



ゼリア新薬

Z E R I A

Hiroki Kato PhD

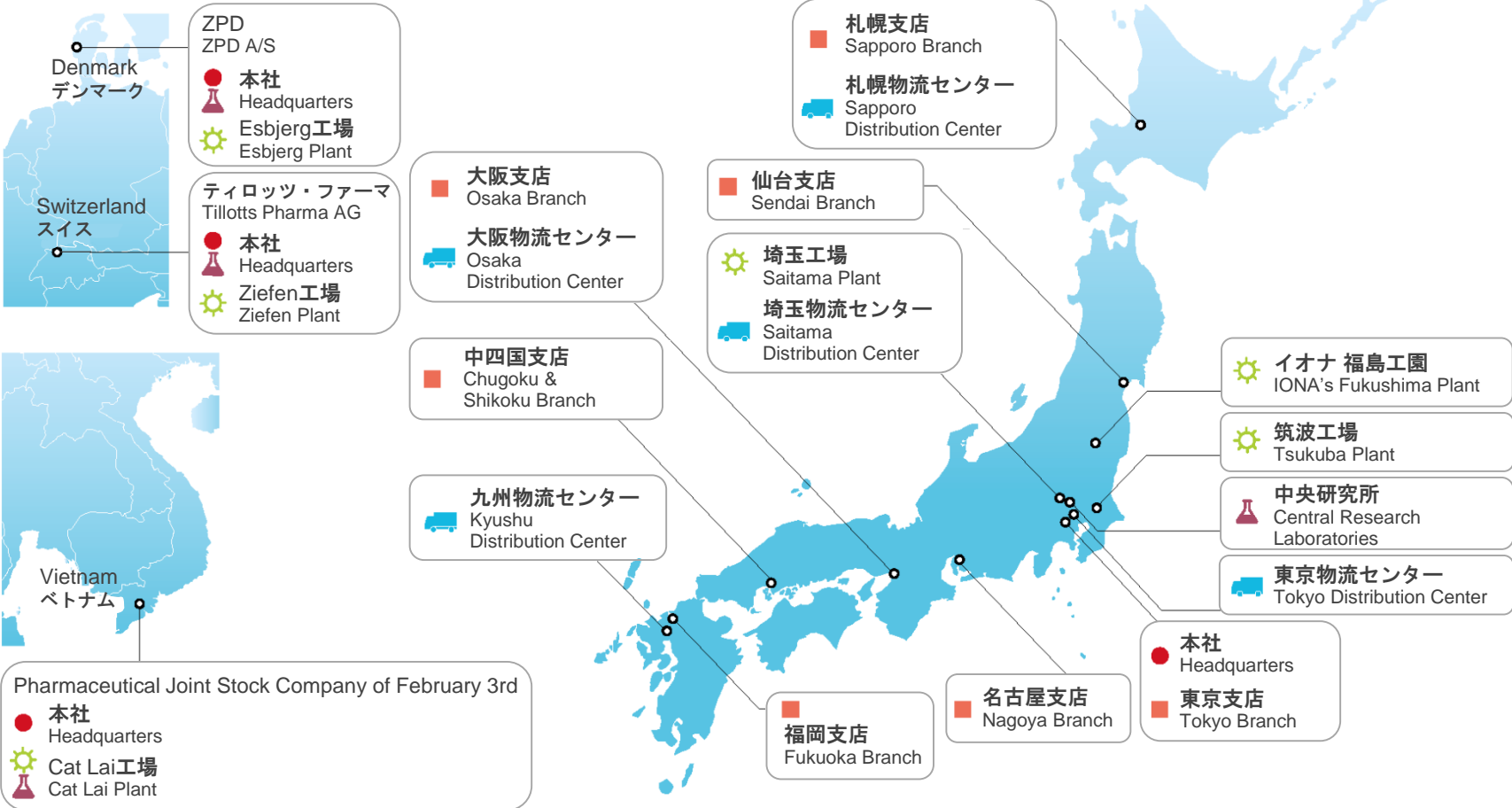
ZERIA USA, Inc.

