Furnished under Rule 12g3-2(b)
ROCHE HOLDING 82-3315

# Roche Investor Updat



Tuesday, April 05, 2005 10:33 AM

Enclosed please find an Investor up-date, as distributed by Chugai today:
http://www.roche.com/iru050405.pdf

If you have any questions, please do not hesitate to contact us.

Sincerely yours,



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**Translation**

April 5, 2005


| | |
|---|---|
| Name of listed company: | Chugai Pharmaceutical Co., Ltd. |
| Code number: | 4519 (Tokyo Stock Exchange) |
| Head office: | 1-9, Kyobashi 2-chome, Chuo-ku, Tokyo |
| President & CEO: | Osamu Nagayama |
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## A Revision of Financial Outlook for Fiscal Year 2005 (January 1 ~ December, 2005)

Chugai Pharmaceutical Co., Ltd. announced that the company revises the interim and full year financial outlooks for fiscal year 2005 (January~December, 2005), originally released on February 10, 2005.

**1. The revision of the non-consolidated interim financial outlook for fiscal year 2005 (January~June, 2005)**

(Millions of yen , %)

| | | Net sales | Recurring profit | Net income |
|---|---|---|---|---|
| Original outlook (Released February 10, 2005) | (A) | 130,500 | 23,200 | 15,100 |
| Revised outlook | (B) | 149,500 | 34,000 | 22,500 |
| Variance | (B-A) | 19,000 | 10,800 | 7,400 |
| (% Change) | (B-A)/A | 14.6 | 46.6 | 49.0 |
| Fiscal Year ended December 31, 2004 | | 137,881 | 22,092 | 13,275 |

**2. The revision of the consolidated interim financial outlook for fiscal year 2005 (January~June, 2005)**

(Millions of yen , %)

| | | Net sales | Recurring profit | Net income |
|---|---|---|---|---|
| Original outlook (Released February 10, 2005) | (A) | 135,000 | 24,700 | 16,000 |
| Revised outlook | (B) | 154,000 | 36,000 | 23,000 |
| Variance | (B-A) | 19,000 | 11,300 | 7,000 |
| (% Change) | (B-A)/A | 14.1 | 45.7 | 43.8 |
| Fiscal Year ended December 31, 2004 | | 142,002 | 23,638 | 13,838 |

**3. The revision of the non-consolidated financial outlook for full fiscal year 2005 (January~December, 2005)**

(Millions of yen , %)

| | | Net sales | Recurring profit | Net income |
|---|---|---|---|---|
| Original outlook (Released February 10, 2005) | (A) | 283,800 | 58,100 | 36,700 |
| Revised outlook | (B) | 300,500 | 64,000 | 41,500 |
| Variance | (B-A) | 16,700 | 5,900 | 4,800 |
| (% Change) | (B-A)/A | 5.9 | 10.2 | 13.1 |
| Fiscal Year ended December 31, 2004 | | 285,149 | 47,591 | 32,778 |

(Reference) Earnings per share 75.50 yen (based on outstanding number of shares as of the end of March 2005)

**4. The revision of the consolidated financial outlook for full fiscal year 2005 (January~December, 2005)**

(Millions of yen , %)

| | | Net sales | Recurring profit | Net income |
|---|---|---|---|---|
| Original outlook (Released February 10, 2005) | (A) | 293,500 | 62,300 | 39,200 |
| Revised outlook | (B) | 310,500 | 68,000 | 43,000 |
| Variance | (B-A) | 17,000 | 5,700 | 3,800 |
| (% Change) | (B-A)/A | 5.8 | 9.1 | 9.7 |
| Fiscal Year ended December 31, 2004 | | 294,670 | 51,990 | 34,117 |

(Reference) Earnings per share 78.23 yen (based on outstanding number of shares as of the end of March 2005)

**5. The reason for the revisions**

As a result of the stronger than expected influenza season, the sales of anti-influenza agent Tamiflu® is expected to significantly outperform(interim ¥23.0 billion, full year ¥24.3 billion) the initial projection(interim ¥5.2 billion, full year ¥8.6 billion). In addition, looking at recent sales trends for other main products, an increase in sales and a change in product mix are expected to occur. As a result, we have decided to revise both interim and full year sales outlooks.

Revisions are also made to the recurring profit and net income: in addition to the increase in gross profit, a portion of the selling, general and administrative expenses is expected to be shifted to the latter half of the year, while increased expenses in relation to factors such as active recruitment of sales representatives are expected throughout the year.

For the operating income, revisions are as follows:

Non-consolidated, interim: outlook (initial) ¥21.7 bil - (revised) ¥31.5 bil
Non-consolidated, full year: outlook (initial) ¥56.5 bil - (revised) ¥61.0 bil
Consolidated, interim: outlook (initial) ¥23.8 bil - (revised) ¥34.0 bil
Consolidated, full year: outlook (initial) ¥61.3 bil - (revised) ¥66.0 bil

* The Company bases its forecasts on assumptions that are believed to be reasonable under information available at the time of the forecasts. Actual results may materially differ from these forecasts due to potential risks and uncertainties.

