



## North East Asia Hub (NEAH)

Sept 24, 2013

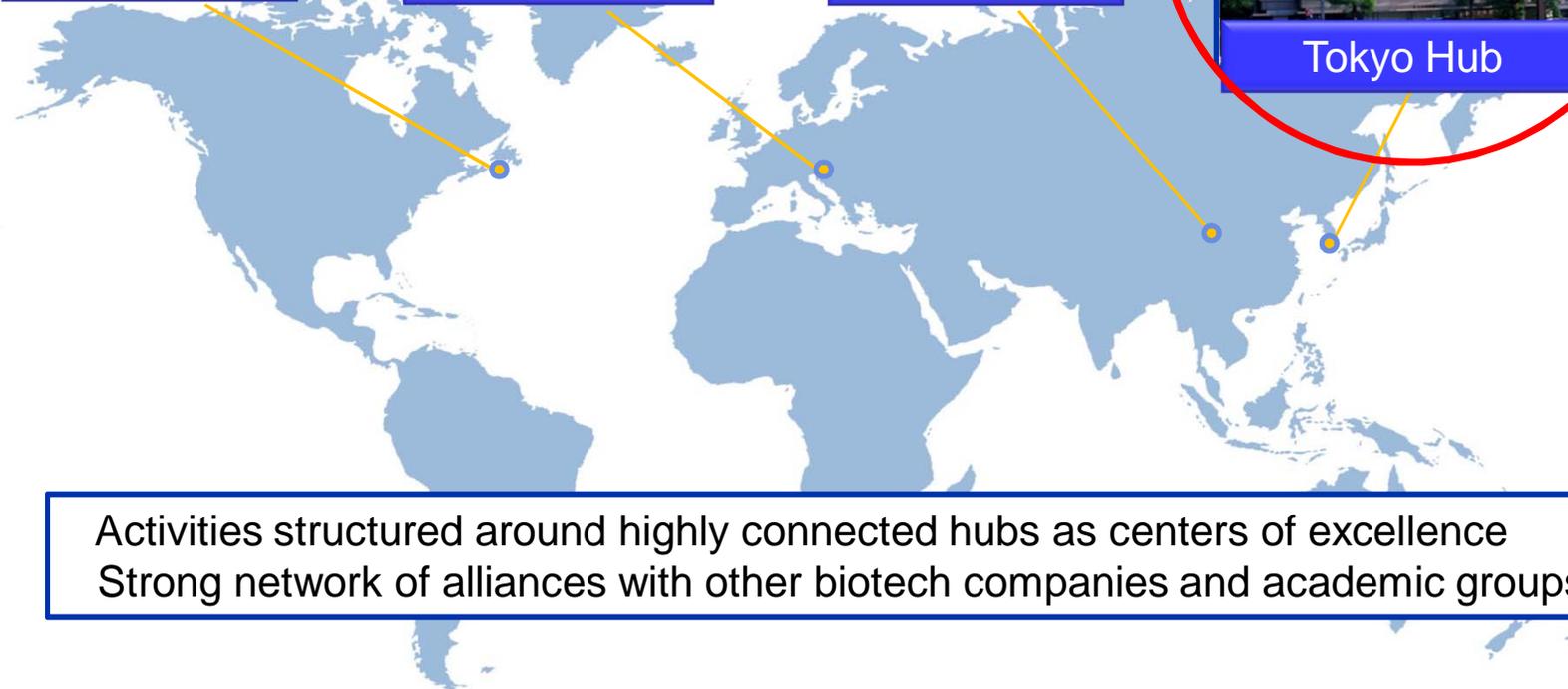
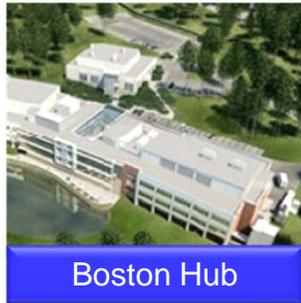
Koichi Katsura, M.D., Ph.D.

Head of R&D Japan

Site Head of R&D NEAH

Merck Serono Co., Ltd.

