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## Kyowa Hakko Kirin Announces Strong Growth in First Half Profits

**Tokyo, August 2, 2011--** Kyowa Hakko Kirin Co., Ltd. (Kyowa Hakko Kirin; TSE 4151) today announced its consolidated financial results for the first half of the fiscal year ending December 2011 (the six-month period from January 1, 2011 to June 30, 2011).

Net sales for the first half were ¥186.3 billion (down 8.4% compared to the first half of the previous fiscal year), while operating income was ¥29.9 billion (up 38.0%), recurring income was ¥30.2 billion (up 35.3%) and net income was ¥17.7 billion (up 78.9%).

The sale of Kyowa Hakko Chemical was completed at the end of March, which will allow us to focus group resources on our Pharmaceuticals business, while in April, Kyowa Hakko Kirin completed the acquisition of ProStrakan Group, a UK specialty pharmaceuticals company. We aim to leverage the existing development and sales framework of ProStrakan in Europe and the U.S. to significantly advance our global strategy by accelerating new drug development and expanding sales globally. Also in April we submitted a new drug application (NDA) in Japan for KW-0761, for the treatment of adult T-cell leukemia-lymphoma (ATL). KW-0761 is a humanized monoclonal antibody produced using our unique POTELLIGENT<sup>®</sup> technology. This product is the first antibody for which Kyowa Hakko Kirin has submitted an NDA, and is also the world's first POTELLIGENT<sup>®</sup> antibody to be submitted for marketing approval.

Forecasts for the full year results to December 31, 2011 are unchanged from those announced on July 20, 2011. Forecast consolidated net sales of ¥342 billion represent a decline of 17.3% compared to the previous fiscal year, largely due to the exclusion of the Chemicals segment from consolidation from April 2011. Operating income is forecast to decline by 4.2% to ¥43.5 billion while net income is forecast to increase by 14.9% to ¥25.5 billion.

Commenting on the results, Yuzuru Matsuda, President and CEO of Kyowa Hakko Kirin said, *“Group sales for the first half were affected by the sale of Kyowa Hakko Chemical, which was consolidated only for the first quarter of the year. Despite a tough operating environment group profits were up strongly driven by profit growth from our core Pharmaceuticals and Bio-Chemicals businesses. We also successfully completed the acquisition of ProStrakan Group and we are already collaborating closely to accelerate our global drug development and sales.*

*Kyowa Hakko Kirin aims to pursue its vision of becoming a world-class, R&D based life sciences company, founded on biotechnology with the pharmaceuticals business at its core and our NDA application in April for the world's first POTELLIGENT<sup>®</sup> antibody is a key milestone in realizing our vision.”*

## Segmental performance

*Note: As of the second quarter of the current fiscal year, the Accounting Standards for Disclosure about Segments of an Enterprise and Related Information (ASBJ statement No. 17, March 27, 2009) and the Guidance on Accounting Standard for Disclosures about Segments of an Enterprise and Related Information (ASBJ Guidance No. 20, March 21, 2008) have been applied. Year-on-year comparisons are provided since the segmental classification following application of these accounting standards is the same as that previously used.*

## Pharmaceuticals

In the Pharmaceuticals business, consolidated net sales were ¥112.5 billion (up by 8.8% compared to the same period of the previous year), while operating income was ¥25.1 billion (up 39.7%). Domestic sales of core ethical pharmaceutical products including Nesp, a treatment for renal anemia, were robust while sales of Allelock, an antiallergic agent, and Patanol antiallergic eye drops, were significantly higher than the previous comparable period due to the effects of higher amounts of airborne pollen and other factors. Sales of Regpara, a treatment for secondary hyperparathyroidism during dialysis therapy, Asacol, an ulcerative colitis treatment and Fentos, a transdermal analgesic for persistent cancer pain launched last year, also grew steadily.

In the licensing-out of technologies and export of pharmaceutical products, revenues from licensing-out of technologies were lower than in the same period of the previous fiscal year while exports, primarily those to Asia, performed strongly.

In new drug development in Japan, in the cancer therapeutic area KRN125 began Phase III clinical trials in February targeting chemotherapy induced febril neutropenia. In April we submitted an NDA for anti-CCR4 antibody KW-0761 that targets adult T-cell leukemia-lymphoma.

In the renal anemia area in Japan, renal anemia treatment Nesp began Phase III clinical trials in January to seek approval for pediatric indications.

