Presentation of March 2011 Financial Results

Status of R&D Pipeline

○**Progress in fiscal 2010 and initiatives in fiscal 2011**

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Aim for Early Launch of Newly Developed Products and Enhance and Strengthen the Pipeline

Kyorin

	HOPE 100 Stage 1 FY2010-2015	HOPE 100 Stage 2 FY2016-2019	HOPE 100 Stage 3 FY2020-2023
Tasks at Each Stage	・LCM promotion ・KRP-108 (aim for FY2014 launch) ・KRP-104 (aim to out-license)	Early application and approval of newly developed products Pipeline enhancement and strengthening	Create original new global products

Aim to in-license products

LCM

Mucodyne DS50 Uritos OD tablet
New usages and dosages (QD) for Pentasa, new drug formulations (suppositories)

LCM: Life Cycle Management

Newly Developed Products

Incl. products in-licensed

KRP-108 (asthma)
KRP-104 (diabetes)

Candidates for in-licensing
(respiratory ,otolaryngology and urology)
In-licensing of aclidinium (Feb. 2011)

AS-3201 (diabetic neuropathy)
KRP-209 (tinnitus)
KRP-203 (immunomodulator: IBD)
KRP-110 (constipation and intractable pruritus)
KRP-A B 1102 (COPD)
KRP-AM1977X (respiratory infection)
KRP-AM1977Y (anti-MRSA)

