

# Development Pipeline and Acceleration of Global Development

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Ken-ichi Yanagisawa  
Board Director  
Managing Executive Officer  
Development Division

# Today's Topics



1. Project Overview of the New Company
2. Pursue High Productivity
3. Accelerate Development of Overseas Operations
4. Development Projects
  - TA-7284 (SGLT2 inhibitor)
  - MP-424 (Chronic Hepatitis C)
  - Remicade LCM strategy

(LCM: Life Cycle Management)

# 1. Project Overview of the New Company (In Japan 1)



Mitsubishi Tanabe Pharma

Immunity Respiratory	Phase I	Phase II	Phase III	Filed
In Japan	CNTO-148 (Rheumatoid Arthritis)	MCC-847 (Allergic Rhinitis)	Remicade (Ulcerative Colitis)	Remicade (Crohn's Disease /maintenance)
	★ MP-435 (Rheumatoid Arthritis)	FTY720 (Multiple Sclerosis)	Remicade (Psoriasis)	★ Remicade (Rheumatoid Arthritis /dose escalation)
			Remicade (Ankylosing Spondylitis)	Venoglobulin-IH (IgG <sub>2</sub> deficiency)
			APTA-2217 (COPD)	Venoglobulin -IH (Polymyositis, Dermatomyositis)
			APTA-2217 (Asthma)	
			MCC-847 (Asthma)	
			★ Venoglobulin-IH (Myasthenia Gravis)	
			Venoglobulin-IH (Systemic Sclerosis)	
				★ : staged up

# 1. Project Overview of the New Company (In Japan 2)



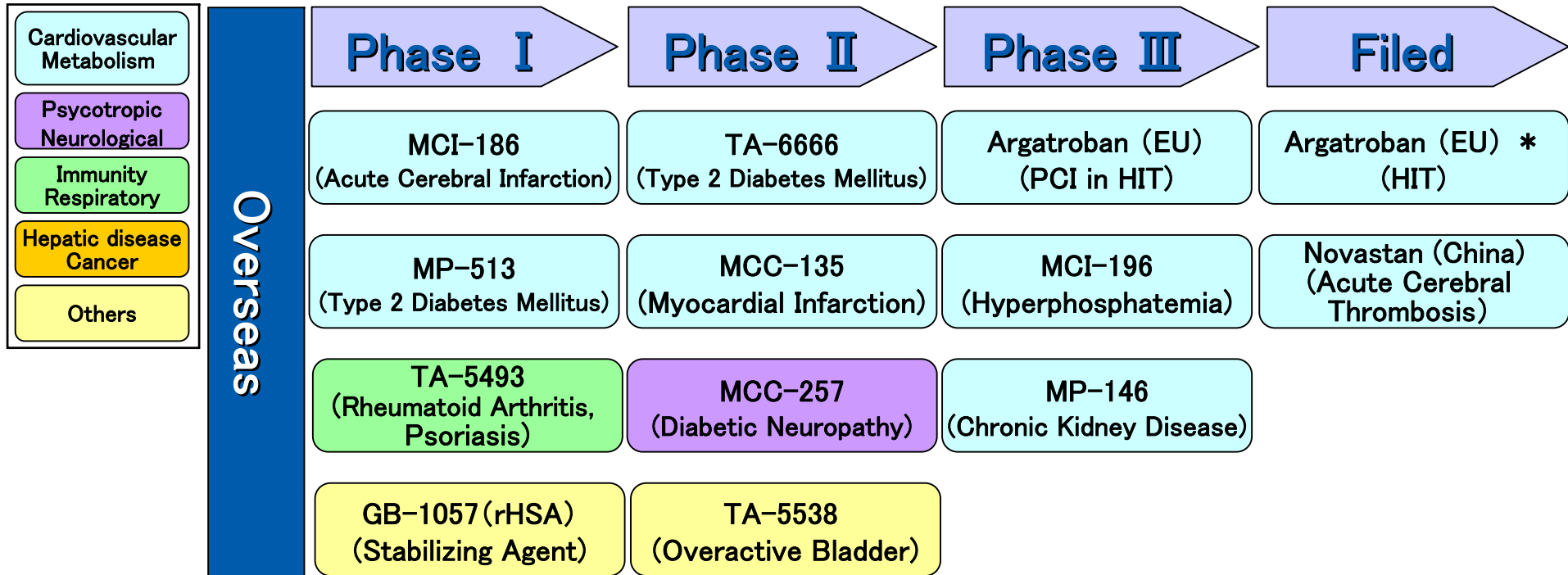
	Phase I	Phase II	Phase III	Filed
★ TA-7284 (Diabetes Mellitus)	Cholebine (Type 2 Diabetes Mellitus)	Anplag (Prevention of Recurrence of Cerebral Infarction)	★ Novastan (HIT: Heparin-Induced Thrombocytopenia)	
TA-6666 (Type 2 Diabetes Mellitus)	MP-513 (Type 2 Diabetes Mellitus)	Maintate (Chronic heart failure)	Neuart (Toxemia of Pregnancy)	
Cholebine (Hyperphosphatemia)		Radicut (Amyotrophic Lateral Sclerosis)	★ Hebsbulin-IH for intravenous (Prevention of reinfection with hepatitis B virus after liver transplant)	
MP-214 (Schizophrenia)		Modafinil (Obstructive sleep apnea)		
MP-424 (Chronic Hepatitis C)		TA-8317 (Breakthrough cancer pain)		
		Valixa (Transplantation)		