In the central nervous system therapeutic area in Japan, approval was received in June for additional applications of Depakene, an antiepileptic drug, for usage and volumes, and its effectiveness and efficiency in averting the onset of migraine headaches.

In other therapeutic areas in Japan, AMG531 (product name Romiplate), a treatment for chronic idiopathic thrombocytopenic purpura was approved and sales were launched in April. Phase III clinical trials for KW-3357, which targets diffuse intravascular coagulation syndrome following a reduction of antithrombin (an anticoagulant component), began in June. Overseas, in Korea approvals have been received for AMG531 (product name: Nplate). In June, ProStrakan, which became a subsidiary in April received approval in the U.S. for Rectiv™, a treatment for chronic anal fissures.

In therapeutic antibody research and development, while strengthening our in-house development pipeline of antibody pharmaceuticals we also developed the global outlicensing of our POTELLIGENT® and COMPLEGENT® technologies via our U.S. subsidiary BioWa, Inc. To date, we have licensing agreements with 18 companies for these technologies and we are actively pursuing our strategy of promoting the fastest possible development of antibody pharmaceuticals that utilize our original technology.

On April 21, 2011, Kyowa Hakko Kirin acquired all outstanding shares of ProStrakan Group plc, a UK-based specialty pharmaceuticals company, and ProStrakan Group, and its ten subsidiaries became consolidated subsidiaries. In terms of accounting treatment, June 30, 2011 will be considered as the date that the acquisition was completed and therefore results from ProStrakan have not been included in the consolidated financial results for the first half of the current fiscal year, although our full year results forecast does reflect inclusion of ProStrakan from July 1,

2011.

### **Bio-Chemicals**

In the Bio-Chemicals business, consolidated net sales were ¥40.3 billion (down by 8.7% compared to the same period of the previous year), while operating income was ¥2.5 billion (up 35.9%). Sales of pharmaceutical and industrial use raw materials, mainly amino acids, nucleic acids and related compounds, increased despite the effects of a strong yen and primarily due to strong growth in sales volumes to Asia of amino acids for intravenous liquids and pharmaceutical raw materials.

In healthcare products, we achieved steady growth through initiatives to strengthen mail-order sales of our *Remake Series*, primarily those of its own brand materials, however sales were lower than in the previous comparable period due to the delay of the planned April renewal of Kirin Health Project *KIRIN Plus-i* related products resulting from the earthquake disaster.

Sales at Daiichi Fine Chemical declined due to a drop in sales volumes and sales prices of certain bulk pharmaceuticals and intermediate products.

### **Chemicals**

*On March 31, 2011, Kyowa Hakko Kirin sold all outstanding shares of Kyowa Hakko Chemical. Since there are no longer any consolidated subsidiaries in the Chemicals business, the Chemicals segment results includes only the consolidated results of the first quarter of the consolidated fiscal year (January 1, 2011 to March 31, 2011).*

In the Chemicals business, compared to the first quarter of the previous year, consolidated net sales were ¥33.5 billion (up by 10.8%), and operating income was ¥2.1 billion (up 216.6%). In the previous comparable period, the six-month period from January 1, 2010 to June 30, 2010, net sales in the Chemicals business were ¥61.2 billion and operating income was ¥1.5 billion.

Both domestic and overseas sales and sales volumes were higher than in the first quarter of the previous year supported by factors including increased demand and strong markets in Asia, and recovery of demand in Japan.

All product areas, including solvents, plasticizer raw materials and specialty chemicals, recorded higher sales volumes and sales revenues than in the first quarter of the previous fiscal year. Particularly strong growth was recorded by products such as specialty chemicals including raw materials for refrigerant oils, which remained strong.

### **Other**

In the Other segment, consolidated net sales were ¥5.3 billion (up by 4.4% compared to the same period of the previous year), while operating income was ¥0.1 billion (down 1.7%).

### **Consolidated results forecasts**

No revisions have been made to the consolidated results forecasts that were announced on July 20, 2011.

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For further information please access: <http://www.kyowa-kirin.co.jp/english/index.html>

*This document is an English translation of parts of the Japanese-language original. All financial information has been prepared in accordance with generally accepted accounting principles in Japan. It contains forward-looking statements based on a number of assumptions and beliefs made by management in light of information currently available. Actual financial results may differ materially depending on a number of factors, including fluctuations in exchange rates, changing economic conditions, legislative and regulatory developments, delays in new product launches, and pricing and product initiatives of competitors.*