New York, U.S.A.
米国 (ニューヨーク)



- 本社 Headquarters
- 支店 Branches
- 🚚 物流センター Distribution Centers
- ⚙️ 工場 Manufacturing Branches
- 🧪 研究部門 Laboratories

Network



Extensive Gastrointestinal Portfolio



Asacol[®]
(ulcerative colitis)



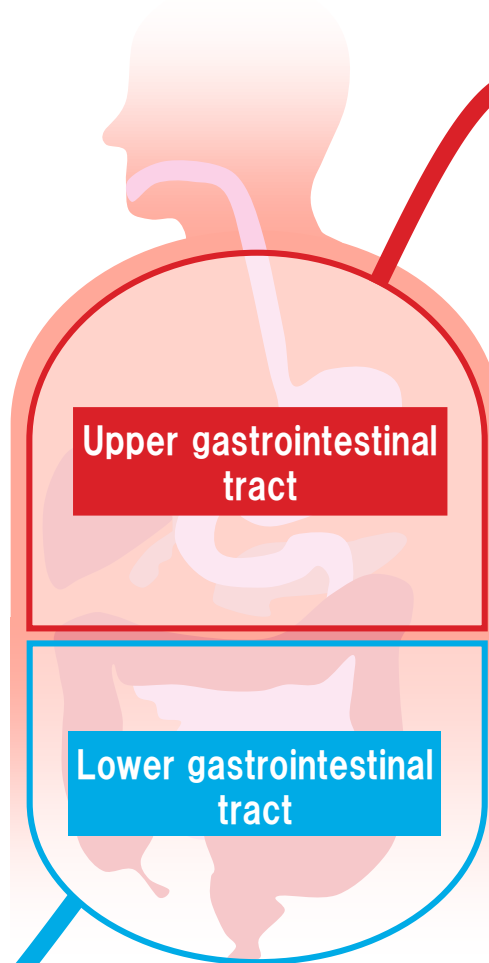
Visiclear[®]
(oral bowel cleansing)



New Lecicarbon[®]
(laxative)



Zentacort[®]
(Crohn's disease)



Acofide[®]
(functional dyspepsia)



Promac[®]
(zinc containing anti-ulcerant)



Acinon[®]
(histamine H₂ receptor antagonist)

Z-360 (pancreatic cancer) *

* Under development



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Why I am in here.

