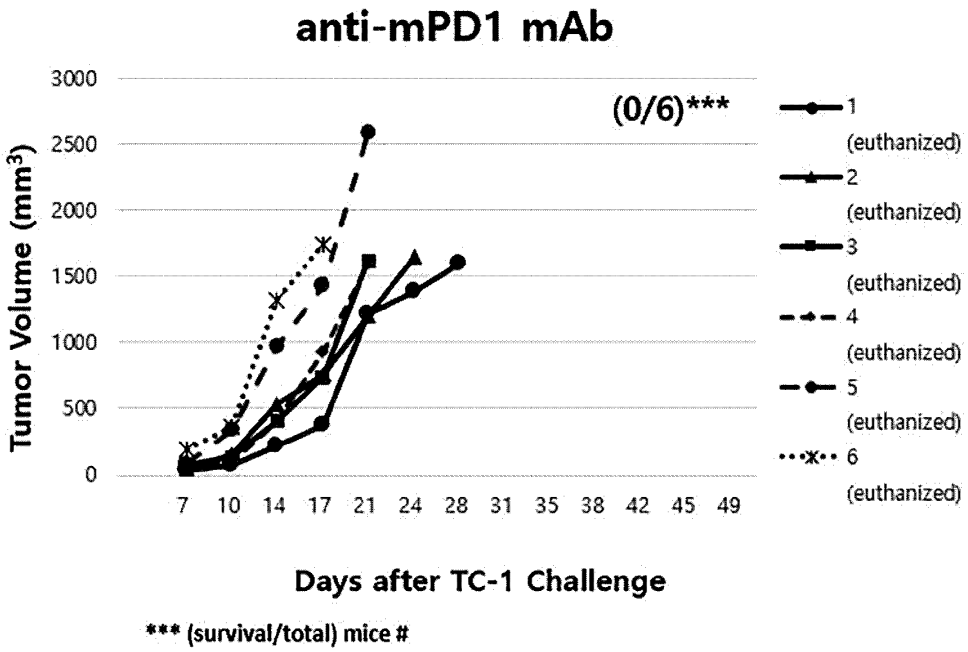

TC-1/Luc
(1x10⁵ cells, s.c)
GX-188E (EP)
(4 μg/animal, i.m)
(approx. 1 mg/human)
Anti-mPD-1 mAb*
(250 μg/animal, i.p.)
D0
D7
D14
D21
D28
D35
D42
D49
Control
anti-mPD1 mAb
GX-188E
GX-188E + anti-mPD1 mAb
C57BL/6 mice
Tumor size & Survival rate

[Fig. 2b]



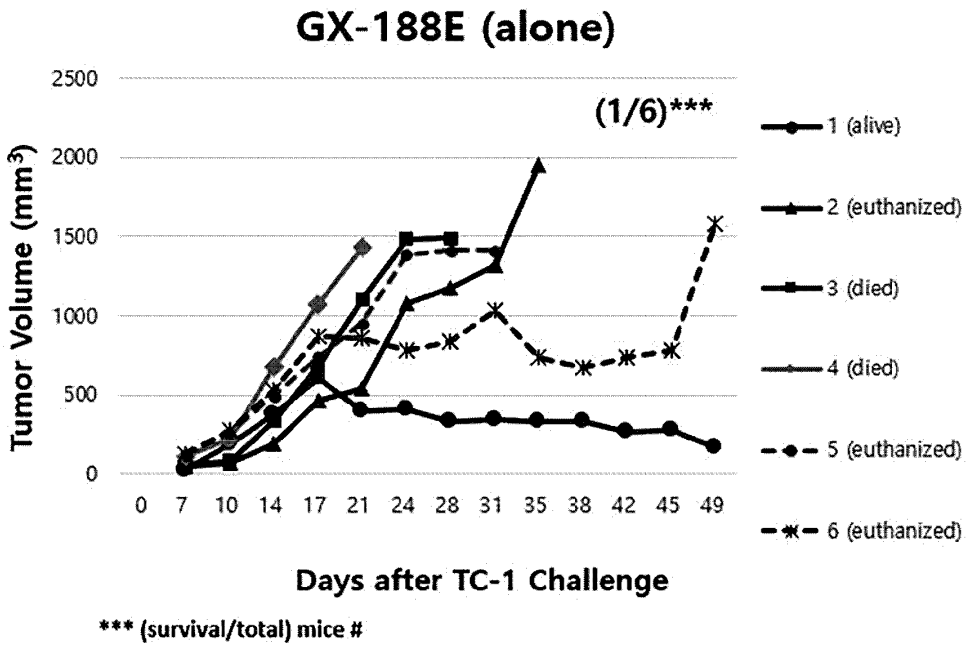
*** (survival/total) mice #

[Fig. 2c]



