Financial Results Ended March 2012

Status of R&D Pipeline

◇Progress and initiatives in fiscal 2012

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Long-Term Vision「HOPE100」

To be a drug manufacturer that is trusted by patients and medical professionals ,and is recognized for its presence in society.

－Establish a strong presence in specialized fields －

【 specialized fields 】◆ FC domain ： respiratory , otolaryngology , urology

◆ Priority Fields ： IBD(inflammatory bowel disorder)

－ Enhance and strengthen the product portfolio and R&D pipeline －

◆**Proprietary Drug Discovery :** Fundamental research domains (inflammation/infectious diseases/immunology) ⇒ Leverage open innovation

◆**In-licensed Products :** Actively explore in-licensing in specified

◆**LCM** ： New formulations, direction for usage and dosages for mainstay products; drug cultivation research

LCM：Life Cycle Management

Drug Development Pipeline: Progress in FY2011 (In-House)

	Product & development code	Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	application	Approval/ Launch
Respiratory	KRP-108			Ph Ⅲ completed		
	KRP-AB1102		Entering Ph Ⅱ			
Urological	Uritos OD tablet					On market in 4/2011
Otolaryngological	KRP-209		Entering Ph Ⅱ			
Infections	KRP-AM1977X	Ph Ⅰ completed				
	KRP-AM1977Y	Preparing for Ph Ⅰ				
Other	Pentasa(UC) Once a day				applicaion	
	Pentasa(UC) suppository			Ph Ⅲ completed		
	KRP-203	Ph Ⅰ completed				
	KRP-110	discontinuation				
	AS-3201		Cancelled co-development			
	KRP-104		abeyance			

Information in the dotted box are changes in FY2011

※Information colored red are changes since November 9/2011

Drug Development Pipeline: Progress in FY2012 (In-House)

	Product & development code	Ph Ⅰ	Ph Ⅱ	Ph Ⅲ	application	Approval/ Launch
Respiratory	KRP-108				application	
	KRP-AB1102		Ph Ⅱ	Entering Ph Ⅲ		
	KRP-AB1102F		Entering Ph Ⅱ			
Urological		Active In-Licensing and Joint Research				
Otolaryngological	KRP-209		Ph Ⅱ			
Infections	KRP-AM1977X	臨床薬理試験(Ph Ⅰ)				
	KRP-AM1977Y	Entering Ph Ⅰ				
IBD	Pentasa(UC) Once a day					Approval
	Pentasa(UC) suppository				application	
	KRP-203		Entering Ph Ⅱ			

Anti-asthmatic KRP-108：Status of Development

■Status of Development

○Application: Aim to file application for approval in FY2012

○Clinical trials: Phase III (Completed in Mar. 2012)

TOPICS **April 20, 2012**

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended *flutiform*® for commercial sale.

◆Study Design: A single-blinded comparative study with an active comparator

Target disease: Adult bronchial asthma
Treatment duration: 8 weeks
Active comparator: Fluticasone
Dosage regimen: Inhaled by twice –a-day dosing (two actuations per dose)

◆Study Design: A non-blinded, non-comparative open study

Target disease: Adult bronchial asthma
Treatment duration: 52 weeks
Dosage regimen: Inhaled by twice-a-day dosing (two or four actuations per dose)

Favorable results seen in all major evaluation categories

Pentasa: Status of Development for New Dosage Form

■Status of Development【New Dosage Form】(Suppository)

○Application: Aim to file application for approval in FY2012

○Clinical trials: Phase III (Completed in Feb. 2012)

◆Study Design: A randomized, controlled, parallel comparative study

Target disease: Ulcerative colitis in active phase

Comparator: Inactive placebo

Dosage regimen: Once a day (rectal insertion)

Efficacy: Substantively different from placebos, with high remission induction rate shown. (p=0.0000)

Safety: Product retains a high degree of safety.