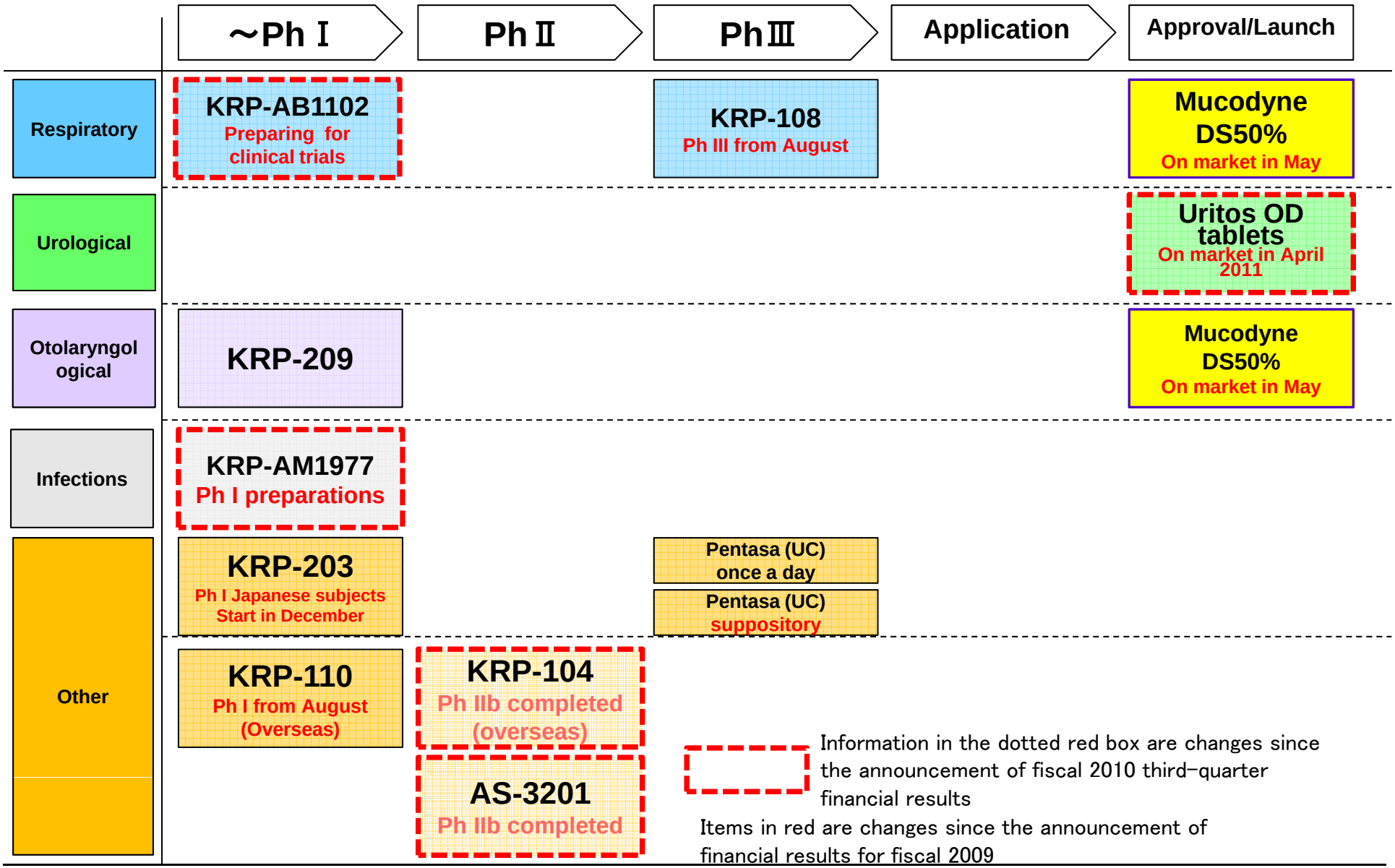
Drugs Originated In-House

Priority Fields for In-House Drugs: Respiratory, Urological, Infections, Others

■**Clarify direction of R&D (Concentrate on FC domain and respond to unmet medical needs)**
・Strengthen R&D portfolio management (development pipeline)
・Evaluation and swift decisions on development projects (early development projects: incl. PCC, POC)

■**Strengthen capacity to create new drugs (restructure the drug discovery network)**
・Review ActivX and KSRL functions (Drug discovery bases in priority domains: cancer research, respiratory research)
・Proactive external collaboration (academia, others)

Drug Development Pipeline: Progress in FY2010 (In-House)



COPD Treatment Agent: KRP-AB1102

Action: **Long-acting muscarine M3 antagonist (LAMA)**
Active ingredient: **Aclidinium Bromide**
Formulation: **Dry Powder Inhaler**

Features:

- **Fewer sistemic side effects**
- **Twice-daily dosage improves symptoms and respiratory function throughout a day**
- **Short period reaching maximum effect**
- **Easy-to-use inhaler device**