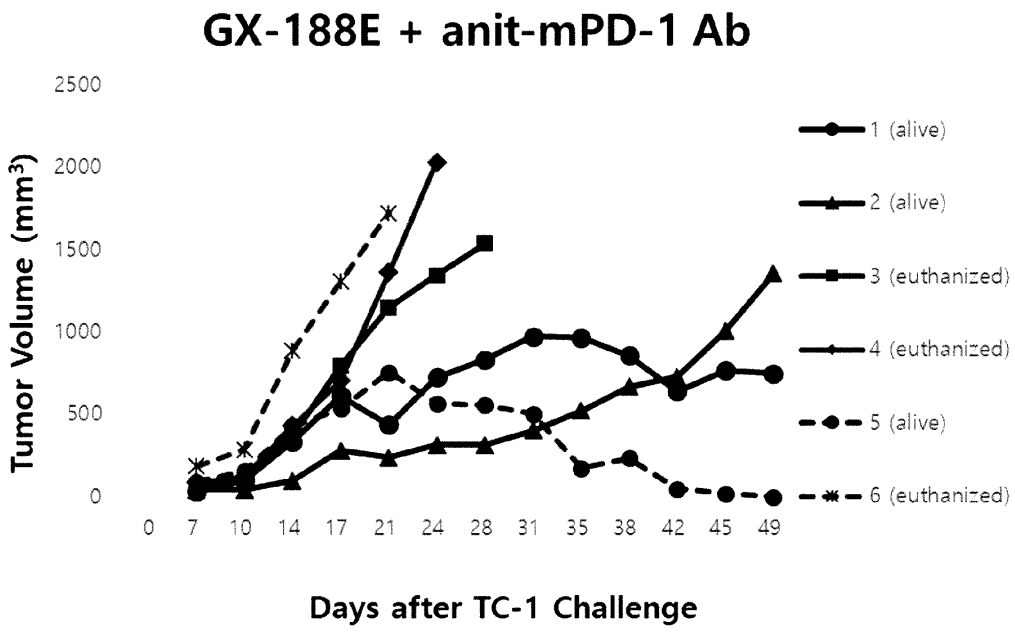
*** (survival/total) mice #

[Fig. 2d]

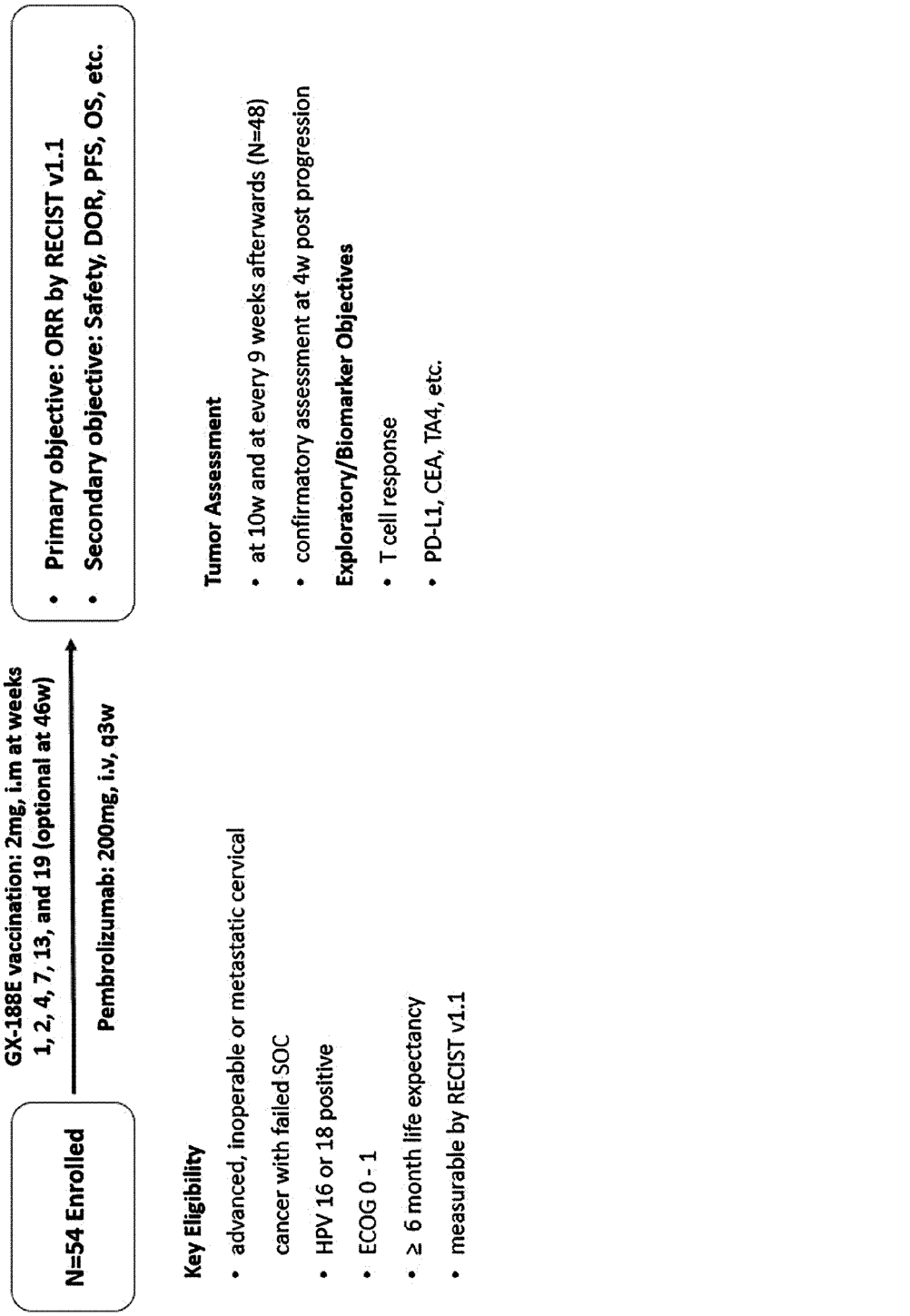


*** (survival/total) mice #

[Fig. 2e]