COPD Treatment Agent: KRP-AB1102

■KRP-AB1102

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

○Clinical trials: Phase II （started in Feb. 2012 ）

◆Study Design： A randomized, Duoble-Blind, Placebo controlled, Parallel-group Comparison Study
Target disease：COPD
Treatment duration：4 week treatment
Active comparator：Inactive placebo
Dosage regimen：Inhaled by twice-a-day dosing

TOPICS

February 24, 2012

The Pulmonary-Allergy Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has adopted a recommendation to approve acridinium 400 micrograms (administered twice daily) after verifying efficacy and safety.

■KRP-AB1102F：launched development of combination drug

Fixed dose combination of LAMA and LABA(Long Acting Muscarinic Antagonist)

◇LAMA : Aclidinium Bromide
◇LABA : Formoterol

Dry powder inhaler: Genuair®

Main R&D Activities -1 (February 3 , 2012 Release)

Ph IIb Application submitted

※Changes from the previous announcement (Feb.3, 2012)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Application submitted (11/2011)		Pentasa (tablet)	Ulcerative colitis	Ferring Pharmaceuticals	New dosage regimen for ulcerative colitis in the remission phase (once a day)	
Preparing for application※		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 ・PhⅢcompleted(2/2012)※
Preparing for application※	(US) SkyePharma : Application submitted (3/2009) (Europe) Mundipharma : Application submitted (3/2010)	KRP-108 (Inhalant)	Anti-asthmatic	SkyePharma PLC	An ICS/LABA combination product, which offers better compliance and convenience to the patients	・License agreement with SkyePharma (4/2008) ・Domestic Ph II completed (4/2010) ・PhⅢcompleted(3/2012)※
Ph Ⅱ (2/2008)	Ph Ⅱ (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.	・Overseas Ph II b completed (3/2011) ・Domestic Ph II b completed (3/2010)

Main R&D Activities -2 (February 3 , 2012 Release)①

POC Project (Pre-clinical ~ Ph II)

※Changes from the previous announcement (Feb.3, 2012)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph I (12/2010)	Ph II (POC) (12/2010) (Novartis)	KRP-203	Transplantation, autoimmune diseases,and 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 (8/2011)	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) Merz:Ph I clinical trial of Japanese patients in US completed (3/2010)
Ph II ※ (2/2012)	(Europe) Almirall : Preparing for application (US) Forest Pharmaceuticals : Preparing for application	KRP-AB1102 (Inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	- New Chemical Entity: Aclidinium Bromide - Long Acting Muscarinic Agonist (LAMA) - Twice Daily administration -Onset of Action on the first day Genuair® 1) Designed with a feedback system, which through a 'colored control window' and an audible click helps confirm that the patient has inhaled correctly 2) Counter for remaining doses 3) Safety features such as an anti-double-dosing mechanism and an end-of-dose lock-out system to prevent use of an empty inhaler	License agreement with Almirall (2/2011)
Preparing for clinical trials ※	(Europe & US) Almirall: Ph III (US) Forest Laboratories : Ph III	KRP-AB1102F (Fixed dose combination inhaled drug)	Chronic Obstructive Pulmonary Disease (COPD)	Almirall	Combination of aclidinium bromide with the long acting beta agonist formoterol : This combination is aimed at providing higher efficacy than each component alone,as well as the improved convenience of having the two products in the same easy to use inhalation device.This is currently in phase III clinical development.	

Main R&D Activities -2 (February 3 , 2012 Release)②

POC Project (Pre-clinical ~ Ph II)

※Changes from the previous announcement (Feb.3, 2012)

Stage		Compound/ Code	Therapy area/Action	Origin	Features	Comments
Japan	Overseas					
Ph I *(8/2011)		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		

others

・AIPHAGAN Ophthalmic Solution 0.1% ： To be released on May 11,2012 ※

・Discontinued development of KRP-110 deleted it from the list of R&D activities. ※

Kyorin
健康はキョーリンの願いです。

■ These forecast figures are based on information currently available to the Company and may include uncertain factors or risk that affect our future performance.
Accordingly, actual business results may materially differ from the forecasted figures due to various factors in the future.