## Japan is one of four key global R&D centers



Activities structured around highly connected hubs as centers of excellence  
Strong network of alliances with other biotech companies and academic groups

## Why has NEAH been established in Japan?

- Partnerships to develop new drugs can be formed in Japan on the foundation of
  - high scientific standard
  - knowledgeable and experienced specialists and trial sites
  - well-developed national health care system
- One of the three pillars in ICH (US, EU and Japan)
  - data quality and compliance assured in accordance with ICH GCP
  - simultaneous development feasible based on ICH Guideline
- PMDA's high performance expected
  - strong intention to eliminate "Drug Lag" among US/EU and Japan
  - staff numbers increased
  - provide predictable response based on science, experience, and feasibility
- National policy to invest more in health care including innovations such as the premium to promote the development of new drugs

# R&D Vision & Strategy

## R&D Japan

### Global Indications

Obtain simultaneous approval<sup>1)</sup> in Japan by joining all the global phase III studies

## R&D North East Asia Hub (NEAH)

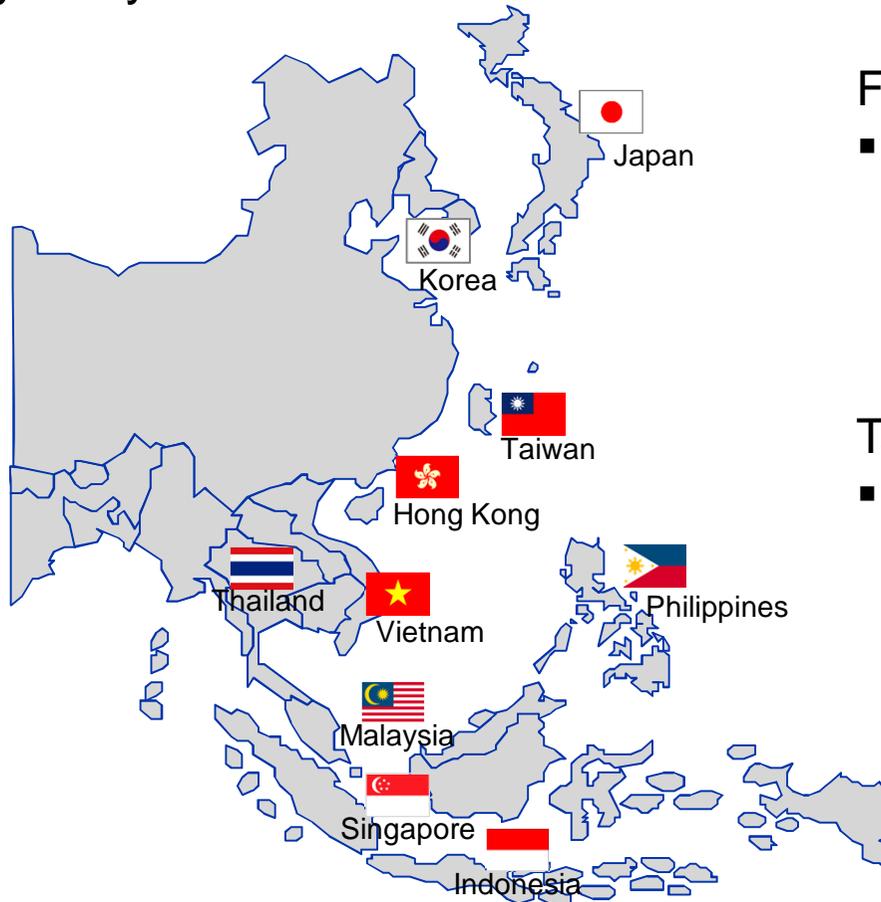
### Asian Indications

Contribute to global growth by initiating and leading Asian indications<sup>2)</sup> development

1. Within 2Q from US/EU approval
2. HCC, Gastric, Esophageal and Biliary Tract Cancers

# Scope of NEAH for Asian Indications

R&D function to get Asian prevalent oncology indications including gastric cancer, esophageal cancer, HCC, and biliary tract cancer led by Tokyo Hub Center



