# **Kyowa Hakko Kirin**Fiscal 2010 Interim Results

**July 28, 2010** 

**President & CEO** 

Yuzuru Matsuda

Kyowa Hakko Kirin Co., Ltd.



#### **Notice**

The figures in this document for the 6-month period from January 1, 2009 to June 30, 2009 are the sum of the figures for the fourth quarter of the fiscal year ended March 31, 2009 (obtained by subtracting figures for the nine month period April 1, 2009 to December 31, 2009 from the figures for the twelve month period to March 2009) and the figures from the first quarter of the fiscal period ended December 31, 2009 (April 1, 2009 to June 30, 3009)

The figures for the 12-month period from January 1, 2009 to December 31, 2009 are the sum of the figures of the fourth quarter of the fiscal year ended March 31, 2009 (obtained by subtracting figures for the nine month period April 1, 2009 to December 31, 2009, from the figures for the twelve month period to March 2009) and the figures for the nine-month fiscal period ended December 31, 2009 (April 1, 2009 to December 31, 3009)



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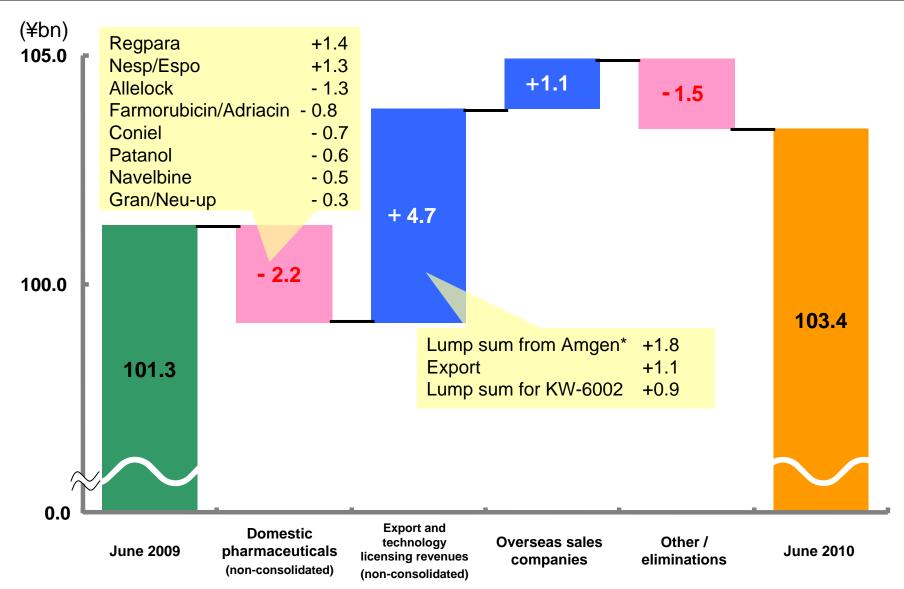
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Summary of fiscal 2010 interim results: P&L