- Cardiovascular Metabolism
- Psychotropic Neurological
- Hepatic disease Cancer
- Others

In Japan

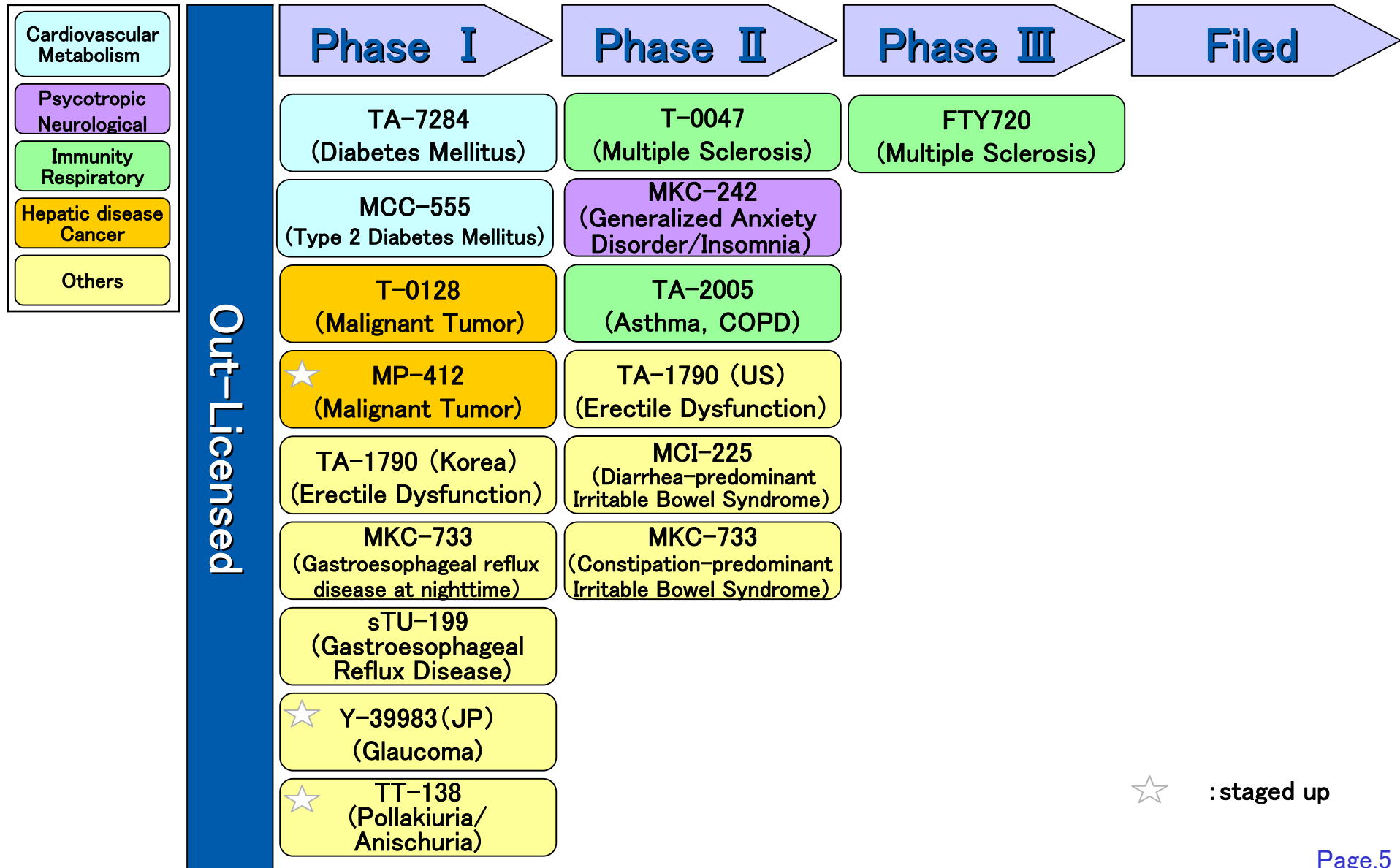
★ : staged up

# 1. Project Overview of the New Company (Overseas)



\* Being Prepared for NDA

# 1. Project Overview of the New Company (Out-Licensed)



Out-Licensed

★ : staged up

# 1. Project Overview of the New Company



	P I	P II	P III	Filed	Approved	Total
In Japan	7	4	14	7	3	35
Overseas	4	4	3	2*		13
Out-Licensed	9	6	1			16

< Changes since previous announcement >

\* Including 1 project being prepared for NDA

## Approved

- Omeprazon (NERD\*\*)
- Omeprazon (Secondary eradication)
- Medway (Hypoalbuminemia)

## Changed

- Maintate (Chronic heart failure) (Filed → PIII)

## Deleted

- Gastrom (PIII in JP, PII OS)
- MCC-977 (OS)
- Y-700 (PI in JP, PII OS)
- TA-1702 (OAB) (OL of PI OS)
- Cleanal (PII in JP)

## Filed

- Remicade (RA dose escalation)
- Hebsbulin-IH (Prevention of reinfection with hepatitis B virus after liver transplant)
- Novastan (HIT)

## New

- TA-7284 (DM) (PI in JP)
- MP-435 (RA) (PI in JP)
- VG-IH (Myasthenia Gravis) (PIII in JP)
- Y-39983 (Glaucoma) (OL of PI in JP)
- MP-412 (Malignant Tumor) (OL of PI in OS)