[Fig. 3]


N=54 Enrolled
GX-188E vaccination: 2mg, i.m at weeks 1, 2, 4, 7, 13, and 19 (optional at 46w)
Pembrolizumab: 200mg, i.v, q3w
Key Eligibility
• advanced, inoperable or metastatic cervical cancer with failed SOC
• HPV 16 or 18 positive
• ECOG 0 - 1
• ≥ 6 month life expectancy
• measurable by RECIST v1.1
• Primary objective: ORR by RECIST v1.1
• Secondary objective: Safety, DOR, PFS, OS, etc.
Tumor Assessment
• at 10w and at every 9 weeks afterwards (N=48)
• confirmatory assessment at 4w post progression
Exploratory/Biomarker Objectives
• T cell response
• PD-L1, CEA, TA4, etc.

[Fig. 4]

Characteristics, N (%)	N=54 GX-188E + Pembrolizumab	N=98 Pembrolizumab[a]
Age, years		
Median (Range)	52 (27-79)	46.0 (24-75)
ECOG performance status		
0	28 (51.9)	34 (34.7)
1	26 (48.1)	64 (65.3)
PD-L1 expression status		
Positive	41 (75.9)	82 (83.7)
Negative	13 (24.1)	15 (15.3)
Unknown		1 (1.0)

[a] *Reference data from Table 1 in J Clin Oncol. 2019; 37(17):1470-1478*

Characteristics, N (%)	N=54 GX-188E + Pembrolizumab	N=98 Pembrolizumab[a]
HPV type		
16	39 (72.2)	N/A
18	13 (24.1)	
16 & 18	2 (3.7)	
Histology of current diagnosis		
Adenocarcinoma	14 (25.9)	5 (5.1)
Adenosquamous carcinoma	-	1 (1.0)
Squamous cell carcinoma	40 (74.1)	92 (93.9)
No. of previous lines of therapy		
Adjuvant and/or neoadjuvant	3 (5.6)	4 (4.1)
1	26 (48.1)	30 (30.6)
2	17 (31.5)	34 (34.7)
≥ 3	8 (14.8)	30 (30.6)

[Fig. 5]

N =54, TRAEs, N (%) [case]	Any Grade	Grade 3	Grade 4
TRAEs by SOC and PT†	**17 (31.5) [38]**	**3 (5.6) [4]**	**1 (1.9) [1]**
Endocrine disorders (Hypothyroidism)	**7 (12.9) [7]**		
Gastrointestinal disorders	**5 (9.3) [9]**		
Diarrhea	2 (3.7) [3]		
Nausea	1 (1.9) [2]		
Vomiting	2 (3.7) [2]		
Gastrointestinal pain	1 (1.9) [1]		
Mucositis oral	1 (1.9) [1]		
Skin and subcutaneous tissue disorders	**4 (7.4) [4]**		
Pruritus	1 (1.9) [1]		
Rash	1 (1.9) [1]		
Urticaria	1 (1.9) [1]		
Purpura	1 (1.9) [1]		
Investigations	**2 (3.7) [4]**	**2 (3.7) [3]**	**1 (1.9) [1]**
Alanine aminotransferase increased	2 (3.7) [2]	1 (1.9) [1]	1 (1.9) [1]
Aspartate aminotransferase increased	2 (3.7) [2]	2 (3.7) [2]	
Musculoskeletal and connective tissue disorders	**3 (5.6)[3]**		
Back pain	1 (1.9) [1]		
Myalgia	1 (1.9) [1]		
Pain in extremity	1 (1.9) [1]		
Nervous system disorders	**3 (5.6) [3]**	**1 (1.9) [1]**	
Syncope	1 (1.9) [1]	1 (1.9) [1]	
Herpes zoster	1 (1.9) [1]		
Dizziness	1 (1.9) [1]		

***Any grode ≥ 2 patients; **TRAE reported as grade 3 or higher regardless of number of patients.**
Abbreviations: TRAEs, Treatment-related adverse events;

[Fig. 6a]