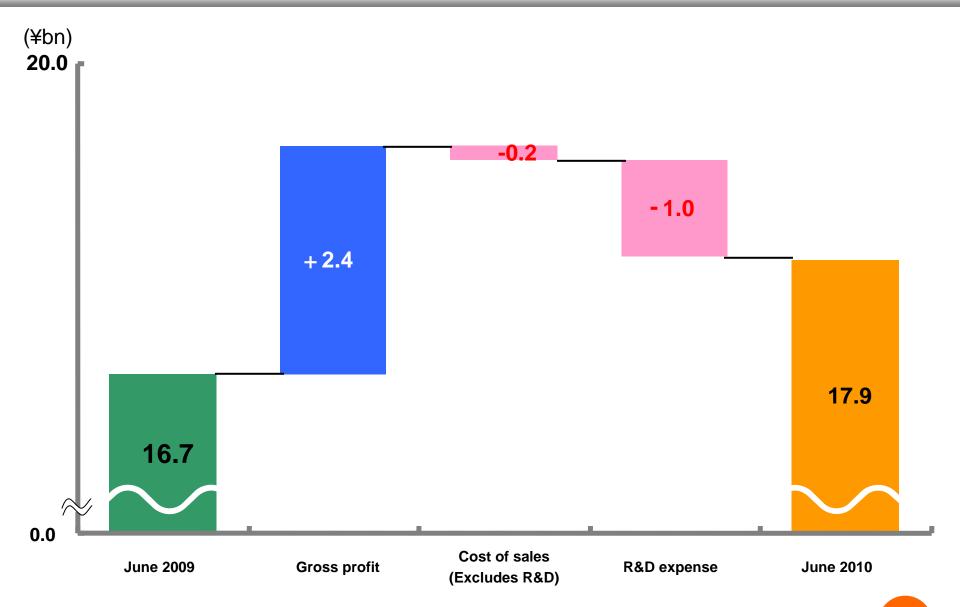


(¥bn)	Net sales	Operating income	Recurring income	Net income
FY2010 interim	203.4	21.6	22.3	9.9
Change	+8.7 (+4.5%)	+7.9 (+58.0%)	+6.6 (+42.3%)	+2.9 (+42.6%)
FY2009 interim	194.7	13.7	15.6	6.9

(¥bn)	FY2009 interim	FY2010 interim	Change
Net sales	101.3	103.4	+2.1
Operating income	16.7	17.9	+1.2
R&D expenses	18.3	19.3	+1.0



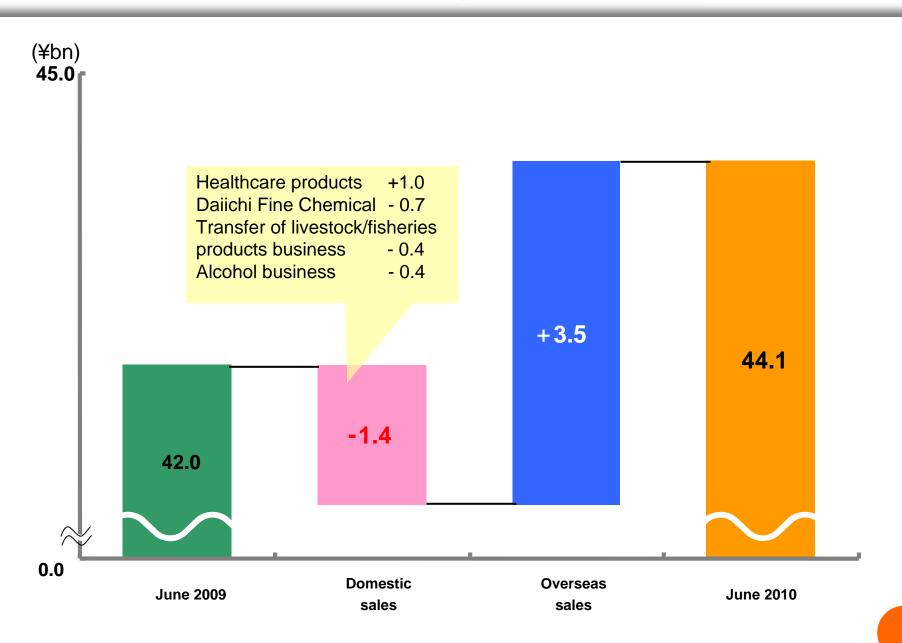
<sup>\*</sup>Lump sum from Amgen: This figure is based on the March 2008 out-licensing contract and is irrespective of milestone payments from progress in clinical development by Amgen.