**We would like to share the
our projects for cervical
caner.**



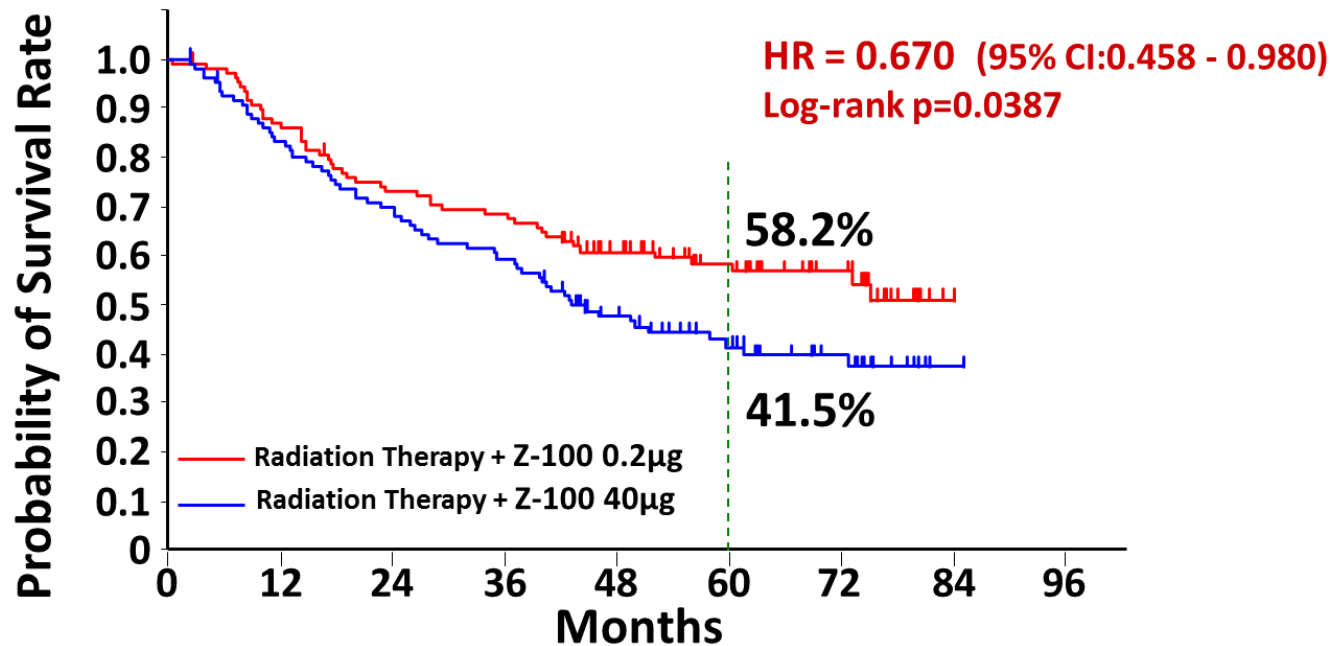
Z-100: Past, Present and Future

Past: the origin of Z-100

- Hot water extract of *Mycobacterium tuberculosis*
 - Mixture of polysaccharides (majorly arabinose, mannose and glucose) and nucleic acid-like substances
- An immunomodulatory agent
 - Known as Specific Substance of Maruyama (SSM) or Maruyama Vaccine
 - Carcinostatic potential was reported by Dr. Chisato Maruyama in 1966

Past: Clinical Development

- The 1st Phase III study (Jun 1995 – Sep 2002)
 - Result (Overall Survival rate)



