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Kyowa Hakko Kirin Third Quarter Operating Income up 10.9%

Tokyo, October 25, 2013-- Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin; TSE 4151) today announced its consolidated financial results for the third quarter of the fiscal year ending December 2013 (the nine-month period from January 1, 2013 to September 30, 2013).

Net sales for the first nine-months of the fiscal year (January 1, 2013 to September 30, 2013) were ¥252.1 billion (up 3.0% compared to the first nine-months of the previous fiscal year), operating income was ¥41.4 billion (up 10.9%) and ordinary income was ¥39.2 billion (up 20.3%). Net income for the nine-month period was ¥23.3 billion (up 51.1%).

- Growth in net sales and operating income was driven by a strong performance from ethical pharmaceutical products in Japan, continued strong growth from ProStrakan, along with some benefits from a further decline in the yen.
- Ordinary income also grew, driven by the increase in operating income in addition to the booking of foreign exchange gains and a decline in losses from equity-accounted affiliates. Net income for the period also increased due to the booking of extraordinary profit from the gain on sale of shares in an affiliated company and other factors.

Commenting on the results, Nobuo Hanai, President and CEO of Kyowa Hakko Kirin said, *"I am pleased to report growth in sales and profits for the nine-month period driven by growth in our domestic pharmaceuticals business and continued strong growth in sales at ProStrakan. The Bio-Chemicals business saw strong improvement in net sales supported by yen weakness. Looking ahead, we will pursue our strategy to develop globally and we will continue to promote the rapid realization of our strengths in therapeutic antibodies with the aim of becoming a world-class, R&D based life sciences company, founded on biotechnology with the Pharmaceuticals business at its core."*

Performance by segment

Note: As of the first quarter of the current fiscal year there has been a revision to the way segments are classified. Year-on-year comparisons shown below are with adjusted figures for the first half of last year reflecting these revisions.

Pharmaceuticals business

1. Results

In the Pharmaceuticals business, net sales were ¥192.7 billion (up 1.7%) and operating income was ¥36.9 billion (up 5.3%).

- Domestic sales of ethical pharmaceutical products were up from the same period in the previous fiscal year despite the impact of drug price revisions, which were implemented in April 2012.
- Sales of core product NESP[®], a treatment for renal anemia, declined year on year due to lower shipments following the launch of unified dosage product which launched in

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December 2012. Sales of Patanol[®] anti-allergy eye drops grew significantly due to the effects of higher amounts of airborne pollen. However, due in part to the impact of generics, sales of ALLELOCK[®], an anti-allergy agent, and sales of CONIEL[®], a hypertension and angina pectoris drug, declined from the same period in the previous fiscal year.

- Sales of REGPARA[®], a treatment for secondary hyperparathyroidism during dialysis therapy, ASACOL[®], an ulcerative colitis treatment, Romiplate[®], a treatment for chronic idiopathic thrombocytopenic purpura, and Fentos[®], a transdermal analgesic for persistent cancer pain, all advanced steadily.
- In May, we launched NOURIAST[®], the world's first antiparkinsonian agent of an adenosine A_{2A} receptor antagonist.
- In July, we launched Onglyza[®], a treatment for type-two diabetes.
- In the licensing-out of technologies and export of pharmaceutical products, exports were steady but licensing revenue for the development of biosimilars from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. declined significantly.
- ProStrakan net sales were ¥16.7 billion (up 44.6%), with strong growth in Abstral[®] a treatment for cancer pain, and other core products. Operating income (after amortization of goodwill, etc.) was ¥0.1 billion (compared to an operating loss of ¥2.5 billion in the comparable nine-month period of the previous fiscal year).

2. Research and development

Oncology

(Domestic)

- We received approval in February for additional indications for intramuscular administration and dosage of Leunase[®], an anti-cancer drug.
- In March we received approval for additional indication of Pheochromocytoma for anti-cancer agent Dacarbazine[®].
- In May we applied for approval for additional indications for pancreatic cancer and dosage and administration of injectable 5-FU.
- In June we filed an application for marketing approval for sustained-duration G-CSF product KRN125 for the treatment of chemotherapy induced febrile neutropenia.
- In June we applied for additional indications of hypercalcemia in patients with parathyroid carcinoma, and hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or who experience recurrent primary hyperparathyroidism for REGPARA[®], a treatment for secondary hyperparathyroidism during dialysis therapy.
- In July we applied for approval for additional indications for untreated CCR4-positive adult T-cell leukemia-lymphoma (ATL), relapsed CCR4-positive peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) and for dosage and administration for POTELIGEO[®], a humanized anti-CCR4 monoclonal antibody.
- Application for Abstral[®], a treatment of cancer pain, was approved in September.

Nephrology

(Domestic)

- Approvals for additional pediatric indications for NESP[®], a treatment for renal anemia, and for the 5µg Plastic Syringe were received in September.

(Overseas)

- In China, we are currently seeking approval of Cinacalcet Hydrochloride (product name in Japan: REGPARA[®]), a treatment for secondary hyperparathyroidism. (Application

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filed in October 2011.)

- In China we began Phase III trials in April for KRN321 (product name in Japan: NESP[®]) for the treatment of renal anemia in patients receiving dialysis.

Immunology and allergy

(Domestic)

- We began Phase III trials in March for KHK4827 for psoriasis.

CNS

(Domestic)

- In February we obtained approval for a time-window extension of thrombolytic agent ACTIVACIN[®] for administration within 4.5 hours after the onset of symptoms of ischemic cerebrovascular disease (up from 3 hours).
- We acquired approval for NOURIAST[®] for the treatment of Parkinson's disease in March, and launched the drug in May.
- We are currently seeking approval for two additional indications for anti-epileptic drug TOPINA[®] for use in infants and for a new formulation (granules). (Application filed in December 2012.)

Other

(Domestic)

- In February, we received approval for an additional indication of Pasetocin[®], a synthesized penicillin drug (as part of triple therapy including proton pump inhibitors and either clarithromycin or metronidazole) for the eradication of *Helicobacter pylori* in *Helicobacter pylori* gastritis infection.

Bio-Chemicals business

Sales in the Bio-Chemicals business increased by 7.1% to ¥61.5 billion, while operating income increased 103.7% to ¥4.5 billion.

Domestic business

- Sales in the pharmaceutical and medical treatment fields increased compared to the previous fiscal year.
- In the pharmaceutical and medical treatment fields, pharmaceutical-use amino acids, nucleic acids and related compounds, and other pharmaceutical raw materials performed steadily.
- *Tranexamic acid* sales declined from the same period of the previous year, during which there was a concentration of shipments.
- In the healthcare field, year-on-year mail-order sales, such as those of ornithine, increased, but sales of food and beverage raw materials declined year on year.

Overseas business

- Sales from overseas businesses were higher than the previous year due in part to a weaker yen.
- In the U.S., sales of some amino acids for supplements declined due to intensifying competition, but overall net sales increased from the same period in the previous year.
- In Europe and Asia, some products such as industrial-use amino acids declined from

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the same period of the previous year due to intensifying competition, but overall net sales increased year on year due to the continued strong performance of infusion-use amino acids.

Consolidated results forecasts

There have been no changes made to the consolidated fiscal results forecast announced July 26, 2013.

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For further information please access: http://www.kyowa-kirin.com/news_releases/index.html

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