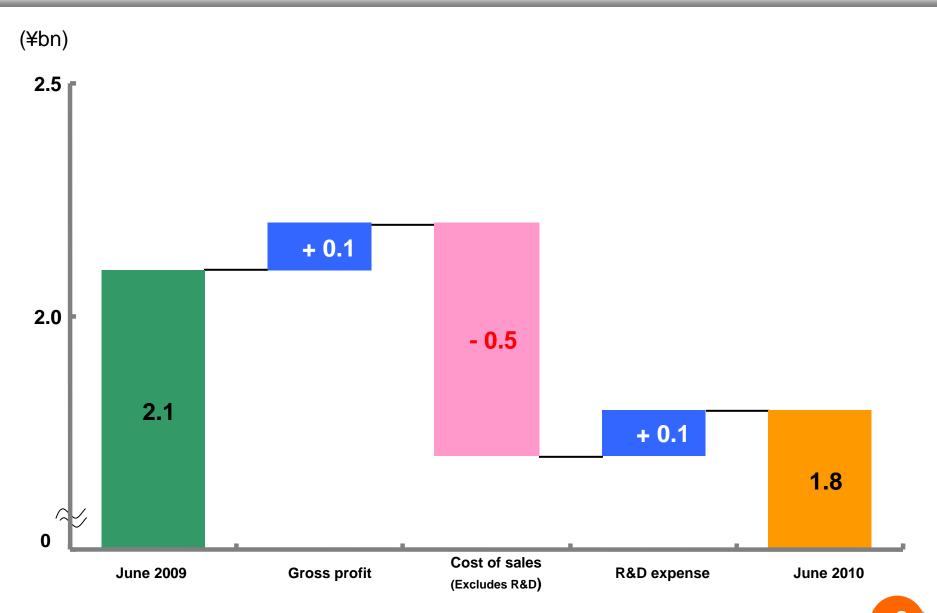


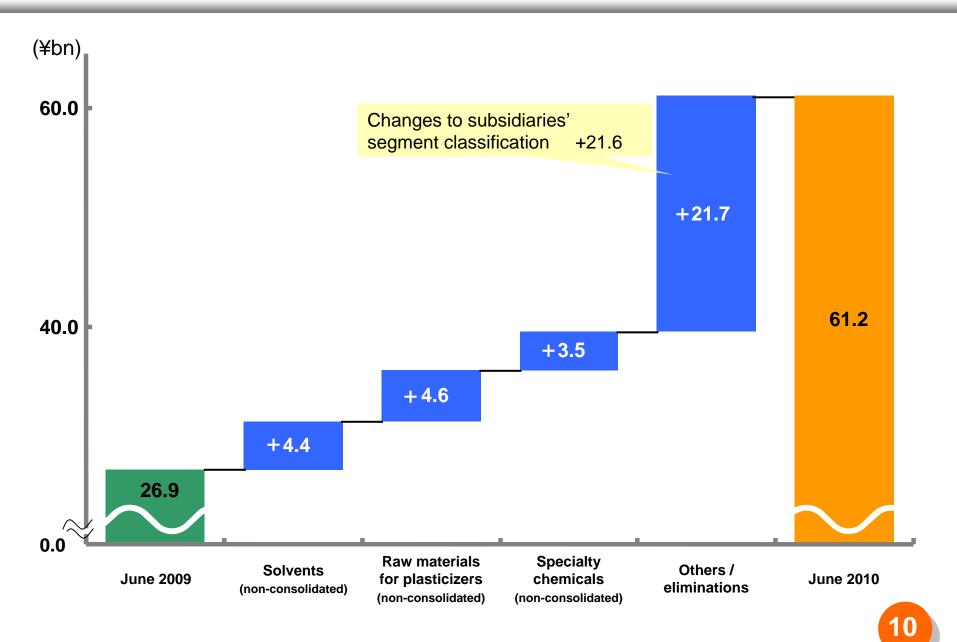
Bio-Chemicals and Chemicals businesses: Sales