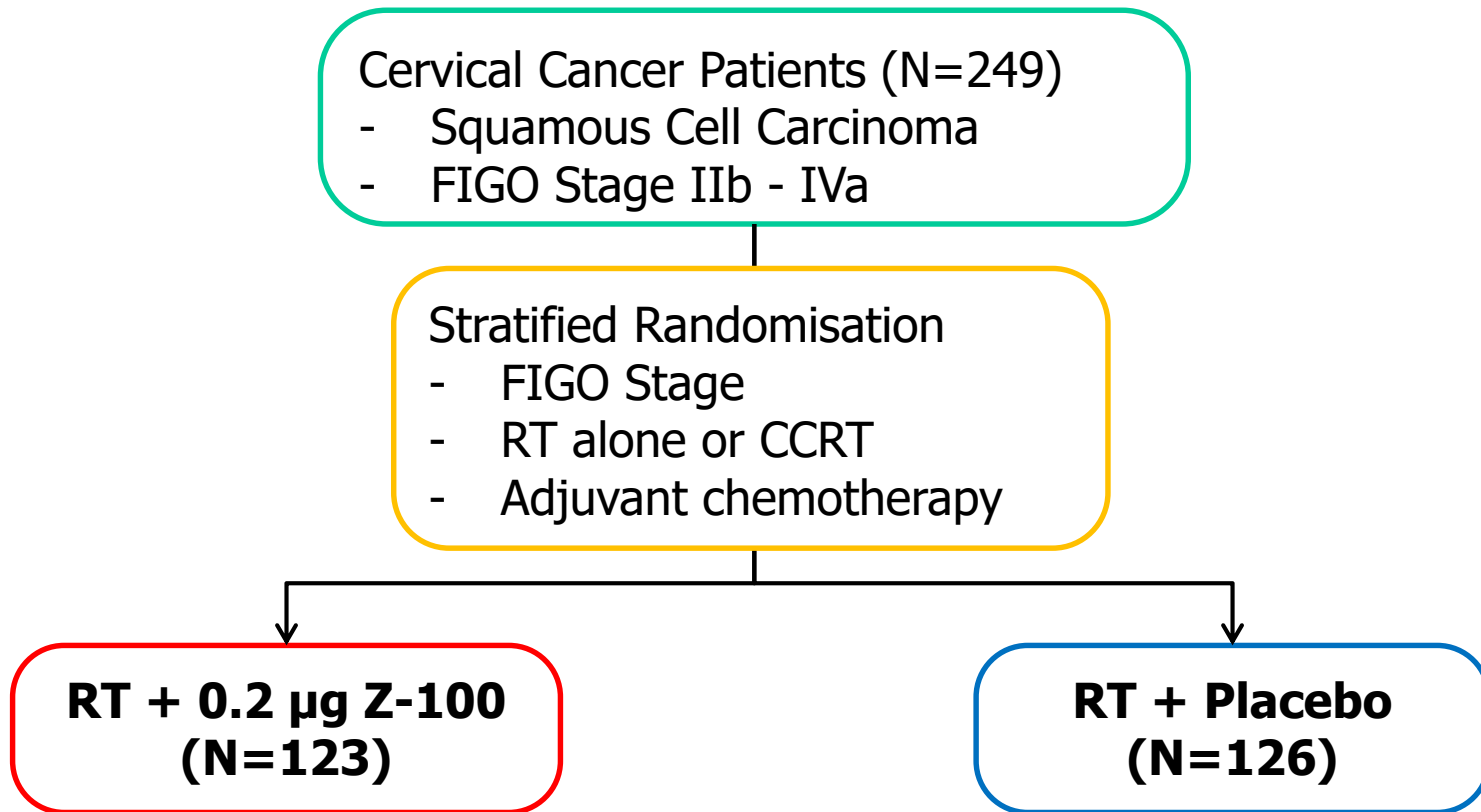
Number at risk

Z-100 0.2µg	109	94	78	73	56	40	25	1	0
Z-100 40µg	108	88	74	63	43	29	17	1	0

Noda *et al.*, *Gynecol Oncol*, 101 (2006) 455-63.

Past: Clinical Development

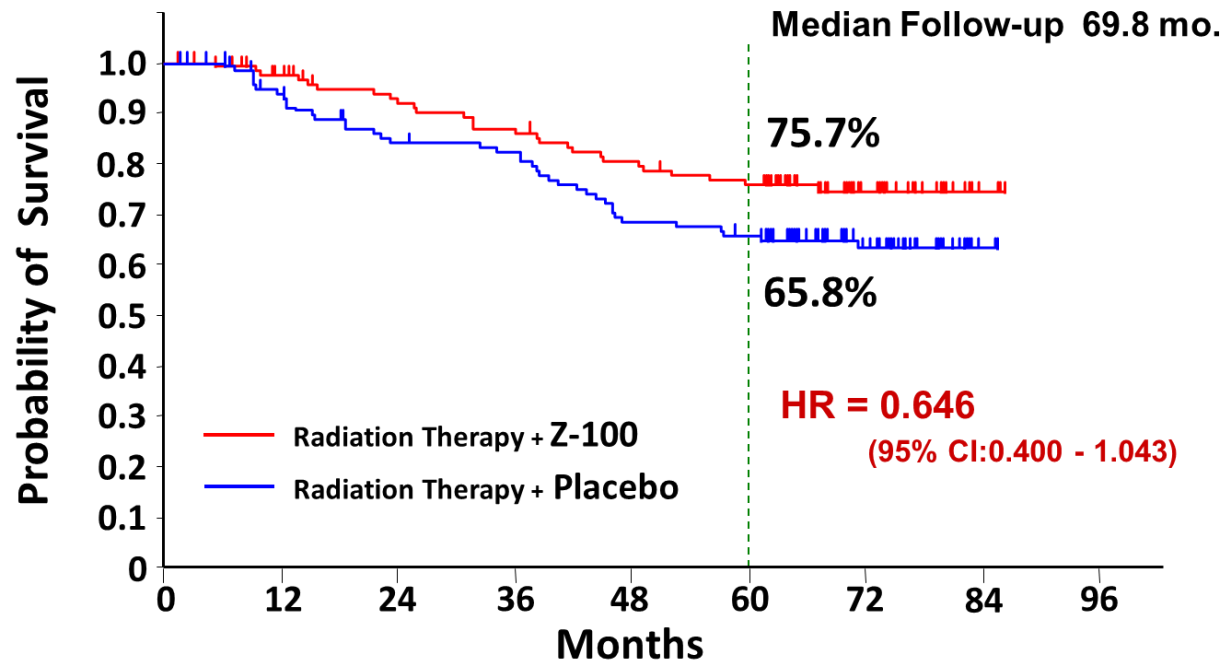
- The 2nd Phase III study (Sep 2004 – Feb 2012)



Sugiyama *et al.*, Ann Oncol, 00: 1-7, 2014.

