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Kyowa Hakko Kirin First Half Operating Income up 6.2%

Tokyo, July 26, 2013-- Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin) today announced its consolidated financial results for the first half of the fiscal year ending December 2013 (the six-month period from January 1, 2013 to June 30, 2013).

Net sales for the first half were ¥169.7 billion (up 2.1% compared to the first half of the previous fiscal year), operating income was ¥27.1 billion (up 6.2%) and ordinary income was ¥26.5 billion (up 14.8%). Net income for the half year was ¥17.6 billion (up 53.4%).

- Growth in net sales and operating income was driven by a strong performance from pharmaceutical products in Japan, continued strong growth from ProStrakan, along with some benefits from a further decline in the yen.
- Ordinary income also grew due to the booking of foreign exchange gains, a decline in losses from equity-accounted affiliates, and the increase in operating profit. Net income for the half year also increased due to the booking of extraordinary profit from the gain on sale of shares in an affiliated company.
- Forecasts for the full year have been revised as shown below in 'Consolidated Results forecasts'.

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 half-year period driven by growth in our domestic pharmaceuticals business and very strong growth in sales at ProStrakan, while the Bio-Chemicals business saw a sharp increase in profits, partly due to yen weakness. We have revised our full year sales and profit forecasts to reflect a weaker than expected yen, a downward reaction in sales of NESP, and a delay in booking certain licensing revenues. 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 ¥129.9 billion (up 1.8%) and operating income was ¥24.1 billion (up 2.5%).

- 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.

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- 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 December 2012.
- Sales of *Patanol* anti-allergy eye drops grew significantly due to the effects of higher amounts of airborne pollen and other factors. However, due in part to the impact of generics, sales of *Allelock*, an anti-allergy agent, remained unchanged, and sales of *Coniel*, a hypertension and angina pectoris drug, declined.
- 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 strongly.
- In May, we launched *Nourias*, the world's first antiparkinsonian agent of an adenosine A_{2A} receptor antagonist.
- In May, we took over the manufacturing and sales rights for *Onglyza*, a treatment for type-two diabetes, from Otsuka Pharmaceutical Co., Ltd. (Sales began in July).
- 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 ¥10.7 billion (up 39.6%), with strong growth in *Abstral* a treatment for cancer pain, and other core products. Operating loss (after amortization of goodwill, etc.) was ¥0.3 billion (down 83.1%).

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 secured approval for the additional indication of pheochromocytoma for anti-cancer drug *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.
- We are currently seeking approval of KW-2246 (overseas name: *Abstral*), for the treatment of cancer pain. (Application filed in November 2012.)

Nephrology

(Domestic)

- We are currently seeking approval for additional pediatric indication for *NESP*, a treatment for renal anemia. (Application filed in September 2012.)

(Overseas)

- In China, we are currently seeking approval of Cinacalcet Hydrochloride (product name in Japan: *Regpara*), a treatment for secondary hyperparathyroidism. (Application filed in October 2011.)

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- In China we began Phase III trials 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).
- In March we acquired approval for *Nourias* for the treatment of Parkinson's disease and began sales 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 2.8% to ¥41.2 billion, while operating income increased 52.1% to ¥3.1 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 first half 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*, were broadly unchanged, 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 first half of the previous year.
- In Europe and Asia, infusion-use amino acids remained strong.

Consolidated results forecasts

Consolidated results for the first half of fiscal year 2013 were positively impacted by a weaker than anticipated yen but sales of core product *NESP* were below initial forecast in reaction to shipments made at the end of 2012. Also, certain licensing revenues included in our initial forecasts are now expected to be booked next fiscal year. In light of these factors we have revised our full-year consolidated earnings forecast.

Revisions to consolidated full-year forecast announced January 31, 2013

	Net Sales	Operating Income	Ordinary income	Net income	Net income per share
	Million yen	Million yen	Million yen	Million yen	Yen
Previous Forecast (A)	338,000	55,000	49,000	30,000	54.80
Revised Forecast (B)	339,000	51,000	48,000	28,000	51.15
Change (B-A)	1,000	(4,000)	(1,000)	(2,000)	-
Rate of change (%)	0.3	(7.3)	(2.0)	(6.7)	-
Fiscal 2012 results	333,158	52,905	49,001	24,199	44.12

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

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