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Kyowa Hakko Kirin Announces Q1 results

Tokyo, April 24, 2013-- Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin) today announced its consolidated financial results for the first quarter of the fiscal year ending December 2013 (the three-month period from January 1, 2013 to March 31, 2013).

Net sales for the first quarter were ¥86.6 billion (down 0.5% compared to the first quarter of the previous fiscal year), operating income was ¥14.4 billion (down 19.8%) and ordinary income was ¥14.8 billion (down 10.5%). Net income for the quarter was ¥10.4 billion (up 23.2%).

- Core products in the Pharmaceuticals business performed well but due to a decline in licensing income, net sales and operating income declined.
- Ordinary income also declined, but net income for the quarter 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, *"The year-on-year comparisons were affected by a decline in licensing revenue and a reduction in standard drug prices in Japan. Nevertheless I am pleased to report continued growth in our core Pharmaceuticals business and a strong increase in profits in our Bio-Chemicals business, which benefited from a weaker yen. 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 quarter of last year reflecting these revisions.

Pharmaceuticals business

Results

In the Pharmaceuticals business, net sales were ¥67.4 billion (up 0.3%) and operating income was ¥13.0 billion (down 22.0%).

- Domestic sales of ethical pharmaceutical products were impacted by a reduction in standard drug prices in Japan, which came into effect in April last year, but core products performed strongly.
 - Sales of *Allelock*, an anti-allergy agent, and *Patanol* anti-allergy eye drops were robust, due to the effects of higher amounts of airborne pollen and other factors. Sales of *NESP*, a treatment for renal anemia declined.
 - Sales of *Regpara*, a treatment for secondary hyperparathyroidism during dialysis therapy, *Asacol*, an ulcerative colitis treatment, *Fentos*, a transdermal analgesic for persistent cancer pain, and *Romiplate*, a treatment for chronic idiopathic thrombocytopenic purpura, all advanced strongly.

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- We are currently in the process of taking over the marketing rights for *Onglyza*, a treatment for type-two diabetes, from Otsuka Pharmaceutical Co., Ltd., which obtained approval for the drug in March.
- In the licensing-out of technologies and export of pharmaceutical products, exports were strong but net sales declined significantly from the first quarter of the previous fiscal year in which we booked licensing revenue from FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. for the development of biosimilars.
- ProStrakan net sales were ¥5.0 billion (up 41.6%), with strong growth in *Abstal*, a treatment for cancer pain, and other core products. Operating loss (after amortization of goodwill, etc.) was ¥0.2 billion (down 75.2%).

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 November 2012, we filed for marketing approval of KW-2246 (overseas name *Abstral*) for cancer pain treatment.

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

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 *Nouriasf* for the treatment of Parkinson's disease.
- 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 decreased 2.9% to ¥19.9 billion while operating income increased 13.6% to ¥1.4 billion.

Domestic business

- Sales in the pharmaceutical and medical treatment fields decreased compared to the previous fiscal year.
 - In the pharmaceutical and medical fields, pharmaceutical-use amino acids, nucleic acids and related compounds, and other pharmaceutical raw materials performed steadily.
 - *Tranexamic acid* sales were down from the first quarter 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 US, sales of amino acids for supplements were somewhat weak due to consumer demand trends and intensifying competition.
 - In Europe and Asia, demand remained strong for amino acids and nucleic acids including infusion-use amino acids, pharmaceutical raw material-use *Citicoline* and raw materials for amino acids.

Consolidated results forecasts

No revisions have been made to the forecasts of consolidated results as announced on January 31, 2013.

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

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