- TT-138 (Pollakiuria/Antischuria) (OL of PI in OS)

# Strengthen Domestic Development



In order to strengthen the domestic business base, focus injection of development resources on the following therapeutic areas.

- ◎Immunity and inflammatory diseases,
- ◎Diabetes and hyperlipidemic diseases, ◎Hepatic diseases

	Ph I	Ph II	Ph III	Filed
<b>Immunity/ Inflammatory Disease</b>	CNTO-148 (RA)  MP-435 (RA)	FTY720 (Multiple Sclerosis)	Remicade * (Psoriasis) (Ulcerative Colitis) (Ankylosing Spondylitis)  Venoglobulin-IH * (Systemic Sclerosis) (Myasthenia Gravis)	Remicade * (Crohn's Disease/maintenance) (RA/dose escalation)  Venoglobulin-IH * (Myositis·IgG <sub>2</sub> deficiency)
<b>Diabetes/ Lipid Metabolism Disorders</b>	TA-6666 (Type 2 Diabetes Mellitus)  TA-7284 (Diabetes Mellitus)	MP-513 (Type 2 Diabetes Mellitus)  Cholebine * (Type 2 Diabetes Mellitus)		
<b>Hepatic Disease</b>	MP-424 (Chronic Hepatitis C)			Hebsbulin-IH * (Prevention of reinfection with hepatitis B virus after liver transplant)

\* : Additional indications, or change in dose and dosage regimen

Shortening of development period by merging strengths and sharing know-how in these therapeutic areas

