

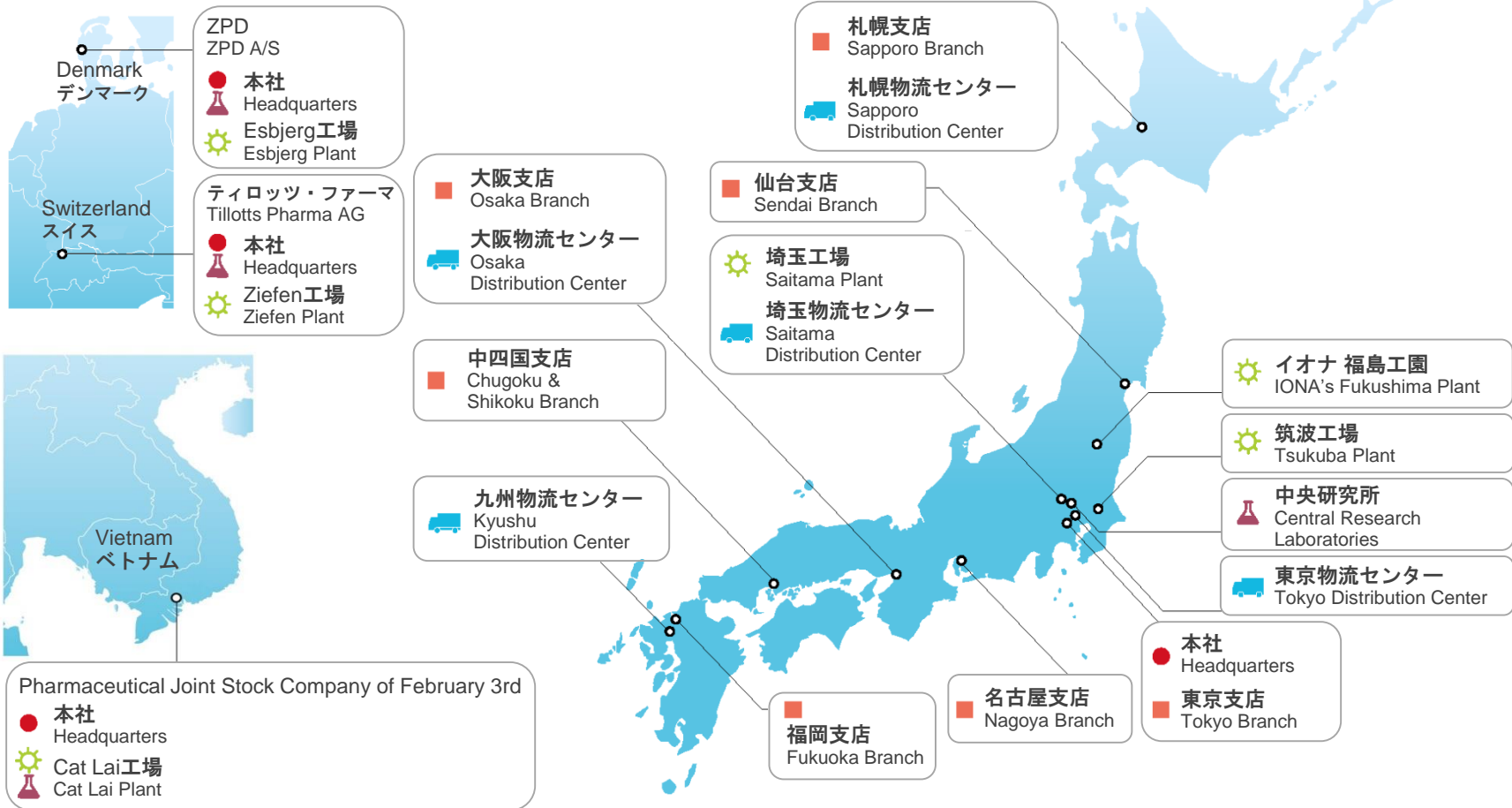
ゼリア新薬

Z E R I A

**Hiroki Kato PhD**  
**hiroki-katou@zeria.co.jp**

# Network

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



# Extensive Gastrointestinal Portfolio



**Asacol<sup>®</sup>**  
(ulcerative colitis)



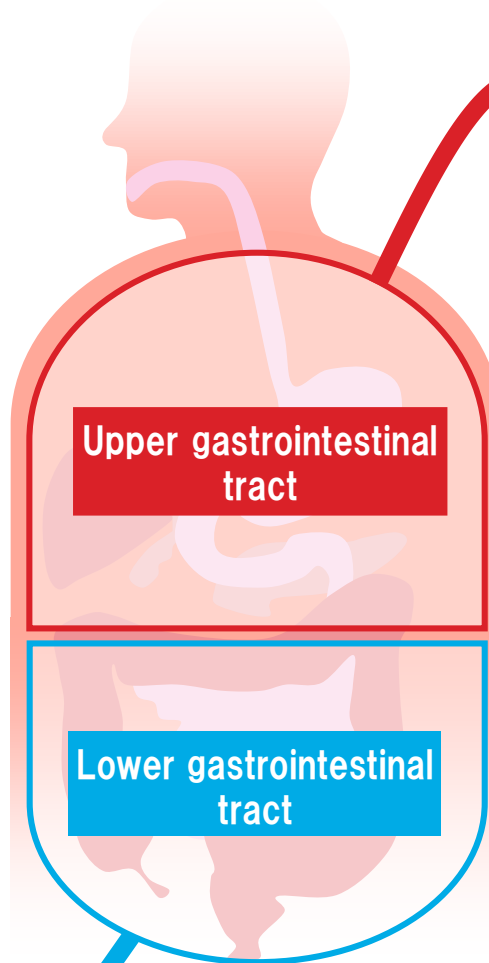
**Entocort<sup>®</sup>/Zentacort<sup>®</sup>**  
(Crohn's disease)



**New Lecicarbon<sup>®</sup>**  
(laxative)



**Visiclear<sup>®</sup>**  
(oral bowel cleansing)



**Acofide<sup>®</sup>**  
(functional dyspepsia)



**Promac<sup>®</sup>**  
(zinc containing anti-ulcerant)



**Acinon<sup>®</sup>**  
(histamine H<sub>2</sub> receptor antagonist)

**Z-360 (pancreatic cancer) \***

\* Under development

# Aloe



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**Why I am in here.**

**The cervical cancer  
eradication is the ardent  
wish of the human race.**



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**The reason why I  
am in here.**

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



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# **Z-100: Past, Present and Future**