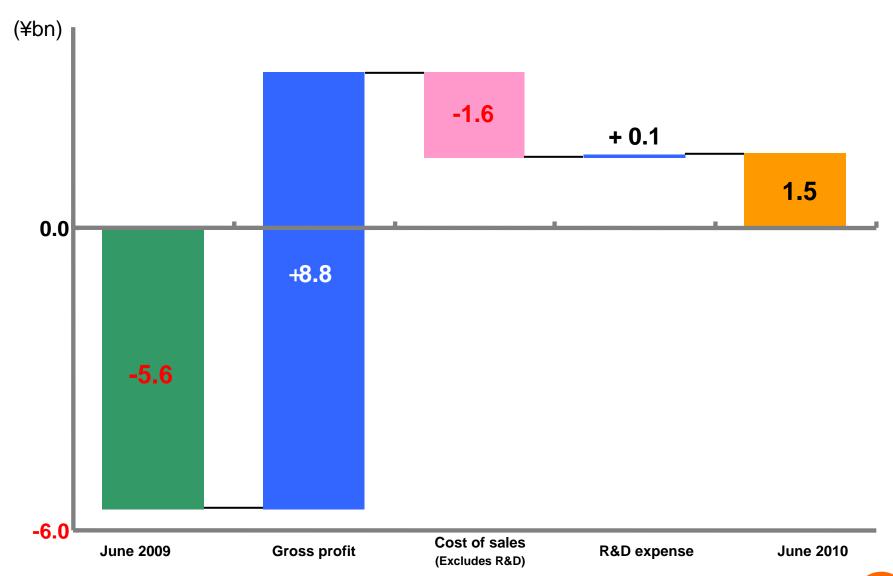


(¥bn)		FY2009 interim	FY2010 interim	Change
	Sales	42.0	44.1	+2.1
Bio-Chemicals	Operating income	2.1	1.8	-0.3
	Sales	26.9	61.2	+34.3
Chemicals	Operating income	-5.6	1.5	+7.2
Forey	¥/\$	¥95/\$	¥91/\$	-¥4/\$
Forex	¥/€	¥127/€	¥121/€	-¥6/€
Naphtha	¥/kl	Approx. ¥30,150/kl	Approx. ¥48,750/kl	Approx. +¥18,600/kl











(¥bn)	Net sales	Operating income	Recurring income	Net income
2010 (JanDec.)	407.0	37.5	39.0	20.0
(Compared to forecast announced Jan.29)	+1.8%	+4.2%	+4.0%	()
2010 (Jan Dec.) (Announced Jan. 29)	400.0	36.0	37.5	20.0
2009 (Jan. – Dec)	407.0	30.9	32.6	10.0



(¥bn)	<b>2009</b> (Jan Dec.)	Fiscal 2010	Change
Sales	207.3	205.0	-2.3
Operating income	31.8	29.0	-2.8
R&D expenses	41.6	42.1	+0.4

• Fiscal 2010 forecasts: Sales of core pharmaceutical products KYOWA KIRIN

(¥bn)	<b>2009</b> (Jan Dec)	Fiscal 2010 (forecast)	% change	Forecasts at beginning of term
Nesp/Espo	48.9	48.3	1%↓	49.7
Coniel	23.3	21.3	9%↓	21.3
Allelock	26.7	26.0	3%↓	26.0
Patanol	7.4	7.5	1% 🕇	7.9
Gran/Neu-up*	17.0	15.1	11%↓	15.1
Depakene	11.2	11.0	2%↓	11.0
Coversyl	4.8	4.4	8%↓	4.4
Regpara	6.8	8.6	26% 🕇	7.3
Permax**	_	2.0	_	2.0
Export and technology out- licensing revenues*	18.0	22.6	26% 🕇	22.6

2009 figures on a shipments basis. 2010 forecasts, on an actual consumption basis.

<sup>\*</sup>Sales of Neu-up were transferred to Yakult Honsha as of March 2010.

<sup>\*\*</sup>Sales of Permax were transferred from Eli Lilly as of April 2010.



	(¥bn)	<b>2009</b> (Jan. – Dec.)	Fiscal 2010 (forecast	Change
Bio-	Sales	90.6	84.0	-6.6
Chemicals	Operating income	3.9	4.0	+0.0
	Sales	64.2	128.0	+63.7
Chemicals	Operating income	-5.5	4.0	+9.5
Forov	¥/\$	¥94/\$	¥91/\$	<b>▲</b> ¥3/\$
Forex	¥/€	¥130/€	¥116/€	<b>▲</b> ¥14/€
Naphtha	¥/kl	Approx. ¥36,000/kl	Approx. ¥48,350/kl	Approx. +¥12,350/kl