ORR N (%)	Safety set (N=51)	Efficacy set[a] (N=48)	PD-L1 status[b]		HPV type		Cell type	
			Positive (N=36/38)	Negative (N=12/13)	HPV16 (N=34/36)	HPV18 or both (N=14/15)	SCC (N=36/38)	AC (N=12/13)
CR	6 (11.8)	6 (12.5)	6 (16.7)	0 (0.0)	6 (17.6)	0 (0.0)	6 (16.7)	0 (0.0)
PR	10 (19.6)	10 (20.8)	9 (25.0)	1 (8.3)	6 (17.6)	4 (28.6)	6 (16.7)	4 (33.3)
SD	8 (15.7)	8 (16.7)	7 (19.4)	1 (8.3)	6 (17.6)	2 (14.3)	7 (19.4)	1 (8.3)
PD	26 (51.0)	24 (50.0)	14 (38.9)	10 (83.4)	16 (47.2)	8 (57.1)	17 (47.2)	7 (58.4)
NE	1 (1.9)	-	-	-	-	-	-	-
BORR	**16 (31.4)**	**16 (33.3)**	**15 (41.7/39.5)**	**1 (8.3/7.7)**	**12 (35.3/33.3)**	**4 (28.6/26.7)**	**12(33.3/31.6)**	**4(33.3/30.8)**
DCR	24(47.1)	24 (50.0)	22 (61.1/57.9)	2 (16.7/15.4)	18 (52.9/50.0)	6 (42.9/40.0)	19(52.8/50.0)	5(41.7/38.5)

[a] Patients not receiving 45 days of treatment are considered non-evaluable for response to GX-188E and may be replaced. [b] Criteria for PD-L1: Positive (CPS ≥ 1), Negative (CPS <1) Abbreviations: BOR, Best Overall Response; DOR, Duration of Response; CR, Complete Response; PR, Partial Response; SD, Stable Disease; PD, Progressive Disease; NE, Non evaluable; DCR, Disease Control Rate; PD-L1,programmed death-ligand 1; SCC, Squamous Cell Carcinoma; AC, Adenocarcinoma

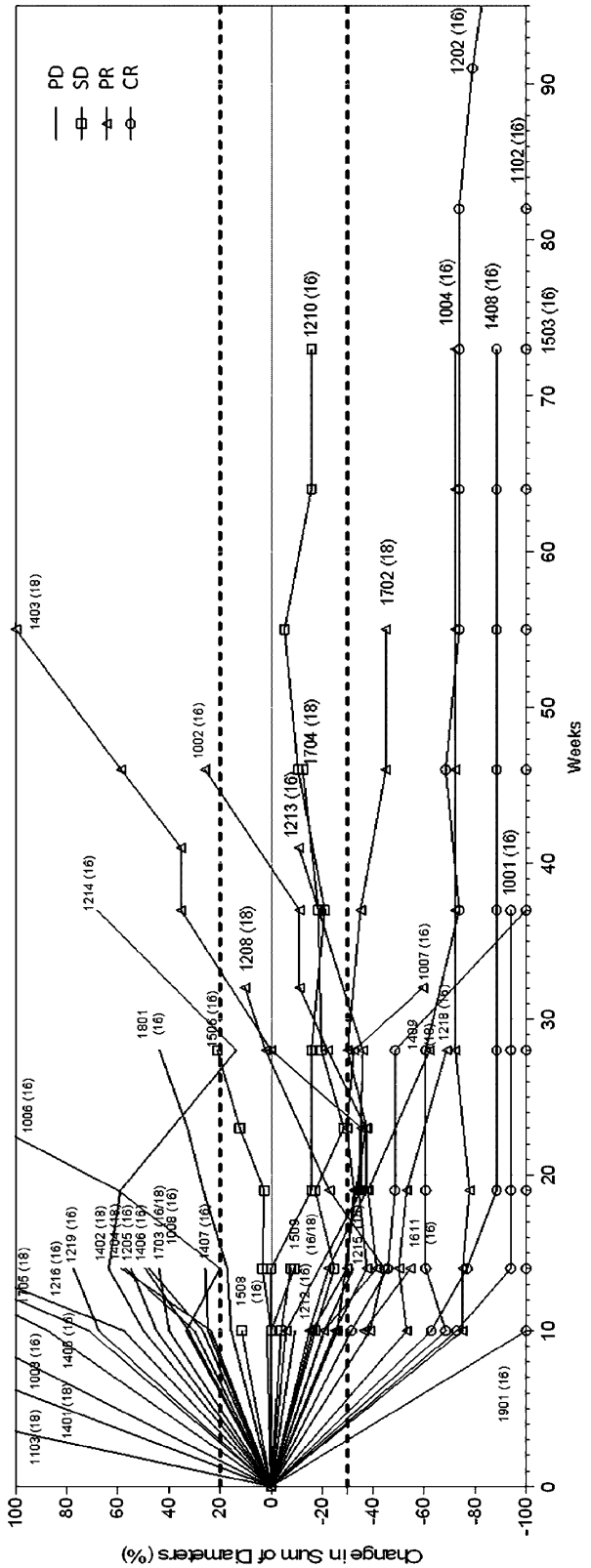
[Fig. 6b]