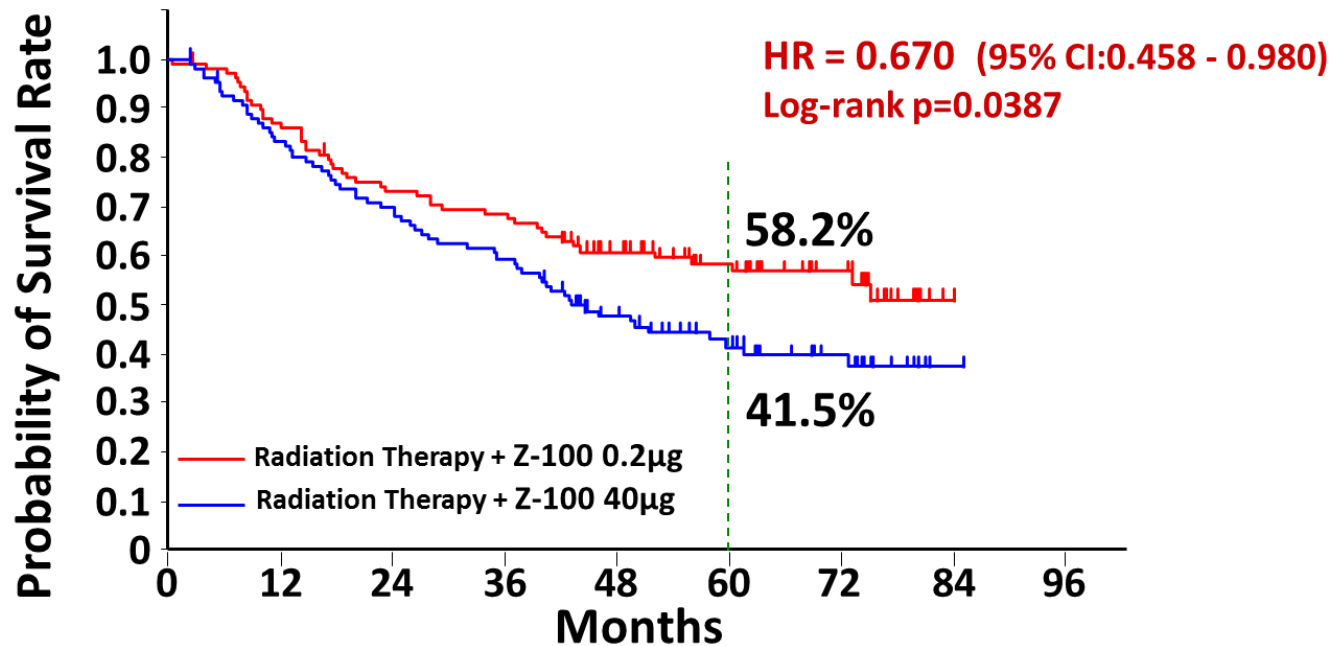
# Past: the origin of Z-100

- 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 1<sup>st</sup> Phase III study (Jun 1995 – Sep 2002)
  - Result (Overall Survival rate)