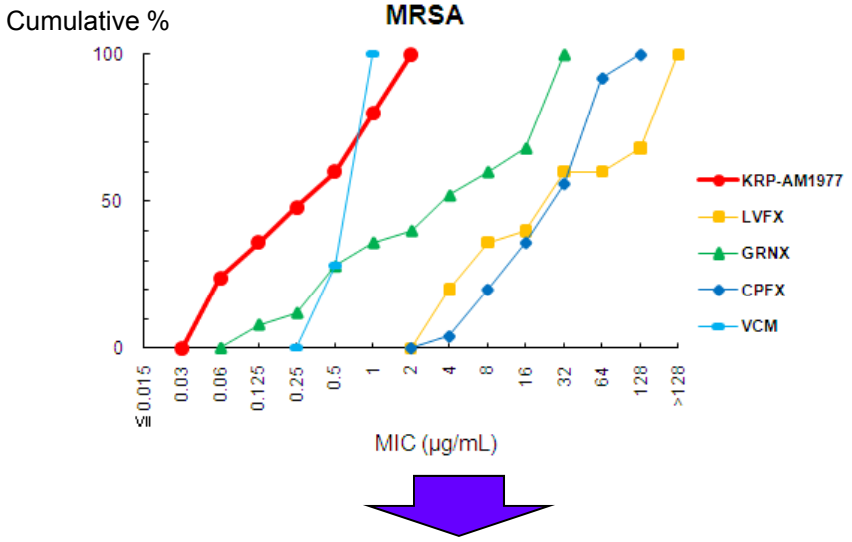
Dry powder inhaler: Genuair®

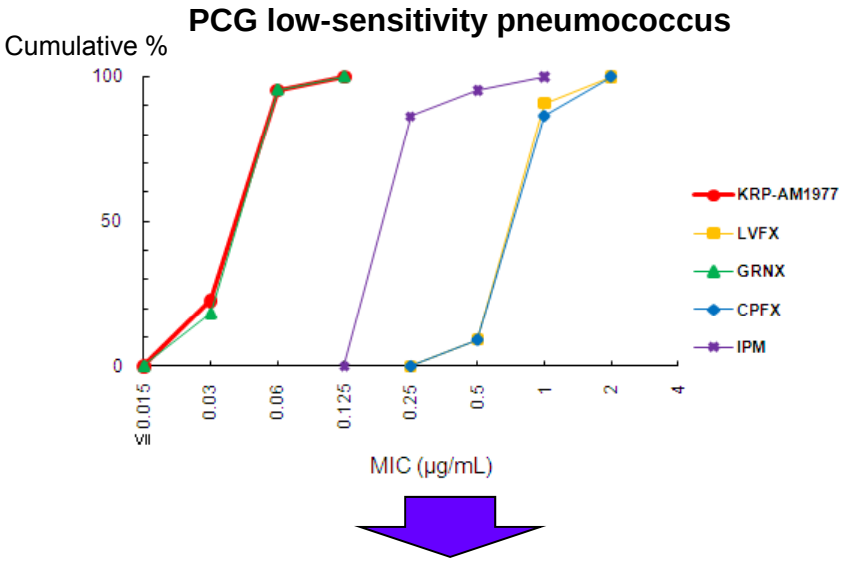
Antibacterial agent: KRP-AM1977

Next-generation quinolone antibacterial agent (anti-MRSA, respiratory) developed by KYORIN Pharmaceutical

〔Features〕

- Superior ability to over come drug-resistant gram-positive bacteria (incl. MRSA)
- Outstanding ADME comparable to GFLX (oral absorption, tissue penetration)
- Higher safety margin is expected by results of preclinical studies