# R&D Pipeline: July 2010



# **Kyowa Hakko Kirin (Phase II onwards)**

Category	Code name/ Product		Stage	Indication	Formulation	In-house or licensed	Remarks
Gategory	name	Japan	Other countries	maloution	1 omidiation	III Hodge of Hoeffocd	Remarks
	KW-0761	Phase II	Phase I/IIa in USA	Cancer (Hematologic tumor)	Injection	In-house	Humanized monoclonal antibody (The exclusive right to develop and commercialize for treatments other than cancer, and except in Japan, Korea, China and Taiwan, was out-licensed to Amgen in March 08)
	KRN321 NESP	Filed Nov/2008		★Chemotherapy induced anemia	Injection	Kirin-Amgen	Long-acting erythropoietin stimulating protein. On sale in Japan as anemia treatment for CKD patients on dialysis since July 2007
Cancer/ Hematology	AMG531	Filed Mar/2010		Immune thrombocytopenic purpura	Injection	Kirin-Amgen	Thrombopoiesis stimulating peptibody
	KW-2246	Filed Feb/2010		Cancer pain Sublingual Licensed from tablet Orexo		Licensed from Orexo	
	KRN125	Phase II		Neutropenia	Injection	Kirin-Amgen	Long-acting G-CSF
	ARQ 197	Phase II		Cancer (Gastric cancer)	Oral	Licensed from ArQule.	
	KRN321 NESP	Approved Apr/2010		★Anemia (not on dialysis)	Injection	Kirin-Amgen	Long-acting erythropoietin stimulating protein. On sale in Japan as anemia treatment for CKD
Kidney	1,120.		Phase II in China	★Anemia (on dialysis)			patients on dialysis since July 2007
	KRN 1493 REGPARA		Phase III in China	Secondary hyperparathyroidism	Oral	Licensed from NPS	Launched in Japan
Immunology/ Allergy	KW-4679 ALLELOCK		Approved in China Jul/2010	Allergy	Oral	In-house	Launched in Japan
CNS	KW-6002	Phase III	Licensed out in North America Jun/2010	Parkinson's disease	Oral	In-house	Entered into a license agreement with Biovail Laboratories International SRL
	KW-6500	Phase III		Parkinson's disease	Injection	Britannia Pharma	



Updated since January 29, 2010 ( Area, Stage, Filed, Approved, Launched etc.) New indications

# R&D Pipeline: July 2010



**Kyowa Hakko Kirin (Phase I)** 

	Code name/	;	Stage			Dayalanad in	
Category	Product name	Japan	Other countries	Indication	Formulation	Developed in- house or licensed	Remarks
	KW-2450		Phase I	Cancer	Oral	In-house	
	KW-2478		Phase I/IIa in USA & Europe	Cancer	Injection	In-house	
Cancer/ Hematology	KRN330		Phase I/IIa in USA	Cancer	Injection	In-house	Fully human monoclonal antibody
o,	BIW-8962		Phase I/IIa in USA	Cancer	Injection	In-house	Humanized monoclonal antibody
	KRN951	Phase I		Cancer	Oral	In-house	
	KHK4563	Phase I		Asthma	Injection	In-house	Humanized monoclonal antibody Being developed by MedImmune as MEDI-563 worldwide except in Japan and other Asian countries
Immunology/ Allergy	Z-206 ASACOL	Phase I		☆ Crohn's disease	Oral (pH dependent controlled- Release formulation)	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma Launched in Japan for ulcerative colitis from December, 2009.
	ASKP1240		Phase I	Organ Transplant Rejection	Injection	In-house	Fully human monoclonal antibody



Updated since January 29, 2010 ( Area, Stage, Filed, Approved, Launched etc.)



New indications

#### R&D Pipeline



#### **Kyowa Hakko Kirin (Phase I)**

(As of July 29, 2009)

	Code name/	Stage				Developed in-house	Remarks
Category Product name		Japan	Other countries	Indication	Formulation	or licensed	
Other	KW-3357	Phase I	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	In-house	Recombinant antithrombin product
	KRN23		Phase I in USA	X-linked Hypophosphatemic rickets/osteomalacia (XLH)	Injection	In-house	Fully human monoclonal antibody

#### (Notes)

In Philippines, an NDA of Filgrastim (G-CSF) has been filed for neutropenia. In Vietnam, an NDA of Pegfilgrastim (peg-G-CSF) has been filed. In Korea, Taiwan and Hong Kong (Macau), NESP (long-acting erythropoiesis stimulating protein) has been approved. In Thailand, Singapore, Malaysia and Philippines, an NDA of NESP has been filed. In India, NESP is currently in phase 3 clinical trials.

In Korea, Taiwan and Hong Kong (Macau), REGPARA (regulator of parathyroid gland) has been approved. In Singapore, an NDA of Regpara has been



Updated since January 29, 2010 (Area, Stage, Filed, Approved, Launched etc.)