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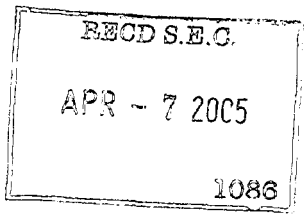
# *Media Release*


Basel, 6 April 2005

## MabThera significantly improves symptoms in patients with rheumatoid arthritis who inadequately responded to anti-TNFα therapies

**Third large randomised trial to evaluate efficacy and safety of MabThera in RA**

Roche, Genentech and Biogen Idec announced today that **REFLEX**[1], a pivotal Phase **III** study of MabThera (rituximab), successfully met its primary endpoint in the group of patients with the most difficult-to-treat rheumatoid arthritis (RA). These patients had an inadequate response or were intolerant to prior treatment with one or more anti-TNFα (biologic) therapies. The study showed that a greater proportion of MabThera treated RA patients achieved a significant improvement of disease symptoms (ACR20[2] response) after 24 weeks, compared to placebo.

"These data suggest that MabThera may offer new hope to patients who have explored all existing therapies. We are pleased that MabThera's value has now been demonstrated in this group of patients with the most difficult-to-treat rheumatoid arthritis and for whom there are currently no adequate treatment alternatives", commented William M. Burns, CEO of Roche's Pharmaceutical Division.

The REFLEX data also complement the excellent results from earlier Phase II studies in less refractory patients, supporting the belief that MabThera has the potential to play a major role for a broad population in the future treatment of rheumatoid arthritis. These data will be presented to the health authorities in due course.

About the **REFLEX** study

The REFLEX study (Randomised Evaluation oF Long-term Efficacy of Rituximab in RA) was conducted in Canada, Europe and the United States and involved 520 adult patients with active rheumatoid arthritis. In this multi-centre, double-blind, placebo controlled study, patients received either a single treatment course of just two infusions of MabThera two weeks apart

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(1000mg i.v. on days 1 and 15), or placebo infusions, in combination with continuing methotrexate (MTX) and a two week course of glucocorticoids. Patients in the MabThera and MTX group had a statistically significant improvement in symptoms compared to patients who received placebo infusions and MTX. A preliminary analysis of the data did not reveal any unexpected safety signals. The most common side effects in the MabThera arm included headache, upper respiratory tract infection and nasopharyngitis. The reported rate of serious adverse events was comparable across the two treatment arms. Patients will continue to be followed to gather longer term safety data.

About MabThera

MabThera is a therapeutic antibody that selectively targets B cells, which play a key role in the inflammatory cascade of RA. By doing so, MabThera aims to break the inflammatory cascade of RA – a series of reactions inflaming the synovia and leading to cartilage loss and bone erosion that is characteristic of the disease. MabThera has also been studied in a Phase IIb study, DANCER (Dose-Ranging Assessment iNternational Clinical Evaluation of Rituximab in RA), which was designed to evaluate the efficacy and safety of varying doses of MabThera in combination with MTX in patients with active RA who currently have an inadequate response to MTX.

MabThera is Roche's leading cancer medicine and has been used for over 7 years for the treatment of a form of lymphatic cancer called non-Hodgkin's lymphoma (NHL) with over 380,000 patients treated to date worldwide.

About Rheumatoid Arthritis

Rheumatoid arthritis is a progressive, systemic autoimmune disease characterized by inflammation of the membrane lining in joints. This inflammation causes a loss of joint shape and function, resulting in pain, stiffness and swelling, ultimately leading to irreversible joint destruction and disability. Characteristics of RA include redness, swelling, pain, and movement limitation around joints of the hands, feet, elbows, knees and neck. In more severe cases of RA the eyes, lungs or blood vessels may be involved. RA may also shorten life expectancy by affecting major organ systems and after 10 years, less than 50% of patients can continue to work or function normally on a day to day basis. RA is one of the most common forms of autoimmune disease and affects more than 6 million people worldwide, up to 2 million of who are in Europe.

ACR improvements

The ACR response is a standard assessment used to measure patients' responses to anti-rheumatic therapies, devised by the American College of Rheumatology (ACR). It requires a patient to have a

defined percentage reduction in a number of symptoms and measures of their disease. For example, a 20 or 50 percent level of reduction (the percentage of reduction of RA symptoms) is represented as ACR20, ACR50. ACR20 indicates a 20 percent improvement in the number of swollen and tender joints, as well as a 20 percent improvement in three of five categories: patient assessment, physician assessment, pain scale, Health Assessment Questionnaire, and acute phase reactants (erythrocyte sedimentation rate or C-reactive protein).

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai.



References:

1. Randomised Evaluation oF Long-term Efficacy of Rituximab in RA
2. The ACR response is a standard assessment used to measure patients' responses to anti-rheumatic therapies, devised by the American College of Rheumatology (ACR). ACR20 indicates a 20 percent improvement in the number of swollen and tender joints, as well as a 20 percent improvement in three of five categories: patient assessment, physician assessment, pain scale, Health Assessment Questionnaire, and acute phase reactants (erythrocyte sedimentation rate or C-reactive protein)

Further information:

About Roche: www.roche.com

About Genentech: www.gene.com

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