ORR N (%)	Safety set (N=51)	Efficacy set[a] (N=48)	PD-L1 Positive[b] HPV 16 (N=27/28)		PD-L1 Positive[b] HPV 18 (N=9/10)		PD-L1 Negative[b] HPV 16 (N=7/8)		PD-L1 Negative[b] HPV 18 (N=5)	
			SCC (N=25/26)	AC (N=2)	SCC (N=4)	AC (N=5/6)	SCC (N=4/5)	AC (N=3)	SCC (N=3)	AC (N=2)
CR	6 (11.8)	6 (12.5)	6 (24.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PR	10 (19.6)	10 (20.8)	6 (24.0)	0 (0.0)	0 (0.0)	3 (60.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)
SD	8 (15.7)	8 (16.7)	5 (20.0)	0 (0.0)	1 (25.0)	1 (20.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)
PD	26 (51.0)	24 (50.0)	8 (32.0)	2 (100.0)	3 (75.0)	1 (20.0)	3 (75.0)	3 (100.0)	3 (100.0)	1 (50.0)
NE	1 (1.9)	-	-	-	-	-	-	-	-	-
BORR		**16 (33.3)**	12 (48.0/46.2)	0 (0.0)	0 (0.0)	3 (60.0/50.0)	0 (0.0/0.0)	0 (0.0)	0 (0.0)	1 (50.0)
DCR		24 (50.0)	17 (68.0/65.4)	0 (0.0)	1 (25.0)	4 (80.0/66.7)	1 (25.0/20.0)	0 (0.0)	0 (0.0)	1 (50.0)

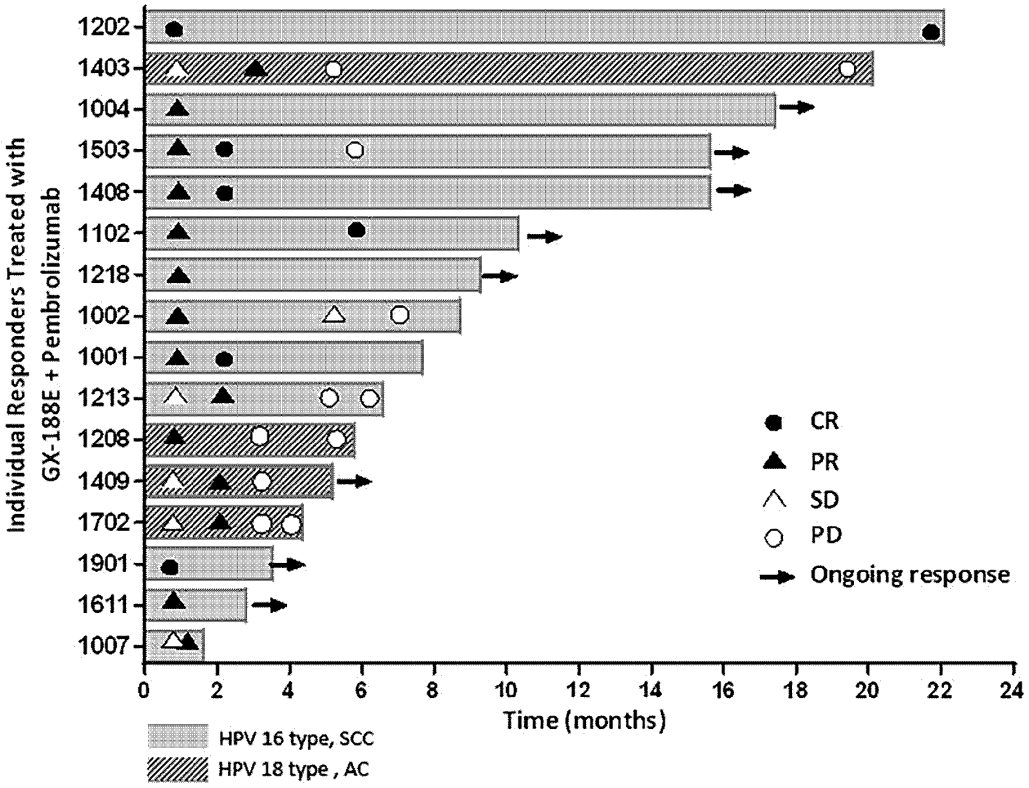
[a] Patients not receiving 45 days of treatment are considered non-evaluable for response to GX-188E and may be replaced. [b] Criteria for PD-L1: Positive (CPS ≥ 1), Negative (CPS <1)

Abbreviations: BOR, Best Overall Response; DOR, Duration of Response; CR, Complete Response; PR, Partial Response; SD, Stable Disease; PD, Progressive Disease; NE, Non evaluable; DCR, Disease Control Rate; PD-L1,programmed death-ligand 1; SCC, Squamous Cell Carcinoma; AC, Adenocarcinoma