Past: Clinical Development

- The 2nd Phase III study (Sep 2004 – Feb 2012)
 - Result: Overall Survival

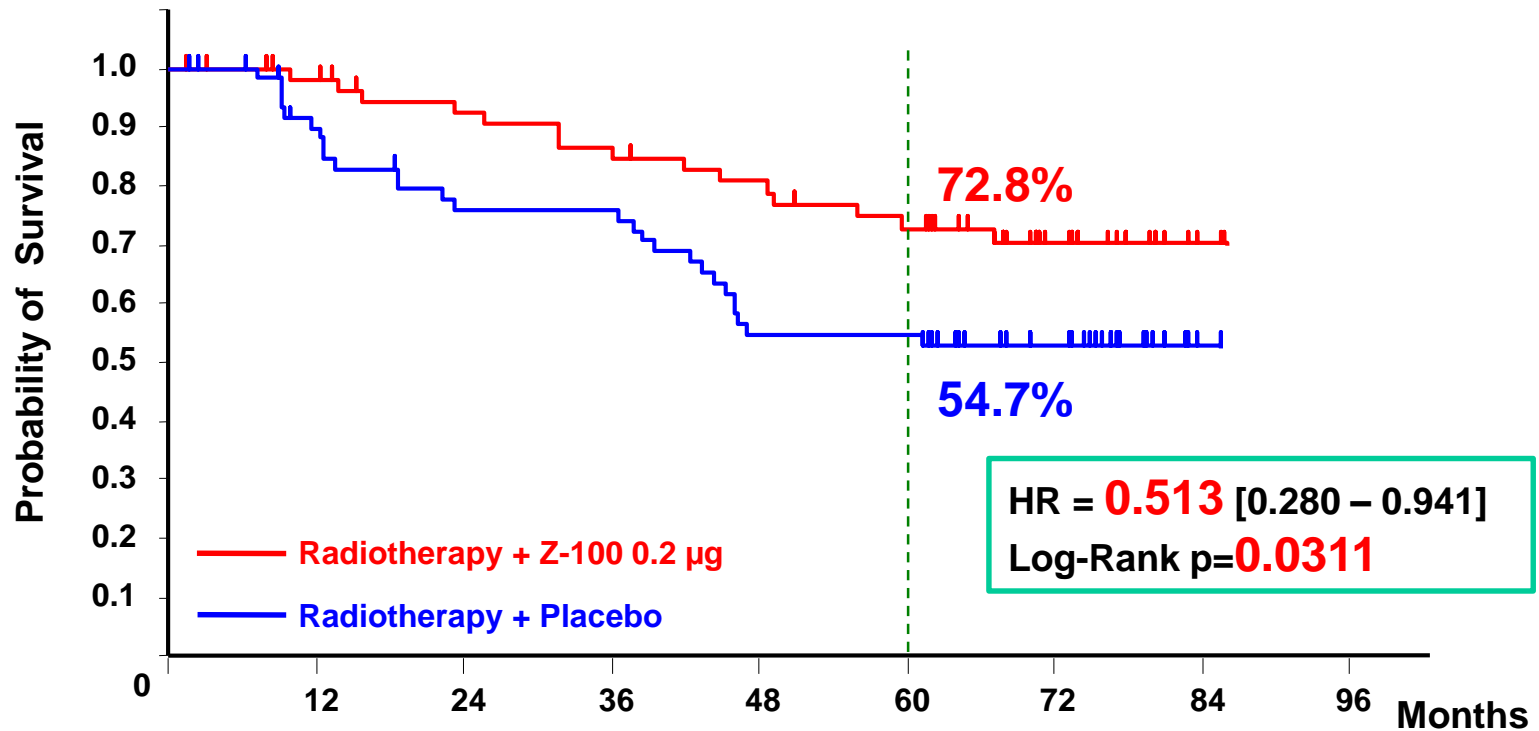


Number at risk	
Z-100	121 109 99 93 85 79 34 3 0
Placebo	122 107 93 90 75 71 36 2 0

Sugiyama *et al.*, Ann Oncol, 00: 1-7, 2014.

Past: Clinical Development

- The 2nd Phase III study (Sep 2004 – Feb 2012)
 - Result: Overall Survival (**FIGO IIIb**)



Number of patients

Z-100	59	54	48	45	41	36	17	2	0
Placebo	63	52	43	43	31	31	19	1	0

Present: Z100-01 Study

- Asia Global Study (780 cases)
 - 120+ sites in 7 countries
 - Malaysia, Japan, Korea, Taiwan, Thailand, Vietnam, Singapore
- Treatment
 - Z100-01 0.2 μg vs Placebo (+RT or CCRT)
- Target
 - Treatment-Naïve Cervical Cancer
 - Squamous Cell Carcinoma
 - FIGO Stage IIIB