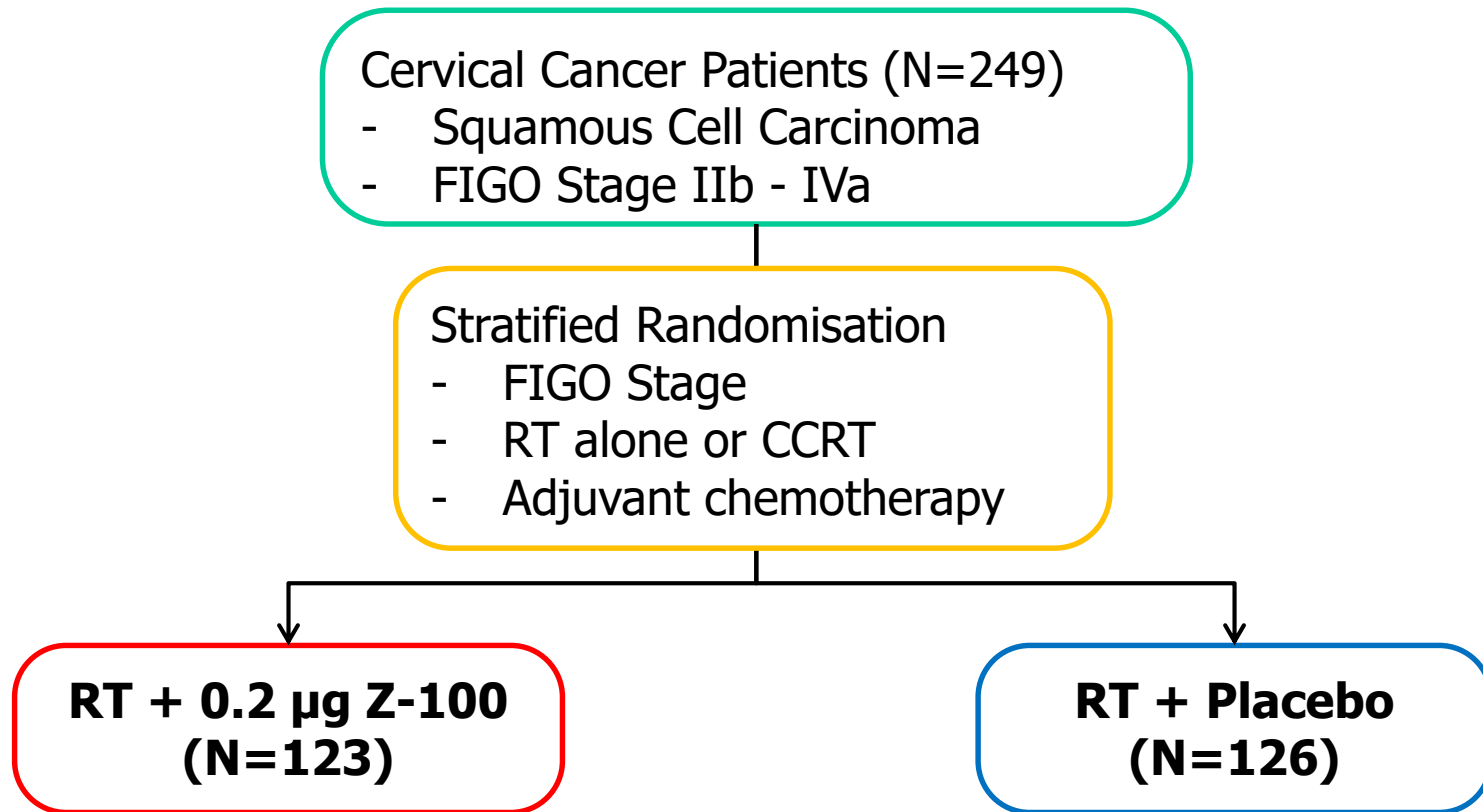
## Number at risk

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