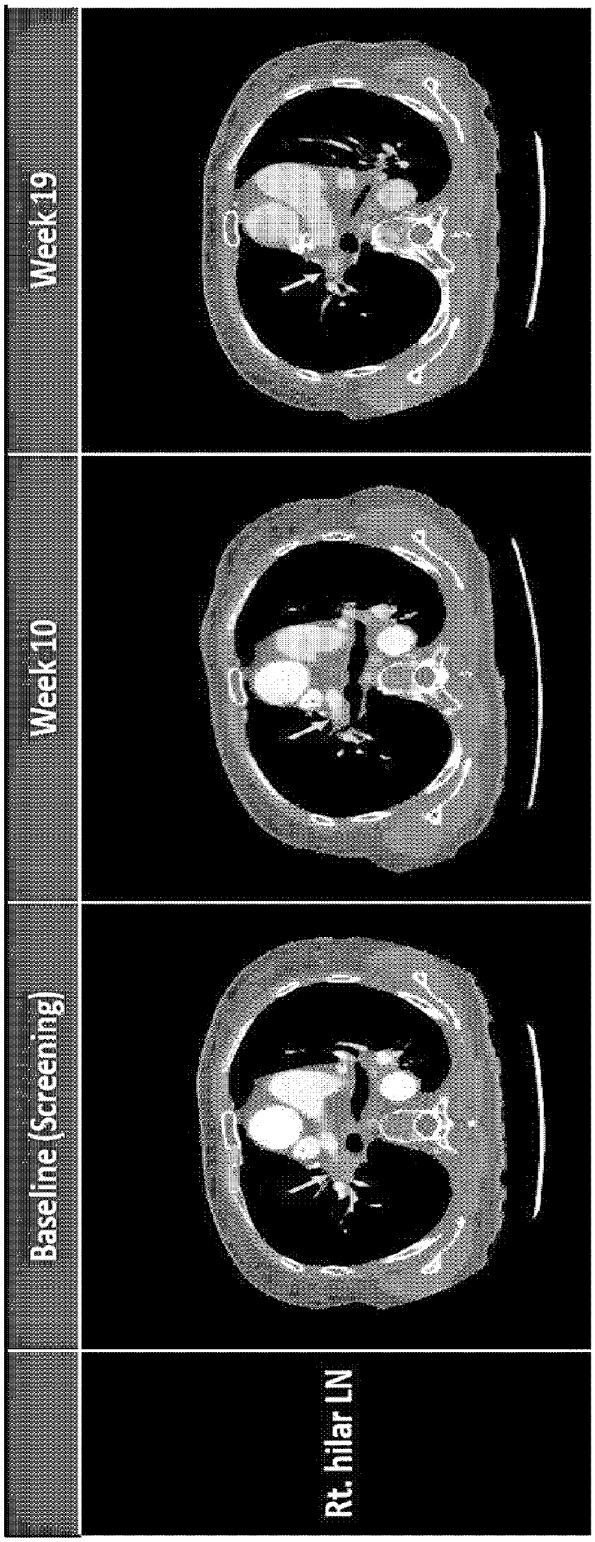
[Fig. 7]


PD
SD
PR
CR
Change in Sum of Diameters (%)
Weeks
100
80
60
40
20
0
-20
-40
-60
-80
-100
0
10
20
30
40
50
60
70
80
90
1403 (18)
1002 (16)
1214 (16)
1801 (16)
1006 (16)
1402 (18)
1219 (16)
1216 (16)
1405 (18)
1103 (18)
1401 (18)
1210 (16)
1704 (18)
1213 (16)
1208 (18)
1702 (18)
1202 (16)
1102 (16)
1004 (16)
1408 (16)
1503 (16)
1001 (16)
1007 (16)
1901 (16)
1611 (16)
1508 (16)

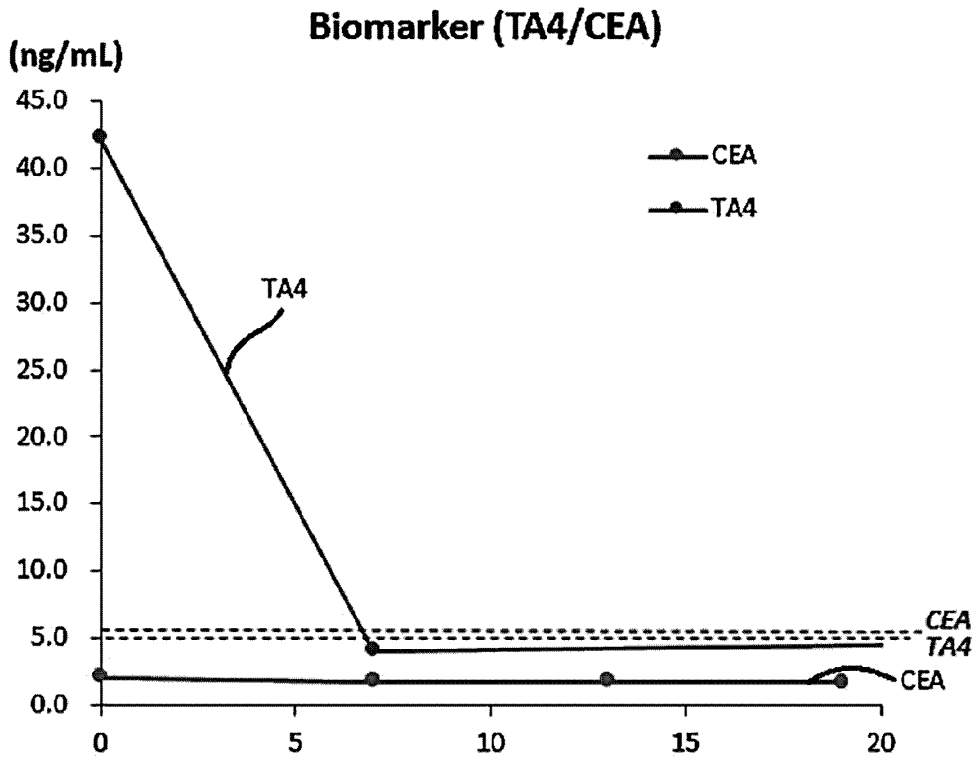
[Fig. 8]