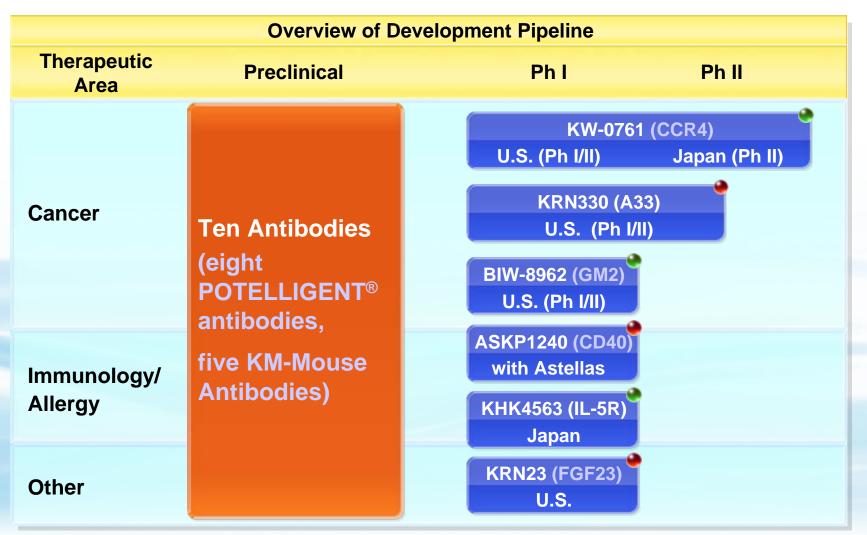
New indications

#### **Kyowa Hakko Kirin (discontinued)**

Code name/ Category Product name		Stage		Indication	Formulation	Developed in-house or	Remarks
Category	1 Toddet Hame	Japan	Other countries	indication i officiation		licensed	Remarks
Cancer/ Hematology	KRN654	Phase I/II		Essential thrombocythemia	Oral	Shire	transferred to Shire based on portfolio re- assessment
ricinatology	KW-2449		Phase I/IIa In USA	Cancer	Oral	In-house	Based on portfolio reassessment
Kidney	PB94 PHOSBLOCK (RENAGEL)		Filed in China Jun/2008	Hyperphosphatemia	Oral	Licensed from Chugai	Approval not expected in the current NDA filing

# Antibody pharmaceutical pipeline (as of July 2010)

#### **KYOWA KIRIN**



: POTELLIGENT® Technology

: KM-Mouse Technology

# Licensing-out antibody pharmaceuticals (as of July 2010)

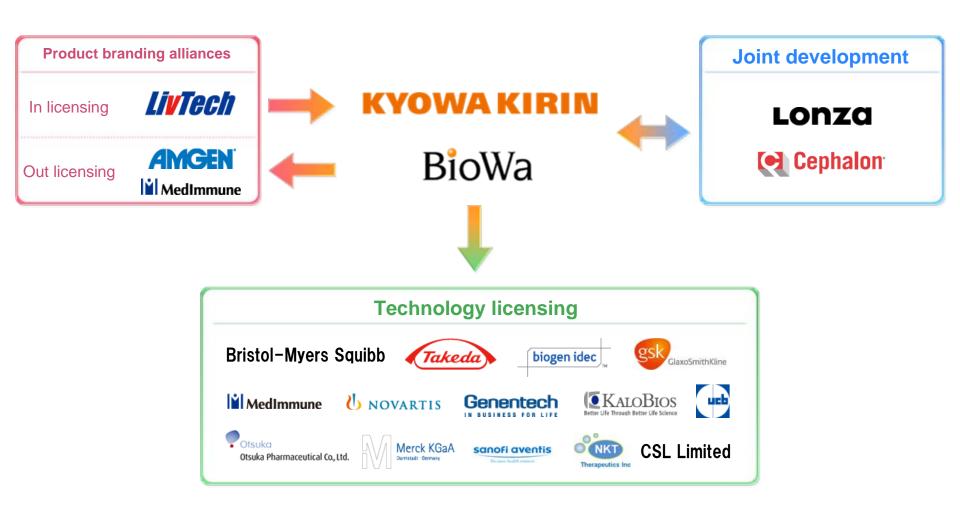
#### **KYOWA KIRIN**

Antibody	Target	Licensee	Reported Stage	Remarks
KW-0761	CCR4	Amgen (Except in JP, CN, KR,TW)	Ph I (AMG 761)	POTELLIGENT®
KHK4563	IL-5R	MedImmune (Except in Japan, Asia)	Ph II (MEDI-563)	POTELLIGENT®
KW-2871	GD3	Life Science Pharmaceuticals	Ph II	
Anti LIGHT antibody	LIGHT	Sanofi aventis (Except in Japan, Asia)	Research	KM-Mouse