Strengthening of project management

# Promotion of Global Development



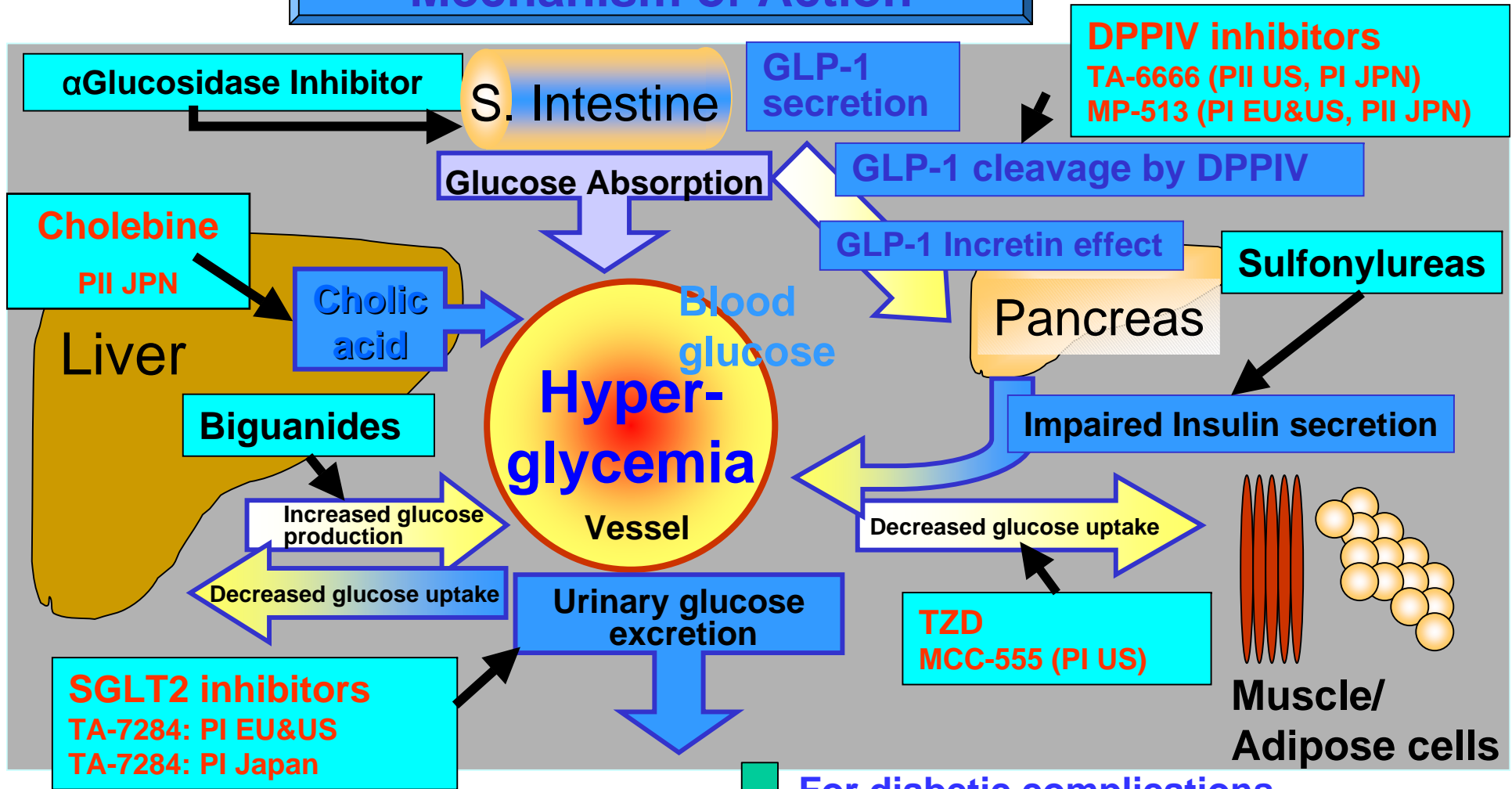
- Promote phase III clinical trials in the U.S. and Europe, with a focus on the renal area.
- Following the renal area, select globally developed areas by 2010.