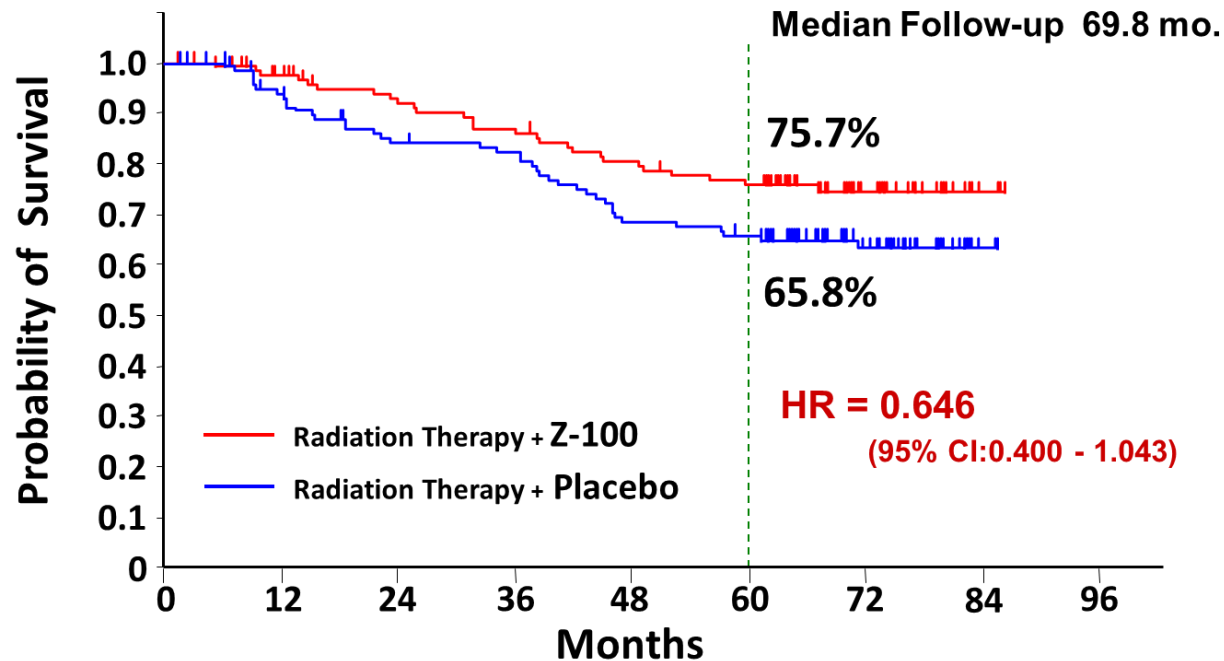
- The 2<sup>nd</sup> Phase III study (Sep 2004 – Feb 2012)