# POTELLIGENT® technology-related alliances



(as of July 2010)



<sup>\*</sup>To date six out-licensed POTELLIGENT® antibodies have entered clinical trials, including those by Bristol-Myers Squibb and Genentech,

# Progress in licensing-out (as of July 2010)



Name	Partner	Phase			Remarks
Name		I	II	III	Kemarks
KW-6002	Biovail	Out-licensed in North America			Parkinson's disease (adenosine A2A receptor antagonist)
Tivozanib (KRN951)	AVEO				Cancer (VEGF receptor inhibitor)
KW-2871 (Low-fucose antibody)	Life Science				Cancer (Anti-GD3 antibody)
MEDI-563 (KHK4563:POTELLIGENT®)	MedImmune				Allergy (Anti-IL-5R antibody)
KRN5500	DARA				Cancer pain
LY2523355	Eli Lilly				Cancer (Mitotic kinesin Eg5 inhibitor)
AMG 761 (KW-0761:POTELLIGENT®)	Amgen				Allergy (Anti-CCR4 antibody)

# Progress in licensing-in (as of July 2010)



Name	Partner	Phase			Remarks
		ı	II	III	1331161113
HFT-290	Hisamitsu Pharmaceutical	Launched		I	Cancer pain (μ-opioid receptor agonist)
KW-2246	Orexo	Filed			Cancer pain (μ-opioid receptor agonist)
SP-01	Solasia	Pre-filing preparations		rations	Vomit (Serotonin antagonist)
KW-6500	Britannia				Parkinson's disease (Dopamine agonist)
ARQ 197	ArQule				Stomach cancer (c-met inhibitor)
Asacol	<b>Zeria</b> Pharmaceuticals				Inflammatory bowel disease (Crohn's disease) *Approved for chronic ulcerative colitis

# KW-0761 Update



#### KW-0761

- An anti-CCR-4 antibody that uses our in-house developed POTELLIGENT® technology (enhanced activity antibody manufacturing technology)
- Kyowa Kirin is conducting clinical trials for hematological cancer applications in Japan and the U.S
- Amgen is conducting clinical trials for allergy applications in the U.K. through a licensing agreement with Kyowa Kirin

#### Hematological cancer treatments: Development status

Japan: Development of ATL (Ph II)

Ph I Paper published: Journal of Clinical Oncology 28:1591-1598

Ph II Completed symptom registration

Application 2011 (planned)Launch 2012 (planned)

U.S.: Development of PTCL and CTCL (Ph I/IIa in progress)

► Ph I Announced preliminary results:

T Cell Lymphoma Forum (Jan. 28-30, 2010)

➤ Ph IIa Completed symptom registration

#### Changes to details of contract with Amgen concerning cancer treatments

- Kyowa Kirin repurchased the development and commercialization rights for cancer areas from Amgen for US\$20m
- Kyowa Kirin holds global development and sales rights for cancer treatments

#### World-class quality

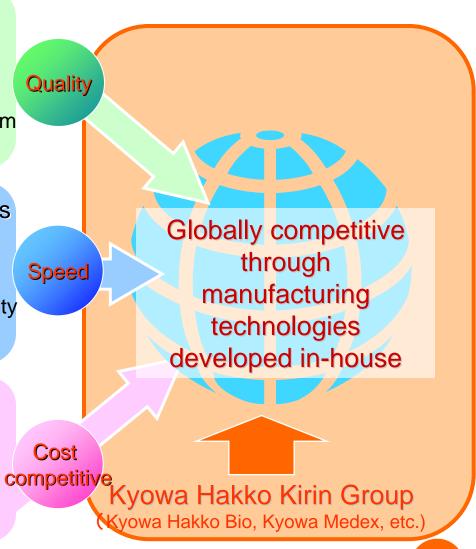
- Applying Espo, Nesp biotechnologies (e.g. Serum-free cell culture system technology) to antibody pharmaceuticals
- Manufacturing and quality assurance system compliant with tri-polar regulations\*

#### Rapid supply of wide variety of antibodies

- Speed—up time to market by consolidating facilities from R&D to market launch
- Use of platform to rapidly supply wide variety of development antibodies