## Major Product Pipeline

	Ph I	Ph II	Ph III
<b>Renal Disease</b>		TA-5538 (Overactive Bladder)	MCI-196 (Hyperphosphatemia) MP-146 (Chronic Kidney Disease)
<b>Diabetes and Related Diseases</b>	MP-513 (Type 2 Diabetes Mellitus)	TA-6666 (Type 2 Diabetes Mellitus)	
<b>Cerebral Diseases</b>	MCI-186 (Stroke)	MCC-257 (Diabetic Polyneuropathy)	

# For the treatment of Diabetes

## Mechanism of Action



### For diabetic complications

**Diabetic complications**

- ★ ACE inhibitor / T1DM nephropathy  
TANATRIL (Launched in JPN)
- ★ Neurotrophin enhancer / Diabetic neuropathy  
MCC-257 PII EU& US

## 2. Pursue High Productivity

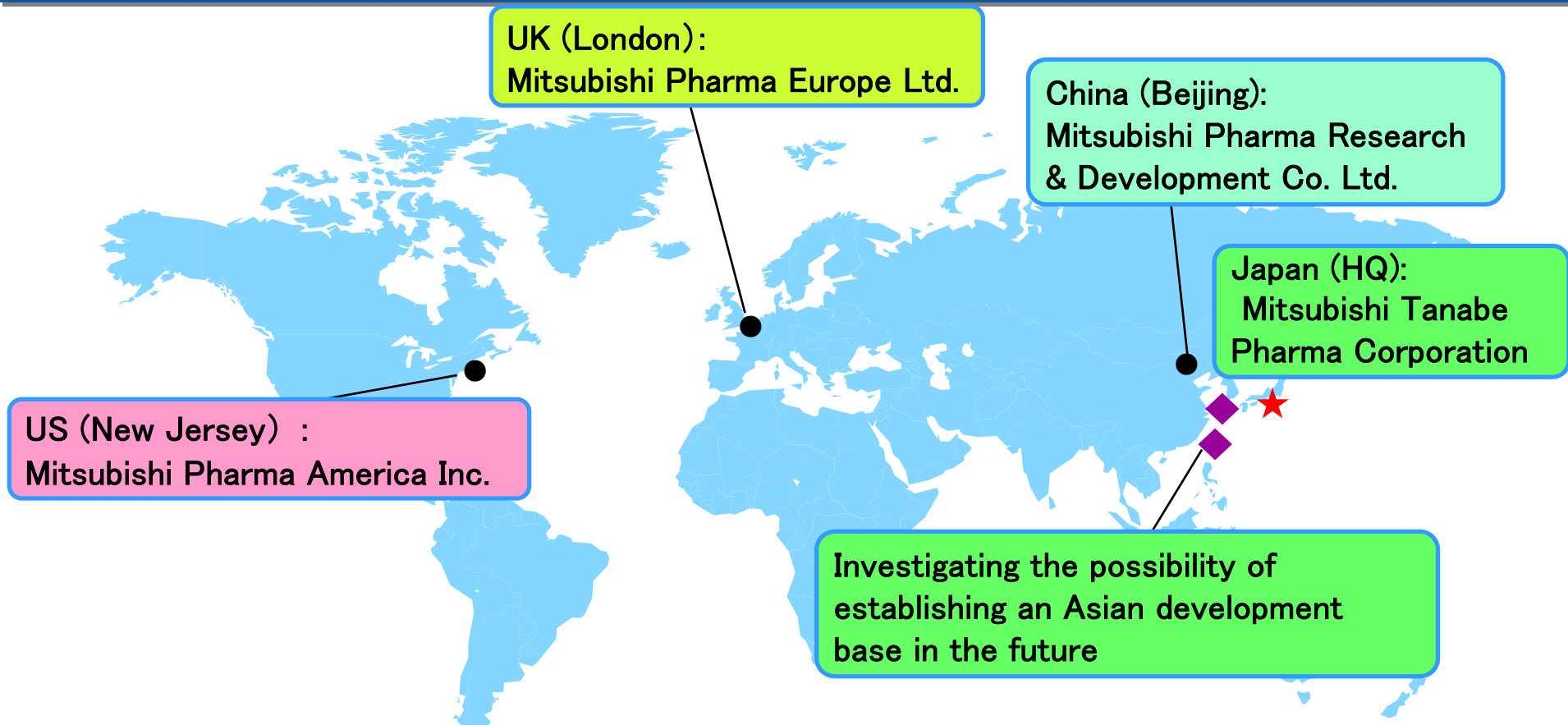


- Improve productivity by integrating knowledge & technology
- Establish an effective project management system
- Expand capabilities of functional organizations to support project team performance (Data Management, Medical Writing, Regulatory Affairs)
- Improve geographical presence and accelerate development process
- Integration & rationalization of development operation systems to achieve optimum effects

