

R&D PIPELINES

Filed - Approved

As of Jan 24th 2012

| Therapeutic Area | Code Name Generic Name | Mechanism of Action | Stage | | Indication | Formulation | In-House or Licensed | Remarks |
|------------------|--|---|-------------------|-----------------------------------|--|-------------|--|---|
| | | | Japan | Other Countries | | | | |
| Oncology | KW-0761 Mogamulizumab | Anti-CCR4 Humanized Antibody | Filed Apr/2011 | | Adult T-cell Leukemia/Lymphoma | Injection | In-House | (※) POTELLIGENT® |
| | Pegfilgrastim | Long-Acting Granulocyte Colony Stimulating Factor | | Filed in Asia | Chemotherapy induced Febrile Neutropenia | Injection | Kirin-Amgen | Asia: Korea and Vietnam |
| Nephrology | Cinacalcet Hydrochloride | Calcium Receptor Agonist | | Filed in Asia | Secondary Hyperparathyroidism | Oral | Licensed from NPS | Asia: Philippine, Malaysia, Thailand and China |
| | Darbepoetin Alfa | Long-Acting Erythropoiesis Stimulating Agent | | Approved in Singapore Jan/2012 | Renal Anemia (on Dialysis) | Injection | Kirin-Amgen | |
| CNS | KW-6500 Apomorphine Hydrochloride | Dopamine Receptor Agonist | Filed Jul/2011 | | Parkinson's Disease | Injection | Licensed from Britannia Pharmaceuticals Limited | |
| | KW-6002 Istradefylline | Adenosine A2a Receptor Antagonist | | Filed in USA | Parkinson's Disease | Oral | In-House | Reimbursement of License from Valeant International SFL for the Development and Commercialization of KW-6002 in the US and Canada. |
| Other | AMG531 Romiplostim | Thrombopoietin Receptor Agonist | | Filed in Asia | Idiopathic (Immune) Thrombocytopenic Purpura | Injection | Kirin-Amgen | Asia: Singapore and Taiwan (Approved in Malaysia on December 2) |

Phase II, Phase III

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|---|--|---|--------------------------------|---|--|--|---|--|--|
| | | | Japan | Other Countries | | | | | |
| Oncology | KW-0761 Mogamulizumab | Anti-CCR4 Humanized Antibody | | Phase I / II in USA | Peripheral T-cell Lymphoma and Cutaneous T-cell Lymphoma | Injection | In-House | (※) POTELLIGENT® | |
| | | | Phase II | | Adult T-cell Leukemia/Lymphoma, Add-on Therapy (for Untreated Patients) | | | | |
| | | | Phase II | | Peripheral T/NK-cell Lymphoma | | | | |
| | KW-2246 Fentanyl citrate | μ -Opioid Receptor Agonist | | Phase III | | Cancer Pain | Sublingual Tablet | Licensed from Orexo | |
| | KRN125 Pegfilgrastim | Long-Acting Granulocyte Colony Stimulating Factor | | Phase III | | Chemotherapy induced Febrile Neutropenia | Injection | Kirin-Amgen | |
| | ARQ197 tyrantinib | c-Met Inhibitor | | Phase II in Japan and Korea | | Gastric Cancer | Oral | Licensed from ArQule | |
| | | | | Phase III in Japan, Korea and Taiwan | | Lung Cancer | | | |
| KW-2478 | HSP90 inhibitor | | | Phase I / II in UK/US/PH | Multiple Myeloma | Injection | In-House | | |
| KRN321 Darbepoetin Alfa | Long-Acting Erythropoiesis Stimulating Agent | | Phase II in Japan and Korea | | ☆Myelodysplastic Syndrome related Anemia | Injection | Kirin-Amgen | Launched in Japan for Anemia of CKD patients | |
| KRN1493 Cinacalcet Hydrochloride | Calcium Receptor Agonist | | Phase III | | ☆HyperCalcemia with Parathyroid Carcinoma or Intractable Primary Hyperparathyroidism | Oral | Licensed from NPS | Launched in Japan for Secondary Hyperparathyroidism | |
| Nephrology | KRN321 Darbepoetin Alfa | Long-Acting Erythropoiesis Stimulating Agent | Phase III | | ☆ Pediatric Renal Anemia | Injection | Kirin-Amgen | Launched in Japan for Anemia of CKD patients | |
| | | | | Phase II in China Phase III in India | Renal Anemia (on Dialysis) | | | | |
| Immunology/Allergy | ASKP1240 | Anti-CD40 Fully Human Antibody | Phase I | Phase II in USA | Organ Transplant Rejection | Injection | In-House | Jointly Developed with Astellas | |
| | KHK4563 Benralizumab | Anti-IL-5 Receptor Humanized Antibody | Phase II in Japan and Korea | | Asthma | Injection | In-House | Being Developed by MedImmune as MEDI-563 Worldwide except in Japan and other Asian Countries POTELLIGENT® | |
| | Z-206 Mesalazine | pH Dependent Controlled Release Tablet | Phase II | | ☆ Crohn's Disease | Oral | Licensed from Zeria Pharma. | Jointly Developed with Zeria Pharma Launched in Japan for Ulcerative Colitis. | |
| CNS | KW-6002 Istradefylline | Adenosine A2a Receptor Antagonist | Phase III | | Parkinson's Disease | Oral | In-House | | |
| | KW-6485 Topiramate | Antiepileptic Drugs | Phase III | | ☆ Pediatric Epilepsy | Oral | Licensed from Janssen Pharmaceutical KK. | Launched in Japan for Use as an Epileptic Drug | |
| Other | KW-3357 Antithrombin | Recombinant Human Antithrombin | Phase III | Phase I in Europe | Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency | Injection | In-House | | |