# Improve cost competitiveness through in-house technologies

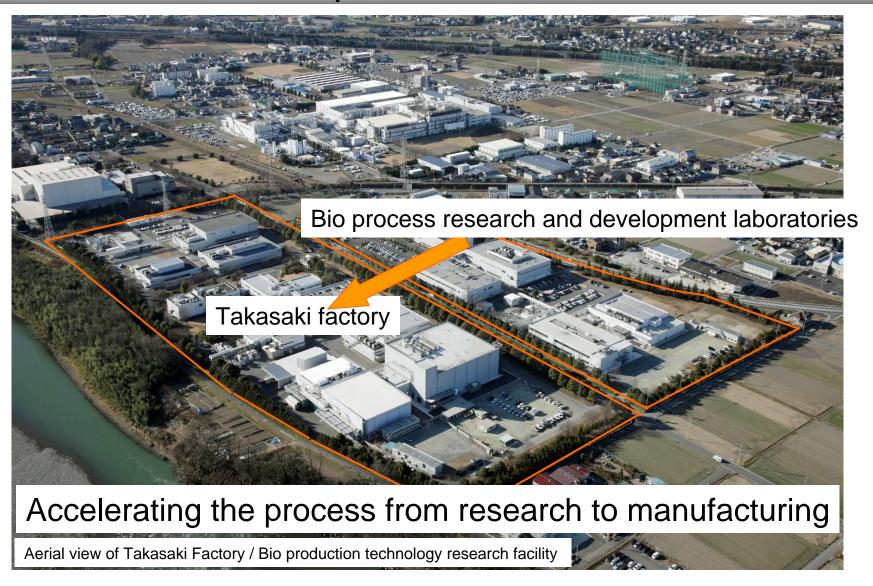
World-class, highly productive cell production technology



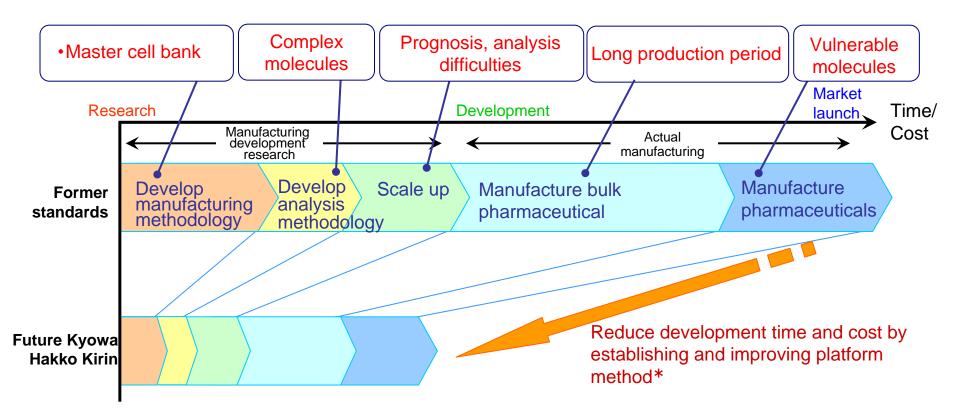
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Strength in manufacturing: Key to success in antibody pharmaceuticals





#### Creating an antibody pharmaceutical production platform



<sup>\*</sup>Platform method: Manufacturing and analysis methodology applicable to a broad range of candidate molecules. Allows rapid and flexible supply of multiple types of high quality therapeutic antibody pharmaceuticals.

# Tokyo Research Park



Name: Tokyo Research Park, New Research Center (Machida City, Tokyo)

Scale: Reinforced concrete, three floors above ground, one below

Height: 22.6m

Total floor space: About 19,000m<sup>2</sup>

Usage: A research facility designed to support the planning and pursuit of new research directions and targets, the development of new bio-pharma products, and the creation of innovative technology to enable ongoing commercialization of novel pharmaceuticals, with a focus on antibody medicines.

#### Characteristics:

- Functionality and flexibility through zoning and segmented research zones
- Ease of communication and comfort through spacious laboratories and wide open interior spaces
  - → A research environment that promotes creativity by encouraging ideas from researchers
- Defined security zoning and comprehensive alarm systems
- Site planned for minimal impact on local community
- Environmental features such as biotope areas and solar power generation systems

# KYOWAKIRIN

If you have any inquiries regarding this presentation please call:

Corporate Communications Department, Kyowa Hakko Kirin Co., Ltd

Tel: 03-3282-0009