Individual Responders Treated with GX-188E + Pembrolizumab
1202
1403
1004
1503
1408
1102
1218
1002
1001
1213
1208
1409
1702
1901
1611
1007
0
2
4
6
8
10
12
14
16
18
20
22
24
Time (months)
CR
PR
SD
PD
Ongoing response
HPV 16 type, SCC
HPV 18 type , AC

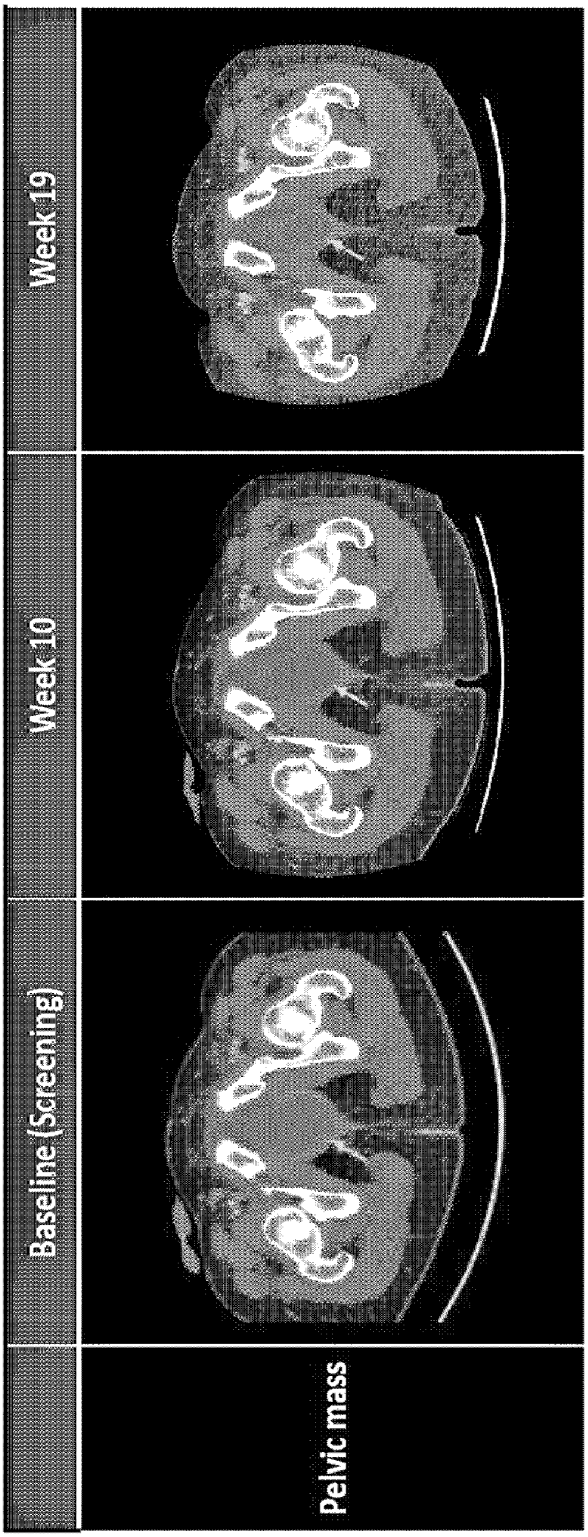
[Fig. 9a]



