

## R&D PIPELINES

Jan 29th 2010

### Phase II, Phase III

Category	Code Name Product Name	Generic Name	Stage		Indication	Formulation	In-house OR Licensed	Remarks
			Japan	Other countries				
Cancer/Hematology	<b>KW-0761</b>		Phase II	Phase I / II a in USA	Cancer (Hematologic tumor)	Injection	Developed In-house	Humanized monoclonal antibody (※)
	<b>KRN321</b> NESP	Darbepoetin Alfa	Filed Nov/2008		☆ Chemotherapy induced anemia	Injection	Kirin-Amgen	Long-acting erythropoiesis stimulating protein An approval has been given in Japan for anemia of CKD patients on dialysis.
	<b>AMG531</b>	Romiplostim	Phase III		Immune thrombocytopenic purpura	Injection	Kirin-Amgen	Thrombopoiesis stimulating peptide The clinical development is being conducted by Amgen Development KK as per agreement
	<b>KW-2246</b>	Fentanyl citrate	Phase III		Cancer pain	Sublingual tablet	Licensed from Orexo	
	<b>KRN125</b>	Pegfilgrastim	Phase II		Neutropenia	Injection	Kirin-Amgen	Long-acting G-CSF
Kidney	<b>PB94</b> <del>PHOSLOCK (RENAUGEL)</del>	Sevelamer Hydrochloride		Filed in China Jun./2008	Hyperphosphatemia	Oral	Licensed from Chugai.	Launched in Japan
	<b>KRN321</b> NESP	Darbepoetin Alfa	Filed Dec/2008		☆ Anemia (not on dialysis)	Injection	Kirin-Amgen	Long-acting erythropoiesis stimulating protein Launched in Japan for anemia of CKD patients on dialysis
			Phase II in China	☆ Anemia (on dialysis)				
Immunology/Allergy	<b>KW-4679</b> <b>ALLELOCK</b>	Olopatadine Hydrochloride		Filed in China Jul./2008	Allergy	Oral	Developed In-house	Launched in Japan
	<b>Z-206</b> <b>ASACOL</b>	Mesalazine	Phase III		Inflammatory bowel disease (Crohn's disease)	Oral <small>(4th degree controlled-release formulation)</small>	Licensed from Zeria Pharma.	Jointly developed with Zeria Pharma
CNS	<b>KW-6002</b>	Istradefylline	Phase II	Filed in USA Apr./2007	Parkinson's disease	Oral	Developed In-house	
	<b>KW-6500</b>	Apomorphine Hydrochloride	Phase II		Parkinson's disease	Injection	Licensed from Britannia Pharma.	

### Phase I

Category	Code Name Product Name	Generic Name	Stage		Indication	Formulation	In-house OR Licensed	Remarks
			Japan	Other countries				
Cancer/Hematology	<b>KW-2450</b>			Phase I in USA	Cancer	Oral	Developed In-house	
	<b>KRN654</b>	anagrelide hydrochloride	Phase I / II		Essential thrombocythemia	Oral	Licensed from Shire.	
	<b>KW-2449</b>			Phase I / II a in USA	Cancer	Oral	Developed In-house	
	<b>KW-2478</b>			Phase I in Europe	Cancer	Injection	Developed In-house	
	<b>ARG 197</b>		Phase I		Cancer	Oral	Licensed from ArGule.	
	<b>KRN330</b>			Phase I / II a in USA	Cancer	Injection	Developed In-house	Fully human monoclonal antibody
	<b>B I W-8962</b>			Phase I / II a in USA	Cancer	Injection	Developed In-house	Humanized monoclonal antibody
Immunology/Allergy	<b>KRN951</b>		Phase I		Cancer	Oral	Developed In-house	
	<b>ASKP 1240</b>			Phase I	Organ Transplant Rejection	Injection	Developed with Astellas.	Fully human monoclonal antibody
Other	<b>KW-3357</b>	Antithrombin	Phase I	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	Developed In-house	Recombinant antithrombin product
	<b>KRN23</b>			Phase I in USA	X-linked Hypophosphatemic rickets/osteomalacia (XLH)	Injection	Developed In-house	Fully human monoclonal antibody

(※) KW-0761 is outlicensed to Amgen Inc. on March 6th, 2008, with an exclusive right to develop and commercialize KW-0761 worldwide, except in Japan, Korea, China and Taiwan. Kyowa Hakkio Kirin has retained the development and commercialization rights in these countries. (Amgen has initially acquired the rights in all non-oncology indications, and Kyowa Hakkio Kirin will continue its development activities in oncology until the completion of Phase II a. At that time, Amgen may elect to reimburse Kyowa Hakkio Kirin for its oncology-related development costs, expand its license to include oncology and assume the development and commercialization of KW-0761 in oncology settings.)

(Note)  
In Philippines, an NDA of Filgrastim (G-CSF) has been filed for neutropenia.  
In Thailand, Singapore, Malaysia, and Philippines, NESP (Long-acting erythropoiesis stimulating protein) has been filed. In Korea, Taiwan, and Hong Kong, NESP was approved.  
In Korea and Taiwan, REGPARA (Calcimimetic agent) has been filed. In Hong Kong (Macao), REGPARA was approved.

Updated since October 29th, 2009 (Area, Stage, Filed, Approved, Launched etc.)

★ New indication

### Discontinued

Category	Code Name Product Name	Generic Name	Stage		Indication	Formulation	In-house OR Licensed	Reason
			Japan	Other countries				
Immunology/Allergy	<b>NU206</b>			Phase I in Australia	Inflammatory bowel disease	Injection	Developed with ARCA biopharma (the former Nuvelo).	Portfolio management
Cancer/Hematology	<b>AGS-003</b>			Phase II in USA and Canada	Renal Cell Carcinoma	Injection	Developed with Argos.	Portfolio management
	<b>AGS-004</b>			Phase II in USA and Canada	HIV	Injection	Developed with Argos.	Portfolio management