**Target by 2010**

- Reduce standard full development time
- Simultaneous NDA/MAA submission in the 4 regions (US, EU, Japan and Asia)

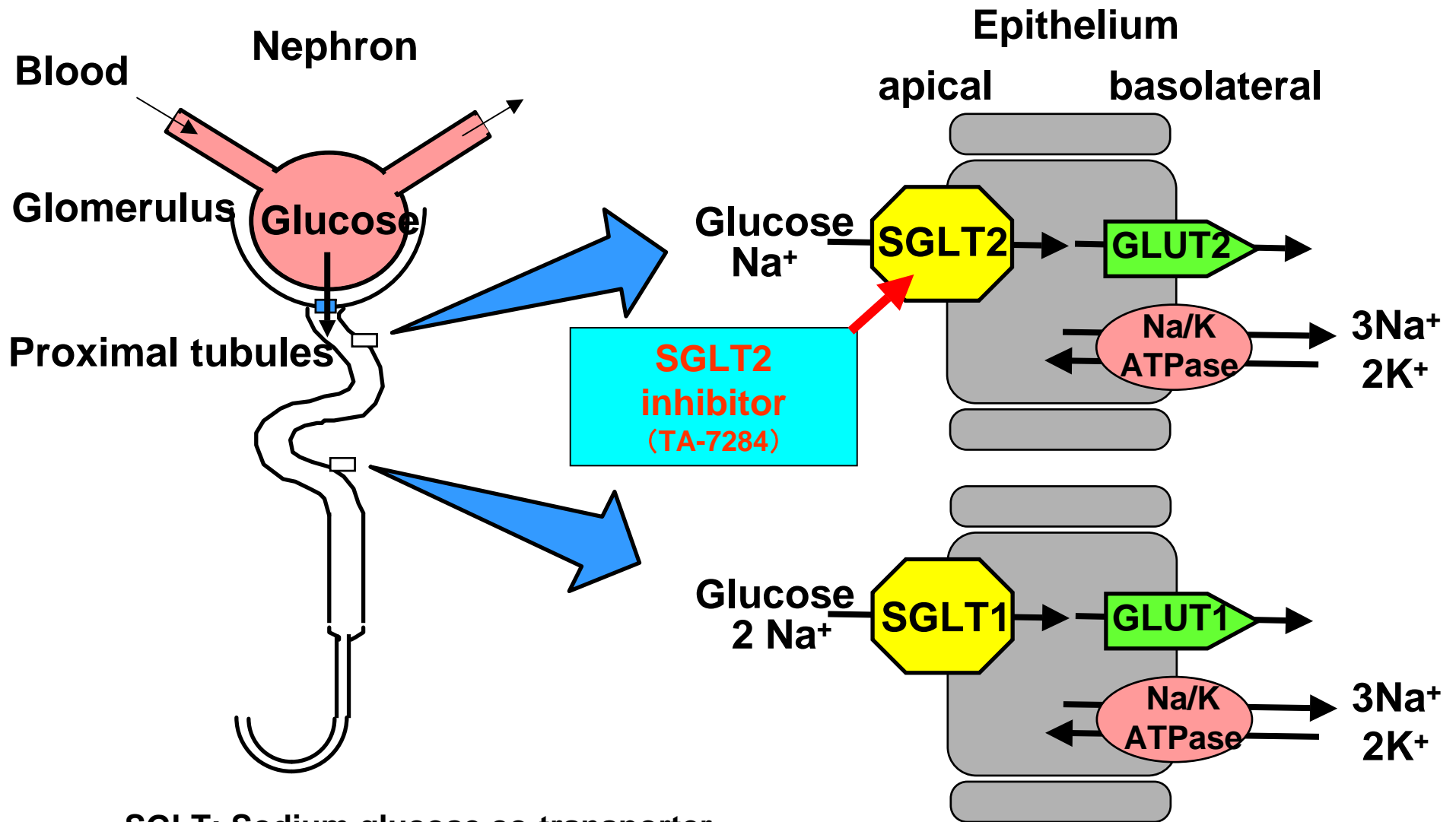
### 3. Accelerate Development of Overseas Operations



- To establish a global project management structure
- To establish a system to conduct multinational studies and reinforce development principles