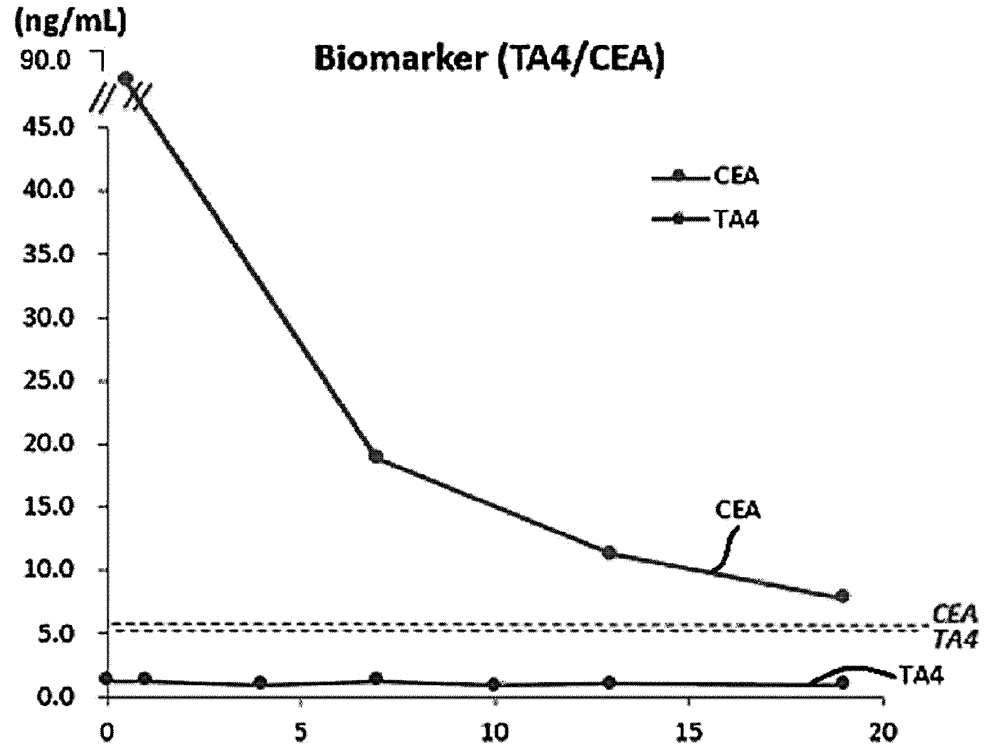
[Fig. 9b]


Biomarker (TA4/CEA)
(ng/mL)
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
0
5
10
15
20
CEA
TA4
TA4
CEA
CEA
TA4
CEA

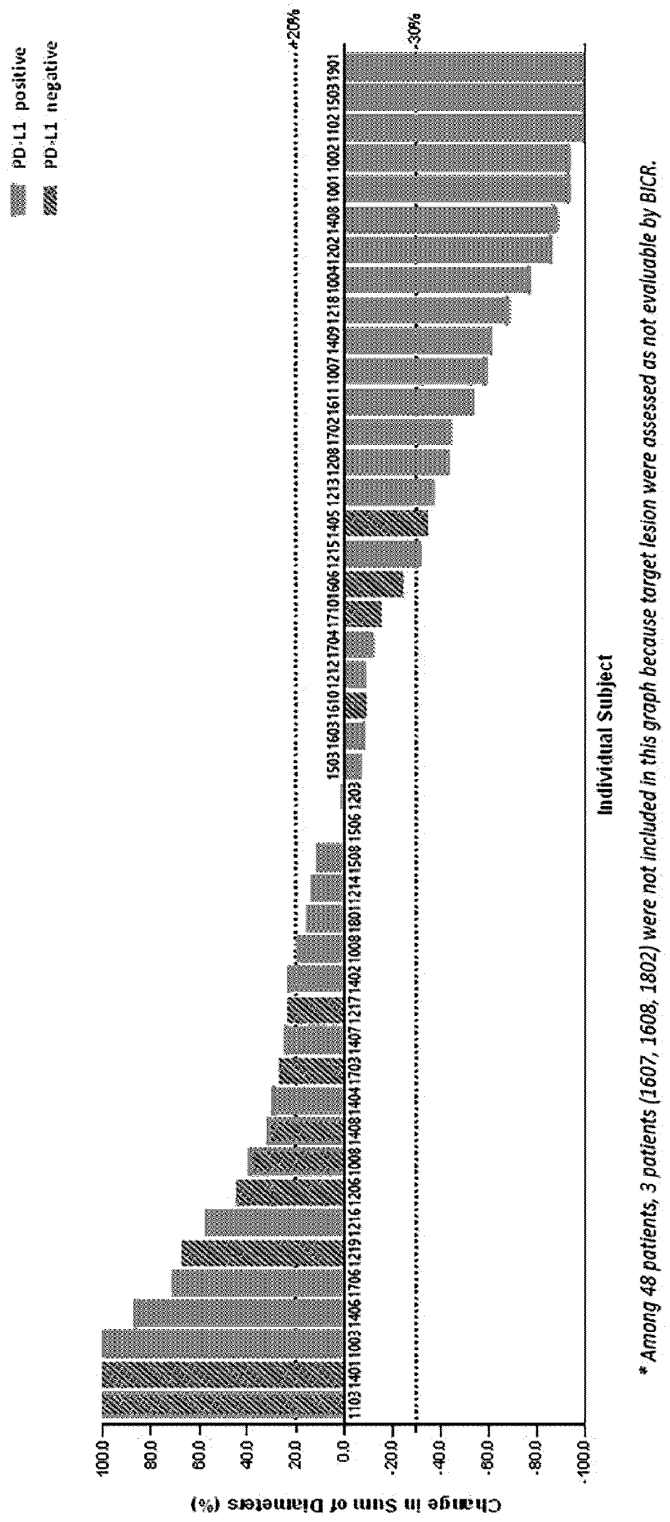
[Fig. 9c]



[Fig. 9d]


(ng/mL)
Biomarker (TA4/CEA)
90.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
0
5
10
15
20
CEA
TA4
CEA
CEA
TA4
TA4

[Fig. 10]



** Among 48 patients, 3 patients (1607, 1608, 1802) were not included in this graph because target lesion were assessed as not evaluable by BICR.*