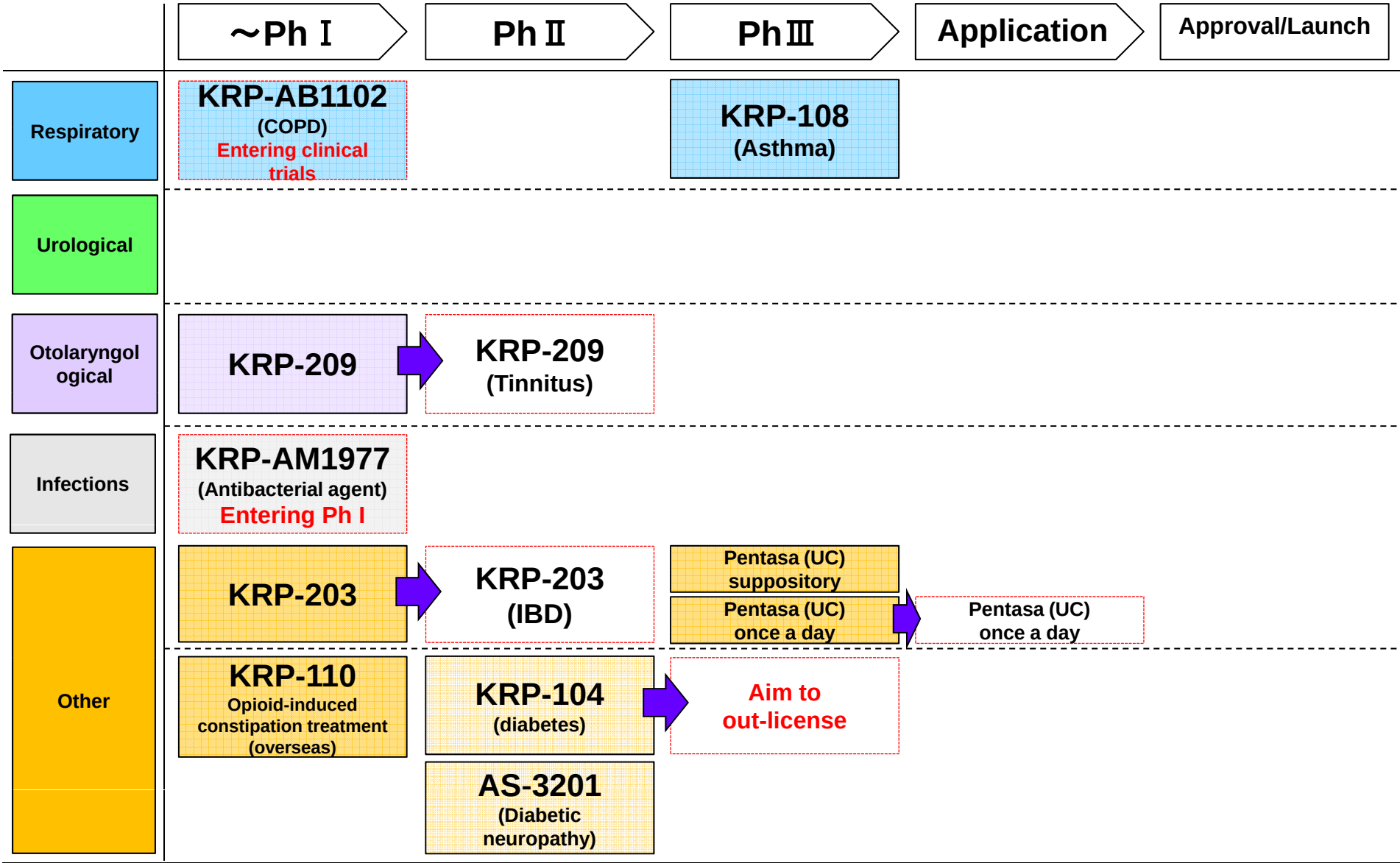
KRP-AM1977Y

➢Planning development of an injection as an anti-MRSA drug

KRP-AM1977X

➢ Planning development as an oral treatment for respiratory infection (including otolaryngology)

Drug Development Pipeline: Progress in FY2010 (In-House)



Main R&D Activities①（ May 11 , 2011 Release)

Ph IIb Application submitted

※：Changes since previous announcement (3Q of fiscal 2010) shown

Stage		Compound /Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
PhⅢ (12/2009)		Pentasa (tablet)	Ulcerative colitis	Ferring Pharmaceuticals	New dosage regimen for ulcerative colitis in the remission phase (once a day)	
PhⅢ (11/2010)		Pentasa (suppository)	Ulcerative colitis	Ferring Pharmaceuticals	Consideration of a new dosage form for the active phase of ulcerative colitis (once a day)	*Development of a new dosage form
PhⅢ (8/2010)	(US) SkyePharma : Application submitted (3/2009) （Europe） Mundipharma : Application submitted (3/2010)	KRP-108 (Inhaled drug)	Anti-asthmatic	SkyePharma PLC	An ICS/LABA combination product, which offers better compliance and convenience to the patients	・License agreement with SkyePharma (4/2008) ・Ph II completed in domestic (4/2010)
PhⅡ (3/2005)	Eisai: Ph III	AS-3201 (tablet)	Diabetic neuropathy	Dainippon Sumitomo	Aldose reductase inhibitor to reduce the sorbitol accumulation in the cell, and improve diabetic neuropathy	・Co-development with Dainippon Sumitomo (domestic only) ・Ph II completed in domestic (3/2011) ※
PhⅡ （2/2008）	PhⅡ （9/2007）	KRP-104	Anti-diabetes agent	In-house	A DPPIV inhibitor to reduce blood glucose through suppression of the degradation of insulin-releasing hormone. Diabetic therapy with fewer side effects is expected than existing treatments.	・Ph II b in overseas (11/2009) ・Ph II b in domestic completed (3/2010)

Other Comments

・Uritos OD Tablet 0.1mg (orally disintegrating tablet of immidafenasin (INN), a drug for overactive bladder: Application (4/2011) ※

Main R&D Activities②（ May 11 , 2011 Release)

POC Project (Pre-clinical ~ Ph II)