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

# Past: Clinical Development

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

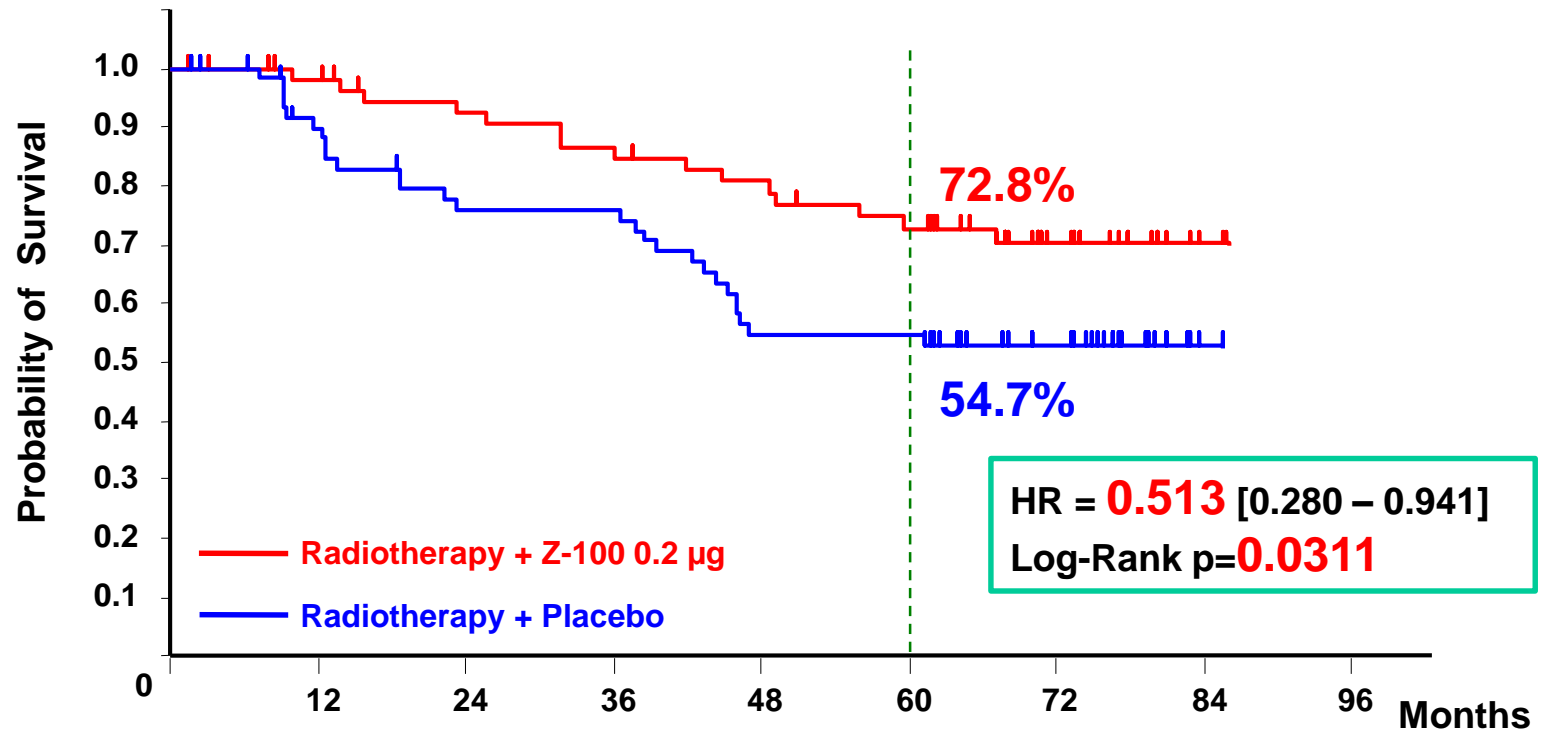


Number at risk	
Z-100	121    109    99    93    85    79    34    3    0
Placebo	122    107    93    90    75    71    36    2    0

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

# Past: Clinical Development

- The 2<sup>nd</sup> 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  $\mu\text{g}$  vs Placebo (+RT or CCRT)
- Target
  - Treatment-Naïve Cervical Cancer
  - Squamous Cell Carcinoma
  - FIGO Stage IIIB

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

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