# 4. Development Projects: Diabetes

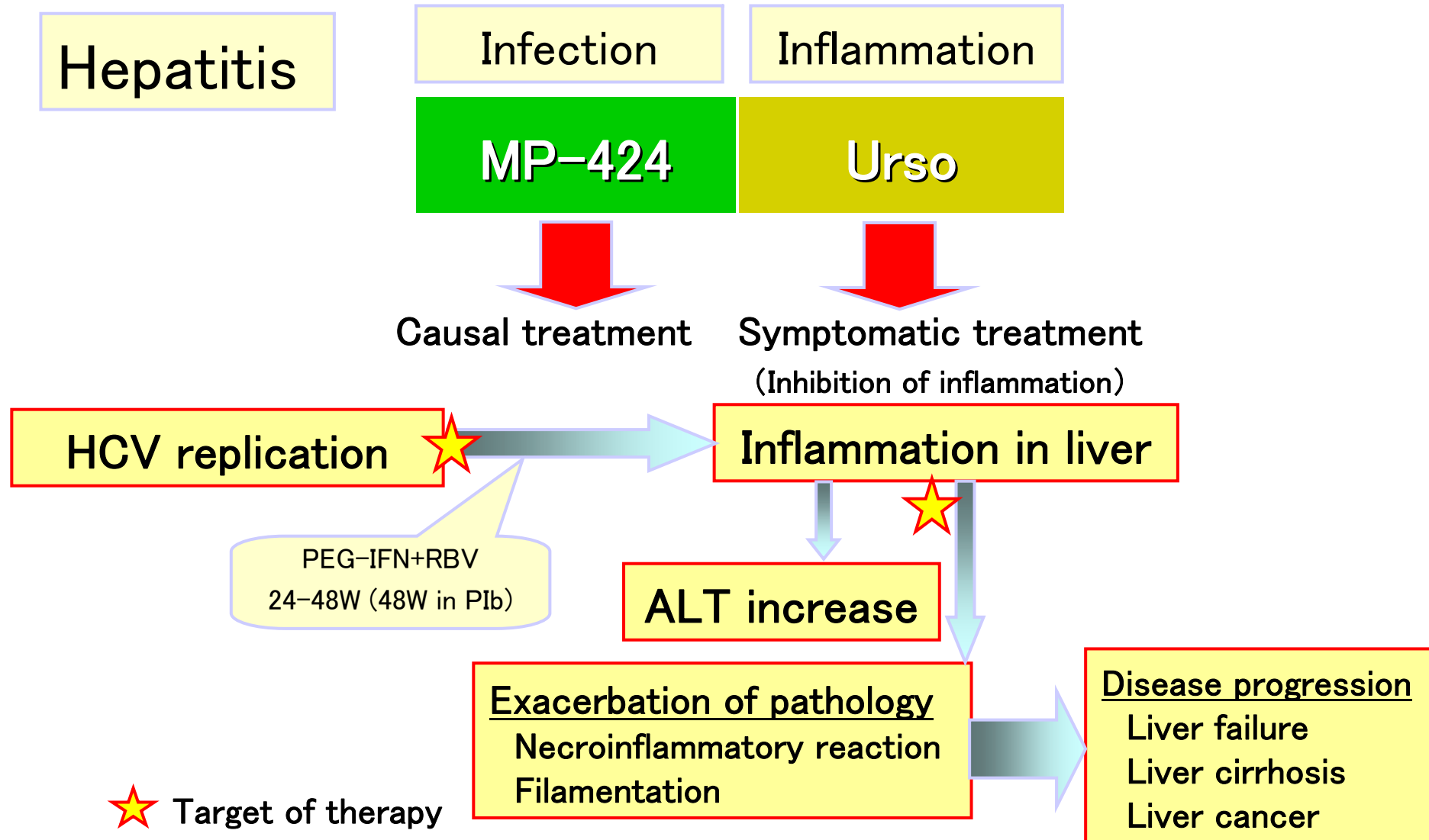
(TA-7284: SGLT2 inhibitor)