※: Changes since previous announcement (3Q of fiscal 2010) shown

Stage		Compound/Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph Ⅰ preparations		KRP-AM1977X ※ (Oral agent)	New quinolone synthetic antibacterial agent	In-house	①Superior ability to combat drug-resistant gram-positive bacteria (incl. MRSA) ②Outstanding ADME (oral absorption, tissue migration) ③High degree of safety expected since safety hurdles cleared prior to clinical trials	
Ph Ⅰ preparations		KRP-AM1977Y ※ (Injection)	New quinolone synthetic antibacterial agent	In-house		
Preparing for clinical trials	(Europe) Almirall : Preparing for application (US) Forest Pharmaceuticals : Preparing for application	KRP-AB1102 ※ (Inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	This bronchodilating agent has an acetylcholine receptor antagonist action that offers long-lasting improvement for breathing difficulty and shortness of breath associated with COPD. ①Fewer sistemic side effects ②Twice-daily dosage improves symptoms and respiratory function throughout a day ③Short period reaching maximum effect	License agreement with Almirall (2/2011)
	Ph Ⅰ (8/2010)	KRP-110	Opioid-induced constipation and intractable pruritus	In-house	A highly selective μ-opioid receptor antagonist. It is expected to block constipation induced by opioid analgesics without interrupting the analgesic effect of opioids. It is orally effective in various itching models, indicating potential of a novel anti-itch drug for intractable pruritus.	
Ph Ⅰ (12/2010)	Ph Ⅱ (POC) (12/2010) (Novartis)	KRP-203	Transplantation and autoimmune diseases treatment IBD	In-house	An immunosuppressant with a novel mechanism called an S1P-agonist. It may have a better safety profile than previous ones as well as an excellent effect under concomitant use with other types of immunomodulator.	License agreement with Novartis (2/2006) New license agreement IBD (11/2010)
Ph Ⅱ preparations	Ph Ⅲ Merz	KRP-209	Tinnitus	Merz	KRP-209 (Neramexane) is expected to improve the patients' annoyance and difficulties in their life caused by tinnitus mainly through its two pharmacological properties: 1) NMDA antagonistic activity and 2) Nicotinic acetylcholine antagonistic activity	License agreement with Merz (11/2009) Ph I clinical trial in Japanese (single dose PK) in US completed by Merz (3/2010)

Main R&D Activities③（May 11 , 2011 Release)

Licensing Development

※：Changes since previous announcement (3Q of fiscal 2010) shown

Compound/Code	Licensee/Collaborative research	Stage	Therapy area/Action	Origin	Comments
Alphagan /AlphaganP	Senju Seiyaku	Application submitted ※ (3/2011)	Glaucoma	Allergan (US)	・Licensed from Allergan (Cross license of gatifloxacin ophthalmic solution) ・License-out to Senju (5/2004)
Ketas	MediciNova (US)	Overseas Ph II (8/2005)	Cerebrovascular disorders	In-house	・KYORIN grants MediciNova an exclusive license in all countries worldwide except for Japan, China, South Korea and Taiwan to develop, manufacture and sell the compound and products for the multiple sclerosis indication (10/2004) Result of Ph II was reported in April 2008
KCA-757	MediciNova (US)	Overseas Ph III (Anti-bronchial Asthma: 11/2006) Overseas Ph Ⅱ/Ⅲ (Interstitial cystitis: 5/2005)	Anti-bronchial asthma and interstitial cystitis agent	In-house	・KYORIN grants MediciNova an exclusive license in all countries worldwide except for Japan, China, South Korea and Taiwan to develop and sell the compound and products ・Interstitial cystitis: Result of Ph II/III was reported in January 2007 and development ceased ・Bronchial asthma: Clinical trial overseas was discontinued.
KRP-203	Novartis (Switzerland)	Overseas Ph Ⅱ (POC) (12/2010)	Transplantation and autoimmune diseases IBD*	In-house	・Granted right to develop and commercialize KRP-203 worldwide for use as an immunosuppressant in organ transplants, and right to develop and commercialize KRP-203 worldwide except in Japan, Korea, China and Taiwan for the treatment of autoimmune diseases and other diseases (February 2006)) *New license agreement IBD (November 2010