## Focus counties for Clinical Study

- Korea, Taiwan, Hon Kong & Singapore in addition to Japan



## Target counties for Market Authorization

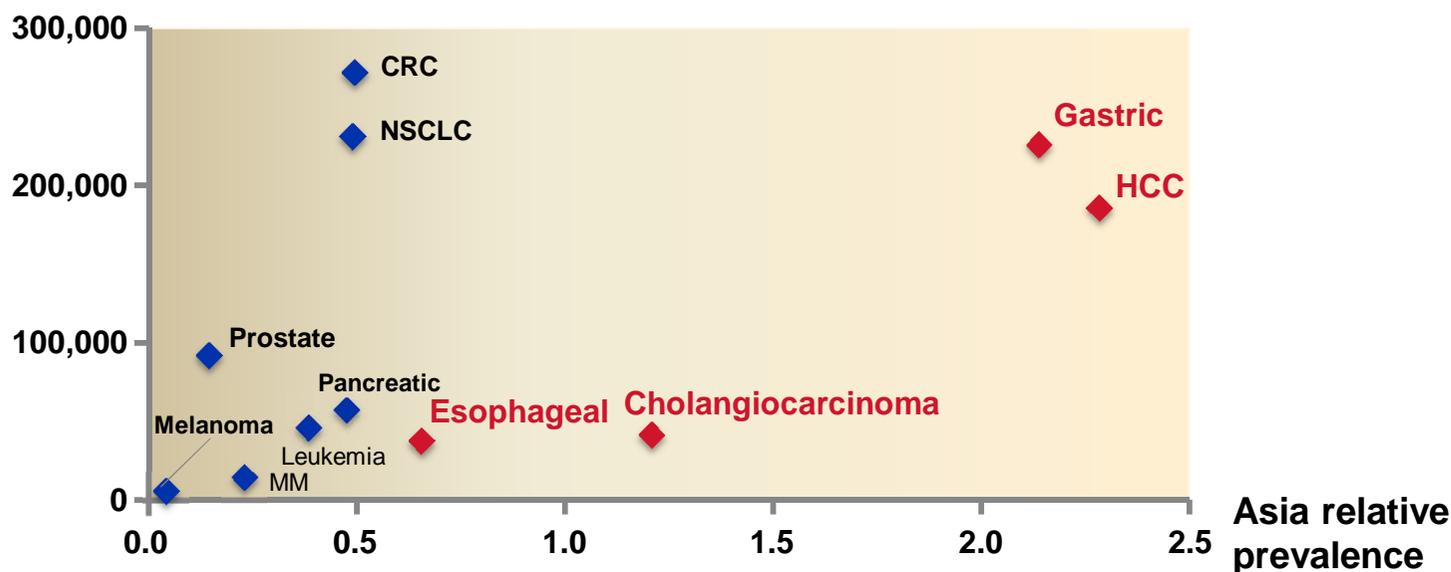
- Philippines, Indonesia, Malaysia, Vietnam & Thailand in addition to the above countries



# Four Indications Identified as Asian Indications

**Indications with Asia relative prevalence > 1  
+ Esophageal with relative prevalence in Japan 2.1 times more than EU/US**

Patient Population<sup>1)</sup> in 9 Asian countries<sup>2)</sup> and Japan in 2020



$$\text{Asia relative prevalence} = \frac{\text{"2020 patient population per 100,000 persons in 9 Asian countries and Japan"}}{\text{"2020 patient population per 100,000 persons in Europe<sup>3)</sup> & US"}}$$

1. defined as "the number of new cases arising in a year"

