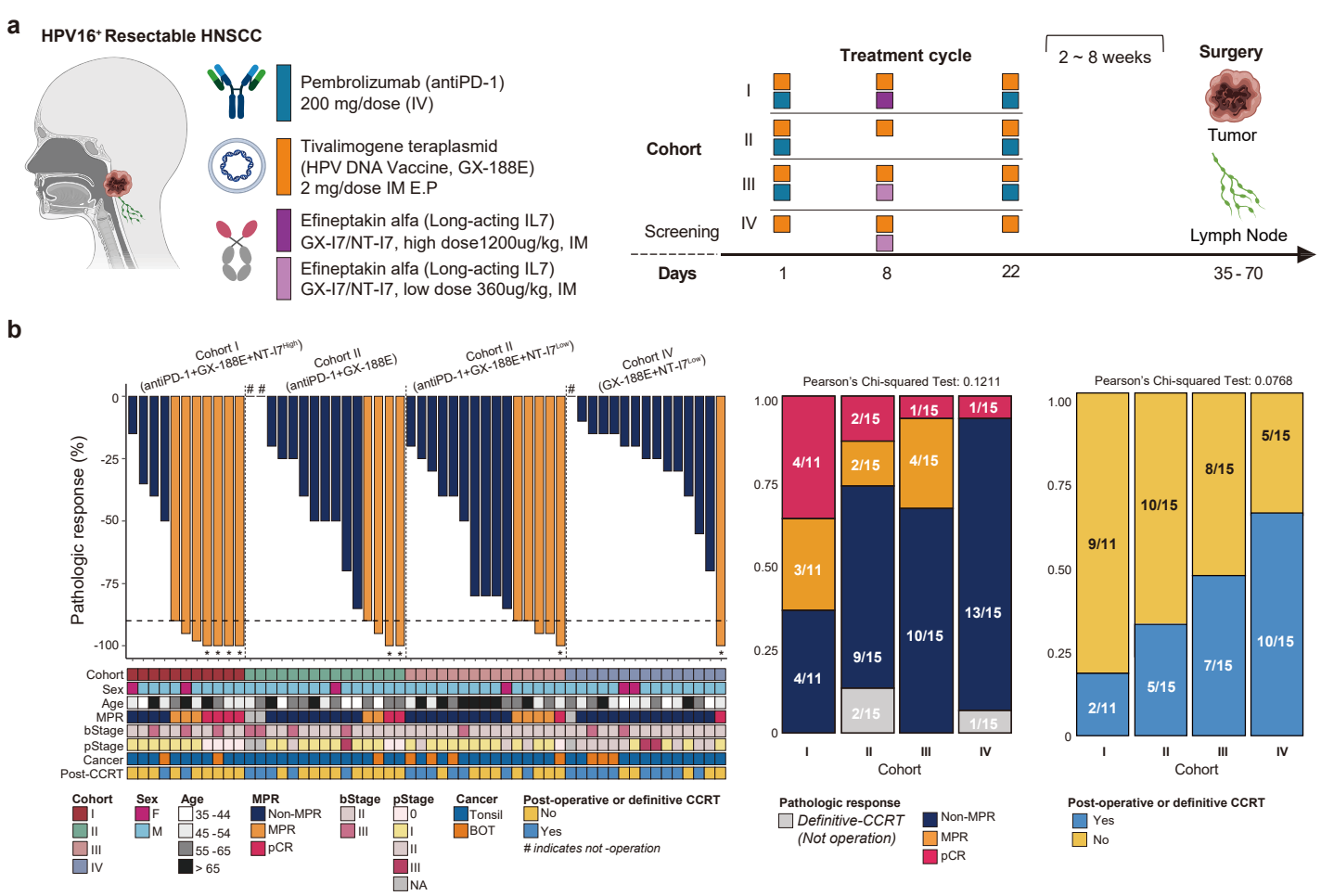

a
HPV16+ Resectable HNSCC
Pembrolizumab (antiPD-1)
200 mg/dose (IV)
Tivalimogene teraplasmid
(HPV DNA Vaccine, GX-188E)
2 mg/dose IM E.P
Efineptakin alfa (Long-acting IL7)
GX-I7/NT-I7, high dose1200ug/kg, IM
Efineptakin alfa (Long-acting IL7)
GX-I7/NT-I7, low dose 360ug/kg, IM
Treatment cycle
2 ~ 8 weeks
Surgery
Tumor
Lymph Node
Cohort
I
II
III
IV
Screening
Days
1
8
22
35 - 70
b
Cohort I (antiPD-1+GX-188E+NT-I7High)
Cohort II (antiPD-1+GX-188E)
Cohort II (antiPD-1+GX-188E+NT-I7Low)
Cohort IV (GX-188E+NT-I7Low)
Pathologic response (%)
Cohort
Sex
Age
MPR
bStage
pStage
Cancer
Post-CCRT
Pearson's Chi-squared Test: 0.1211
Pearson's Chi-squared Test: 0.0768
4/11
3/11
4/11
2/15
2/15
9/15
2/15
1/15
4/15
10/15
1/15
13/15
9/11
2/11
10/15
5/15
8/15
7/15
5/15
10/15
Cohort
Pathologic response
Definitive-CCRT (Not operation)
Non-MPR
MPR
pCR
Post-operative or definitive CCRT
Yes
No
# indicates not -operation
c
Baseline
D22
PostOP
2yr
Gate on CD8+T
HPV16 E6/E7 OLPs (+)
HPV16 E6/E7 OLPs (-)
CD137 (APC)
CD69 (PE-Cy7)
IFNγ (BV785)
TNFα (FITC)
d
Gate on CD8+T
Pathologic response
Non-MPR
MPR
pCR
CD69+CD137+ (%)
TNFα+IFNγ+ (%)
Timepoint
Baseline
D22
PostOP
2yr
e
Baseline
D22
PostoP
2yr
E6/E7 OLPs
Control
TNTC
PMA
001
014
Patients
Non-MPR
MPR
IFNγ spots per 1*10⁶ Cells
f
Lunit SCOPEIO (Pre)
Lunit SCOPEIO (Post)
MPR
pCR
Indication
Tumor area
Tumor stromal
Tumor cells
Lymphocytes
AI-based Tumor-infiltrated lymphocytes
p = 0.0033, **
Immune inflamed score
Timepoint
Pre
Post
Immune phenotype change after treatment
Immune phenotype
n=1
n=6
n=2
n=9
Phenotype
Inflamed
Excluded
Deserted

Figure 2