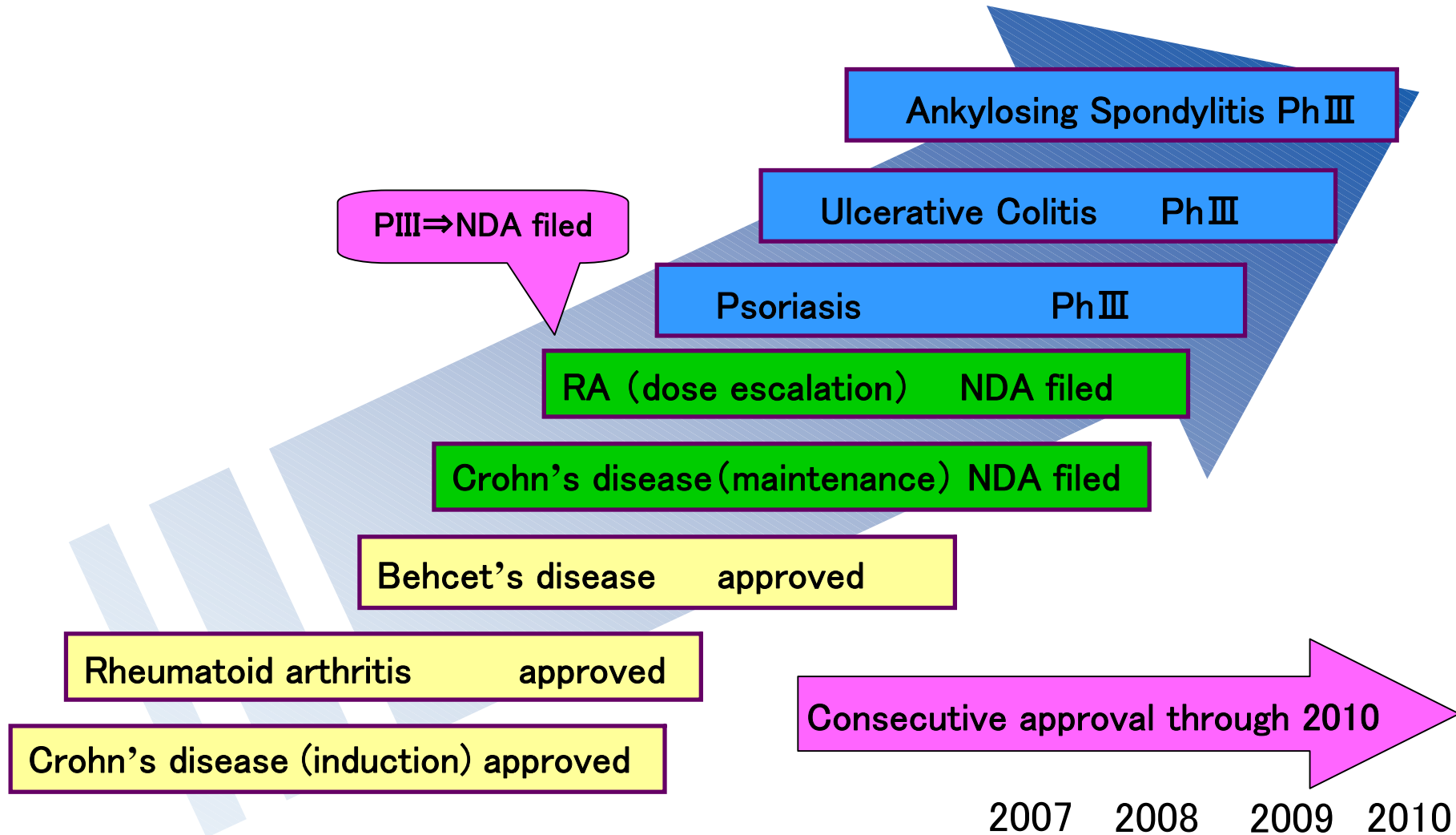
SGLT: Sodium glucose co-transporter

Modified from Tsujihara et. al., Bio Clinica, 13, 324 (1998)

# 4. Development Projects: Hepatitis C (Urso, MP-424)



# 4. Development Projects: Remicade (LCM strategy)



### **Cautionary Statement**

**The statements contained in this presentation is based on a number of assumptions and belief in light of the information currently available to management of the two companies and is subject to significant risks and uncertainties.**

**Information on the companies, excluding the two companies and the new company, is generally based on and referring directly to publicly available information, and the companies have not assumed any responsibility for independently verifying and makes no warranties or representations with respect to the accuracy and completeness of such information.**