2. Korea, Taiwan, Hong Kong, Singapore, Indonesia, Malaysia, Thailand, Viet Nam and Philippines

3. Germany, UK, France, Spain, Italy

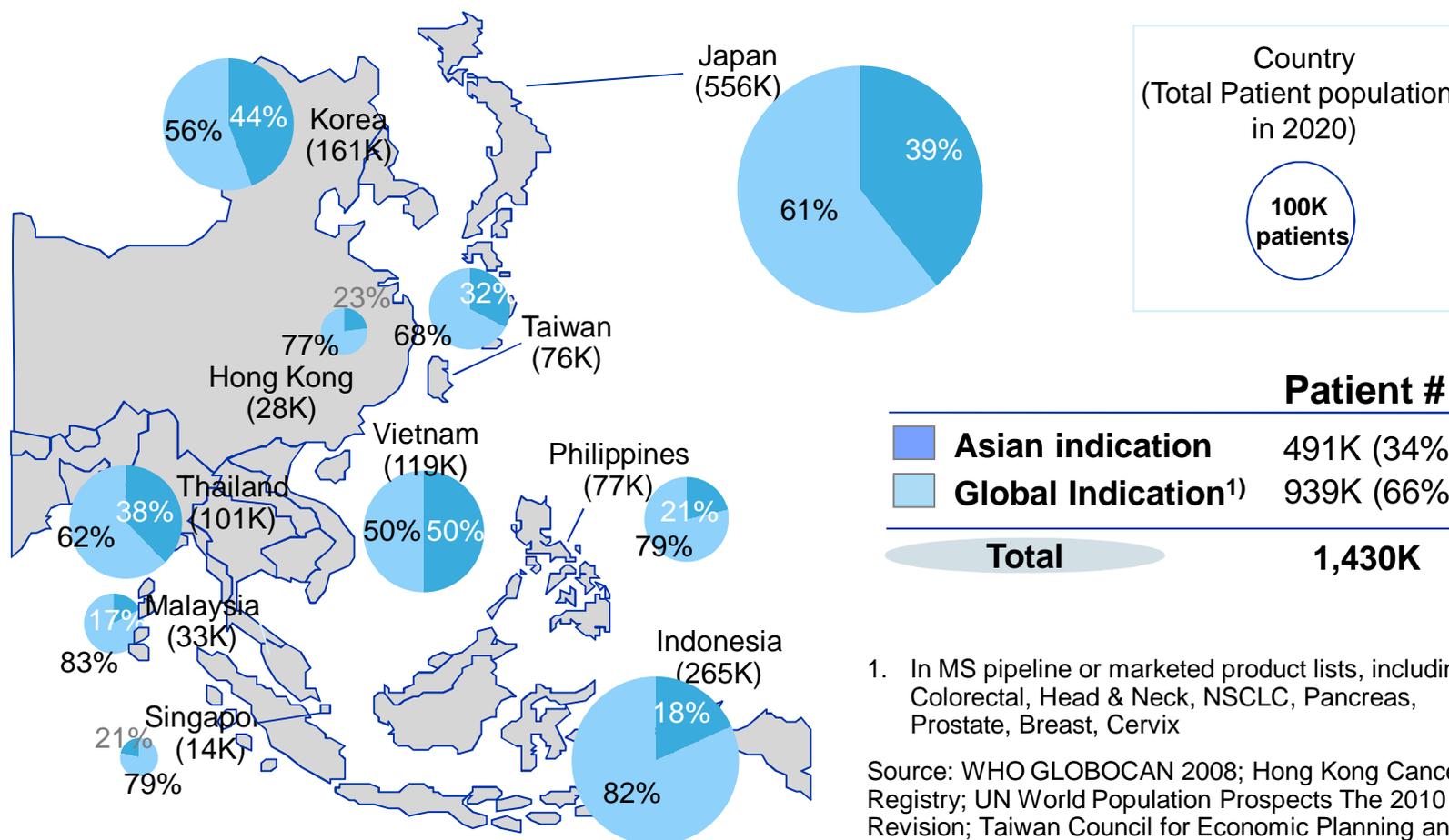
Note: Except for Hong Kong, the population of cholangiocarcinoma includes that of gallbladder cancer only

Source: WHO GLOBOCAN 2008; Hong Kong Cancer Registry; UN World Population Prospects The 2010 Revision; BCG analysis

# Significant Development Opportunity Exists in Asian Indications

Estimated patient population for Asian Indications and Global Indications<sup>1</sup> in 2020

Unit: K (thousand)

