

R&D PIPELINES

Phase II, Phase III

Jul 28th 2010

Category	Code Name Product Name	Generic Name	Stage		Indication	Formulation	In-house or Licensed	Remarks
			Japan	Other countries				
Cancer/Hematology	KW-0761		Phase II	Phase I / II a in USA	Cancer (Hematologic tumor)	Injection	Developed In-house	Humanized monoclonal antibody (※)
	KRN321 NESP	Darbepoetin Alfa	Filed Nov/2008		☆ Chemotherapy induced anemia	Injection	Kirin-Amgen	Long-acting erythropoiesis stimulating protein Launched in Japan for anemia of CKD patients on dialysis from July 2007.
	AMG531	Romiplostim	Filed Mar/2010		Immune thrombocytopenic purpura	Injection	Kirin-Amgen	Thrombopoiesis stimulating protein
	KW-2246	Fentanyl citrate	Filed Feb/2010		Cancer pain	Sublingual tablet	Licensed from Orexo	
	KRN125	Pegfilgrastim	Phase II		Neutropenia	Injection	Kirin-Amgen	Long-acting G-CSF
	ARQ 197		Phase II		Cancer (Gastric cancer)	Oral	Licensed from ArQule	
Kidney	KRN321 NESP	Darbepoetin Alfa	Approved Apr/2010		☆ Anemia (not on dialysis)	Injection	Kirin-Amgen	Long-acting erythropoiesis stimulating protein Launched in Japan for anemia of CKD patients on dialysis
	KRN1493 REGPARA	Cinacalcet Hydrochloride		Phase II in China	☆ Anemia (on dialysis)			
Immunology/Allergy	KW-4679 ALLELOCK	Olopatadine Hydrochloride		Phase III in China	secondary hyperparathyroidism	Oral	Licensed from NPS	Japan: Already launched
CNS	KW-6002	Istradefylline	Phase III	Licensed-out Jun/2010	Parkinson's disease	Oral	Developed In-house	Entered into a license agreement with Biovall Laboratories International SRL
	KW-6500	Apomorphine Hydrochloride	Phase III		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	KW-2450			Phase I in USA	Cancer	Oral	Developed In-house	
	KW-2478			Phase I / II a in EU/US	Cancer	Injection	Developed In-house	
	KRN330			Phase I / II a in USA	Cancer	Injection	Developed In-house	Fully human monoclonal antibody
	BIW-8962			Phase I / II a in USA	Cancer	Injection	Developed In-house	Humanized monoclonal antibody
	KRN951		Phase I		Cancer	Oral	Developed In-house	
Immunology/Allergy	KHK4563		Phase I		Asthma	Injection	Developed In-house	Humanized monoclonal antibody Being developed by MedImmune as MEDI-563 worldwide except in Japan and other Asian countries
	Z-206 ASACOL	Mesalazine	Phase I		☆ Crohn's disease	Oral <small>(pH dependent controlled-release formulation)</small>	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	Developed with Astellas.	Fully human monoclonal antibody
Other	KW-3357	Antithrombin	Phase I	Phase I in Europe	Disseminated intravascular coagulation, Congenital antithrombin deficiency	Injection	Developed In-house	Recombinant antithrombin product
	KRN23			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 Hakko Kirin has retained the development and commercialization rights in these countries. Amgen has initially acquired the rights in all non-oncology indications, and Kyowa Hakko Kirin will continue its development activities in oncology until the completion of Phase IIa. At that time, Amgen may elect to reimburse Kyowa Hakko 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 Vietnam, an NDA of Pegfilgrastim(peg-G-CSF) has been filed.
In Korea, Taiwan and Hong Kong/Macau, NESP(long-acting erythropoiesis stimulating protein) was approved. In Thailand, Singapore, Malaysia and Philippines, an NDA of NESP has been filed. In India, NESP is currently in phase 3 clinical trial.
In Korea, Taiwan and Hong Kong/Macau, REGPARA(regulator of parathyroid gland) was approved. In Singapore, an NDA of REGPARA has been filed.

Updated since April 28th, 2010 (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				
Cancer/Hematology	KRN654	anagrelide hydrochloride	Phase I / II		Essential thrombocythemia	Oral	Licensed from Shire.	Succeeded to Shire based on portfolio re-assessment
	KW-2449			Phase I / II a in USA	Cancer	Oral	Developed In-house	Based on portfolio re-assessment