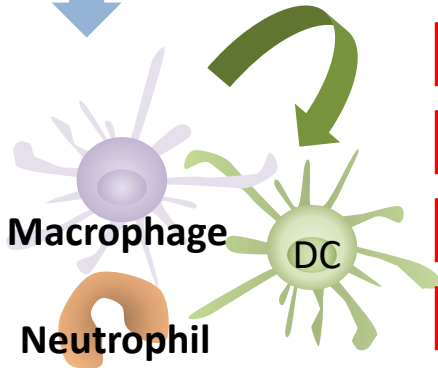
Z-100 Mode of Action

Z-100

*Innate
Immunity*

*Innate Immunity &
adaptive Immunity*

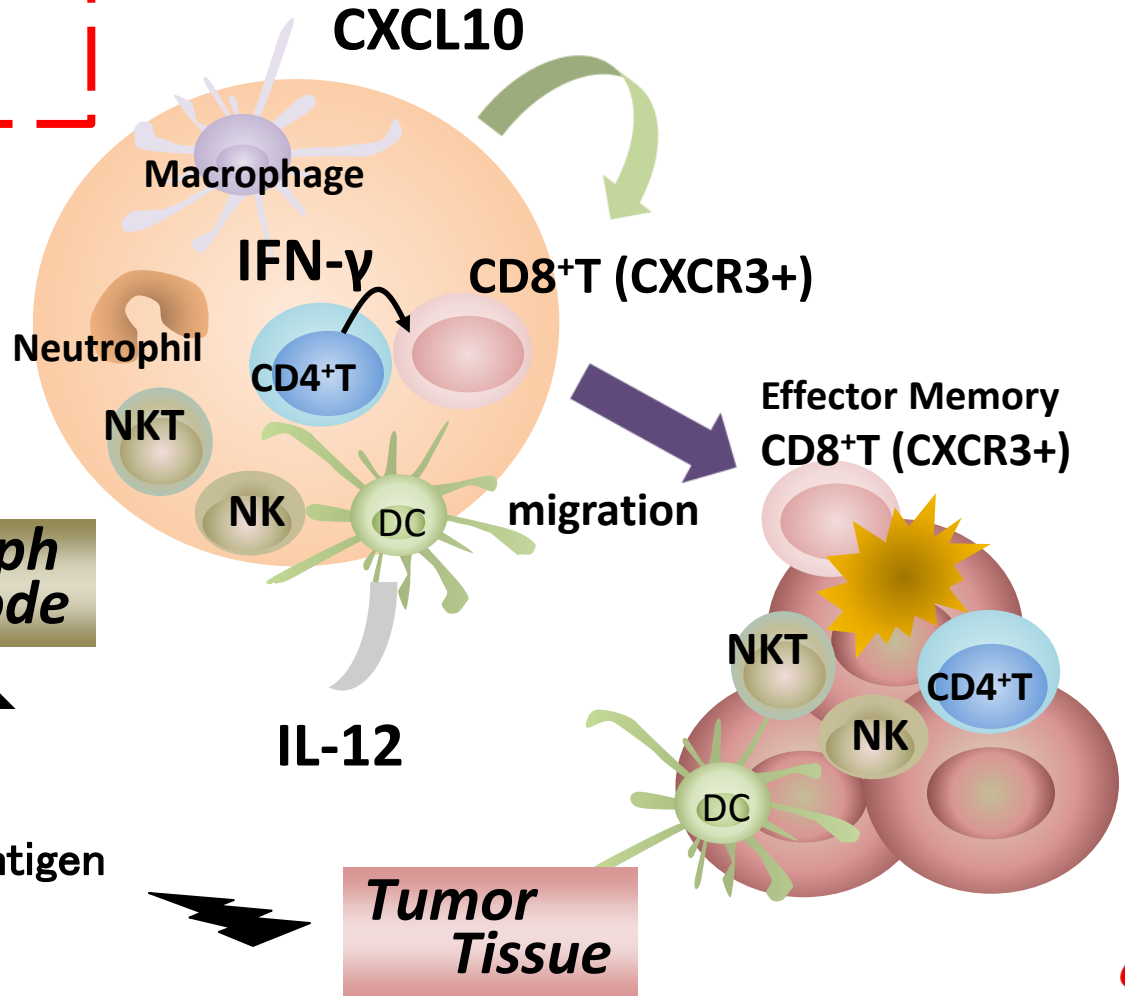
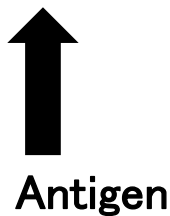
Chemokines
(RANTES, CXCL10 etc)



*Injection
site*



*lymph
node*



**It is different mechanism of
Nivolumab, Pembrolizumab etc.**

**We will be able to support the
treatment for cervical cancer in
future.**