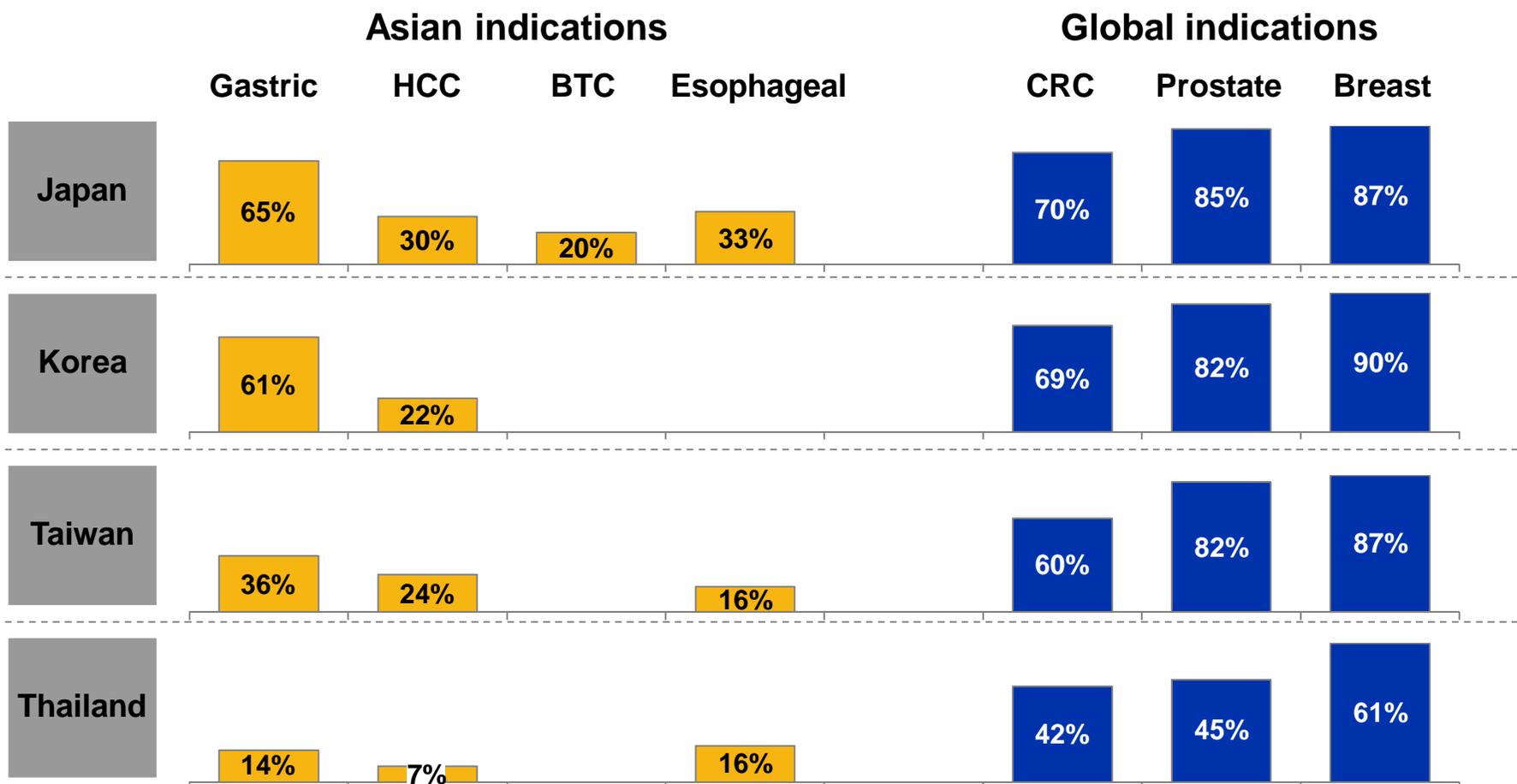


1. In MS pipeline or marketed product lists, including: Colorectal, Head & Neck, NSCLC, Pancreas, Prostate, Breast, Cervix

Source: WHO GLOBOCAN 2008; Hong Kong Cancer Registry; UN World Population Prospects The 2010 Revision; Taiwan Council for Economic Planning and Development; BCG analysis