Phase I

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| | | | Japan | Other Countries | | | | |
| Oncology | KW-2450 | IGF-1 Receptor Signal Inhibitor | | Phase I / II in USA | Cancer | Oral | In-House | |
| | KRN330 | Anti-A33 Fully Human Antibody | | Phase I / IIa in USA | Cancer | Injection | In-House | |
| | B1W-8962 | Anti-GM2 Humanized Antibody | | Phase I / IIa in USA | Cancer | Injection | In-House | POTELLIGENT® |
| | KRN951 Tivozanib | VEGF Receptor Inhibitor | Phase I | | Cancer | Oral | In-House | |
| | KHK2866 | Anti-HB-EGF Humanized Antibody | | Phase I in USA | Cancer | Injection | In-House | POTELLIGENT® |
| | LY2523355 Utronesib | M phase Kinesin Eg5 Inhibitor | Phase I | | Cancer | Injection | In-House | Worldwide Outlicensed to Eli Lilly for the Development and Commercialization of LY2523355 except Japan |
| | CEP-37250/KHK2804 | Anti-Tumor Specific Glycoprotein Humanized Antibody | | Phase I in USA | Cancer | Injection | Cephalon | Jointly Developed with Cephalon POTELLIGENT® |
| KHK2898 | Anti-CD98 Fully Human Antibody | | Phase I in Singapore | Cancer | Injection | In-House | POTELLIGENT® | |
| Nephrology | RTA 402 Bardoxolone Methyl | Antioxidant Inflammation Modulator | Phase I | | Diabetic Nephropathy | Oral | Licensed from Reata | |
| Immunology/Allergy | KHK4827 | Anti-IL-17 Receptor Fully Human Antibody | Phase I | | Psoriasis | Injection | Kirin-Amgen | |
| Other | KHK6188 | Cannabinoid CB2 Receptor Agonist | Phase I | | Neuropathic Pain | Oral | In-House | |
| | KRN23 | Anti-FGF23 fully Human Antibody | | Phase I / II in USA and Canada | X-linked Hypophosphatemic Rickets/Osteomalacia (XLH) | Injection | In-House | |

(※) 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 Hakkō Kirin has retained the development and commercialization rights in these countries. In 2010, KHK paid Amgen US\$20M for the buy-out of Amgen's option to assume the development and commercialization of KW-0761 in oncology setting in Amgen's licensed territory, which was granted under the License Agreement.

Updated since Oct 20th, 2011 (Area, Stage, Filed, Approved, Launched etc.)
☆ New indication

Withdrawal of Application

| Therapeutic Area | Code Name Generic Name | Mechanism of Action | Stage | | Indication | Formulation | In-House or Licensed | Reason |
|------------------|--|--|-------------------|-----------------|-------------------------------|-------------|----------------------------|---|
| | | | Japan | Other Countries | | | | |
| Oncology | KRN321 Darbepoetin Alfa | Long-Acting Erythropoiesis Stimulating Agent | Filed Nov/2008 | | ☆ Chemotherapy induced Anemia | Injection | Kirin-Amgen | The withdrawal of application was made because currently submitted data is insufficient to establish an evidence that is necessary to attain the approval, as a result of discussion with Pharmaceuticals and Medical Devices Agency. |