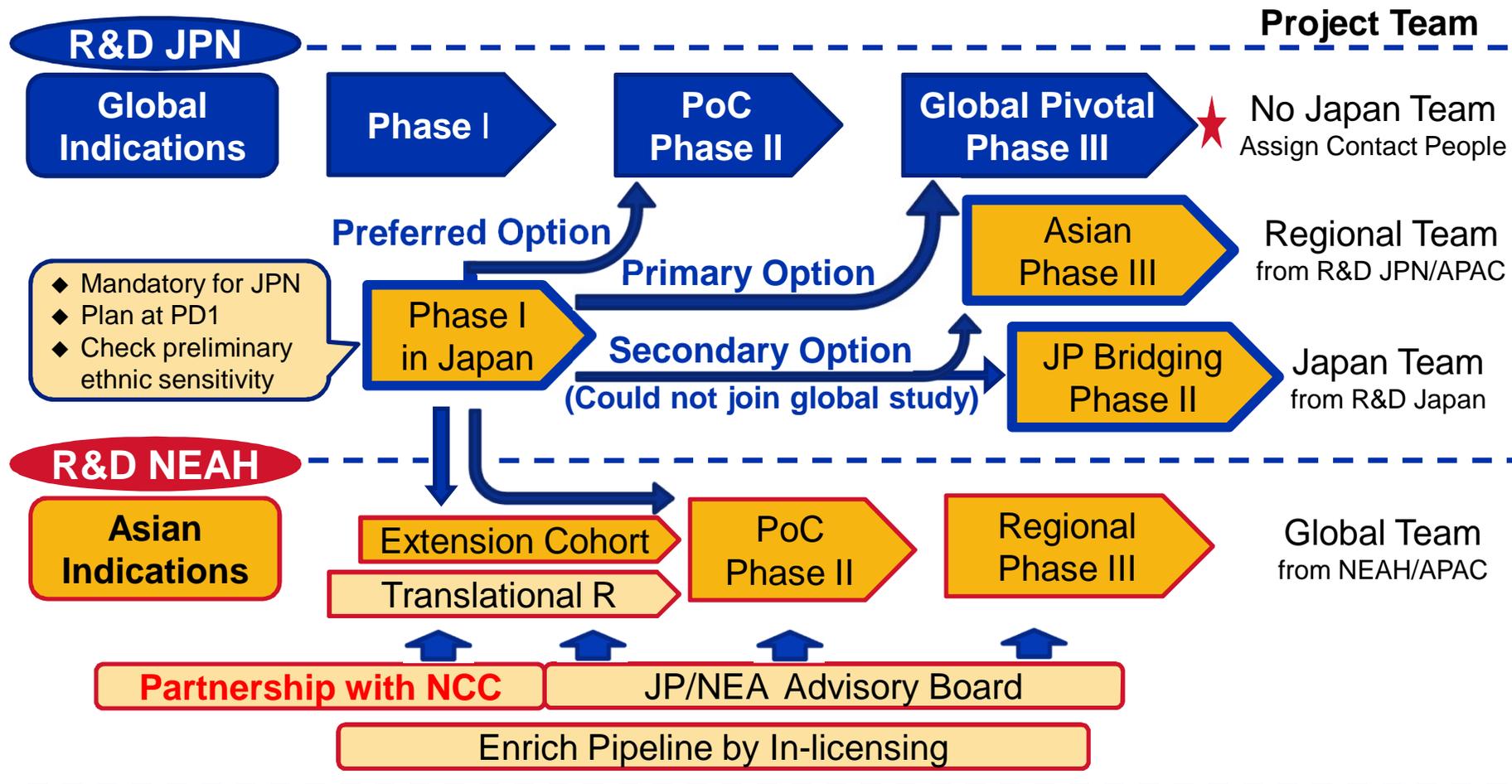
# Unmet Medical Needs in Asian Indications

## 5-Year Survival Rate for Asian & Global Indications



Notes: Year of the data, Japan: 2011, Korea : 2010 Taiwan: 2008 , Thailand: 2011  
 Source: Country healthcare authority / cancer center; World Health Organization

# High Level Dev. Strategy for R&D JPN & NEAH



★ : Simultaneous approval (Lag time in JPN: 2Q)

# Partnership with National Cancer Center

## Scope

- Establish scientific relationship between NCC and MSJ

## Activity of the partnership

- Oncology Science Day (annually)
- Translational research for 4 Asian indications
- Early clinical development: Phase I (FTIH), PoC/Phase II

## Action plan

- **Agreement concluded on August 1<sup>st</sup>, 2013**
- Followed by sectional meeting/committee or specific contracts under the umbrella of Partnership Agreement for identified preclinical & clinical research

# 1st NCC/MS Oncology Science Day Meeting

## 8<sup>th</sup> Sep. 10:00 – 16:00

- |   |               |
|---|---------------|
| 1. Introduction   | 10:00 – 10:15 |
| 2. Oncology Session   | 10:15 – 12:30 |
| 1) Introduction of Exploratory Research and TR activity in NCC/NCCHE  |               |
| 2) Introduction of Pipeline of MS oncology development and discussion |               |
| • Pimasertib, cMETi, DI-17, TH-302, Sym004, New Projects              |               |
| Lunch Break   | 12:30 – 13:15 |
| 3. Oncology Session (Continued)                                       | 13:15 – 14:00 |
| 4. Immuno-oncology Session  | 14:00 – 16:00 |
| 1) Introduction of immunoOncology activity in NCC/NCCHE               |               |
| 2) Overview of Immuno Oncology in MS                                  |               |
| • Selectkine, NHS-IL-12, anti-PD-L1                                   |               |
| 3) Clinical Aspects of Immuno Oncology in MS                          |               |
| • Clinical Development of anti-PD-L1, Opportunity of Asian indication |               |
| 4) Discussion on MS Immuno Oncology development products              |               |





# NEAH Not Only for Asia, But for Entire World