

# Investor Update



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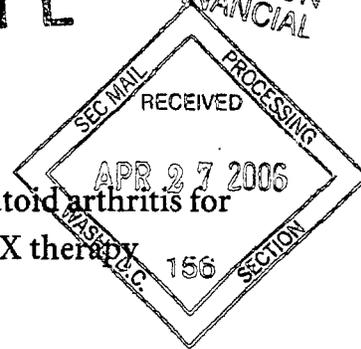
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Basel, 26 April 2006

## Actemra dramatically improves symptoms of rheumatoid arthritis for patients who have had an inadequate response to MTX therapy

### The second Japanese phase III trial meets primary endpoint

New data presented today in Japan have concluded that 80% of patients who received the novel new drug Actemra as monotherapy achieved an ACR20 compared to 25% of patients receiving conventional methotrexate (MTX) therapy after 24 weeks. More importantly, 29% of patients showed an ACR70 compared to 6% of patients in the control arm. Remarkably, this level of symptom control is rarely seen with a single disease modifying anti-rheumatic drug. These main conclusions of the second phase III study in rheumatoid arthritis (RA) conducted by Chugai in patients who have had an inadequate response to MTX, were presented at the Japan College of Rheumatology (JCR) Annual Scientific Meeting held in Nagasaki.

“These data show that treatment with Actemra alone provides a clear benefit in improving signs and symptoms of rheumatoid arthritis – a disease many people suffer from around the world. We look forward to the results of the ongoing phase III programme outside of Japan where Actemra is being studied in several different patient populations, over half of whom have already been enrolled in the various studies” commented Eduard Holdener, Head of Roche Global Pharma Development.

Patients receiving Actemra monotherapy experienced an almost 50% greater reduction in swollen joint count at week twelve of treatment when compared to the reduction achieved with MTX and the swollen joint count in Actemra treated patients was reduced even further by week twenty four. In this study, 80%, 49% and 29% of patients receiving Actemra monotherapy achieved an ACR<sup>1</sup> of 20, 50 and 70 respectively compared to 25%, 11% and 6% respectively in the control arm (p<0.001, p<0.001, and p=0.001 respectively).

### About the study

This phase III clinical trial is a double-blind randomized trial in which 125 patients who had an inadequate response to MTX were allocated to receive either Actemra as a monotherapy at 8 mg/kg I.V. every 4 weeks for 24 weeks or MTX 8mg every week for 24 weeks (the highest recommended weekly dose of MTX in Japan). The primary endpoint of the study was an improvement of ACR20 at week 24. The overall incidence of serious adverse events in the Actemra arm was similar to the control arm (4 and 3 cases respectively).

### About Actemra

Actemra (tocilizumab) is a new humanized anti-human interleukin-6 (IL-6) receptor monoclonal antibody whose novel mechanism of action may provide a new and effective form of treatment for adult RA. It aims to become a major new therapeutic option for the treatment of RA, a disease with a high unmet medical need. Phase II studies have been completed in Japan and Europe. While the Phase III program, including the Prevention of Joint Damage study and the Signs and Symptoms study, has already been completed in Japan by Chugai, collaborative phase III clinical development in RA is underway outside Japan with more than 4000 patients expected to be enrolled in 41 countries including several European countries and the USA. A registration filing for the use of Actemra in adult RA is currently being prepared for submission in Japan.

### 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 affects more than 21 million people worldwide with approximately 3 million people affected in Europe.

### 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. Additional information about the Roche Group is available on the Internet ([www.roche.com](http://www.roche.com)).

**References:**

<sup>1</sup>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% level of reduction (the percentage of reduction of RA symptoms) is represented as ACR20, ACR50 or ACR70. An ACR70 response is exceptional for existing treatments and represents a significant improvement in a patient's condition.

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# Investor Update



Basel, 25 April 2006



## Reminder: Roche's First Quarter Sales 2006 Release Wednesday 26<sup>th</sup> April, 2006

Roche will publish its Sales Results for the 1<sup>st</sup> Quarter of 2006 prior to the opening of the Swiss Stock Exchange on Wednesday 26<sup>th</sup> April, 2006.

07.00 CET (Central European Time) / 1:00 AM EDT (Eastern Daylight Time)

Release will be e-mailed and posted on the Roche IR website.

Presentation slides will be posted on the Roche IR website <http://ir.roche.com>.

14.00 - 15.30 CET / 8:00 - 9:30 AM EDT

Conference call will start with presentations by senior management followed by a Q&A session with live access to the speakers. Participants will be:

Erich Hunziker, Deputy Head of the Corporate Executive Committee and CFO

William M. Burns, CEO Division Roche Pharma

Severin Schwan, CEO Division Roche Diagnostics

Dial in to the conference 10-15 min prior to the scheduled start using the following numbers:

+41 (0) 91 610 56 00 (Europe and ROW)

+1 (1) 866 291 41 66 (USA Toll Free)

+44 (0) 207 107 06 11 (UK)

Alternatively a live audio webcast can be accessed via <http://ir.roche.com>.

A replay of the conference call will be available one hour after the conference call, for 48 hours.

Access is by dialing:

+41 91 612 43 30 (Europe and ROW) or

+1 (1) 866 416 25 58 (USA)

+44 207 108 62 33 (UK)

and will be asked to enter the ID 442 followed by the # sign

A replay of the webcast will be available on demand at <http://ir.roche.com>.

Best regards,

Karl Mahler

Head of Investor Relations

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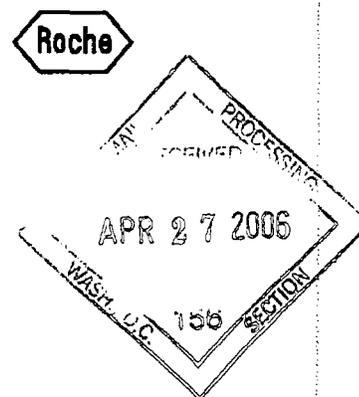
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## Media release



Basel, 26 April 2006

### Roche showed continued strong sales growth in the first quarter 2006 – sales up by 15%

#### Roche Group

- Group sales grew 15% in local currencies and 22% in Swiss francs to 9.8 billion Swiss francs
- Pharmaceutical sales up 19%, three times the global market growth rate
- Outlook for 2006: Group poised for further strong year-on-year growth

#### Pharmaceuticals Division

- Sales rose 19% in local currencies and 26% in Swiss francs
- Sales of the division's successful cancer medicines grew very strongly, advancing 52%\*
- Rheumatoid arthritis indication for MabThera/Rituxan launched in the US
- CERA in renal anemia filed in the US
- Herceptin filed in major markets for treatment of early HER-2 positive breast cancer
- Tamiflu sales continue to grow strongly (+37%)
- First filings for Avastin and Tarceva in Japan
- Positive phase III results from study with Xeloda in stomach cancer
- New data confirm that adding Avastin to standard chemotherapy doubles progression-free survival in advanced breast cancer patients

#### Diagnostics Division

- Sales rose 3% in local currencies and 8% in Swiss francs
- Immunochemistry portfolio generates solid double digit growth (+16%)
- Maturation of Accu-Chek Advantage impacted Diabetes Care sales as anticipated — new Accu-Chek portfolio performing well in the marketplace
- New sepsis test launched and automated blood screening system cleared for marketing in Europe

\* Unless otherwise stated, all percentage changes are period-over-period changes and are based on results in local currencies.

Commenting on the Group's performance in the first quarter of 2006, Roche Chairman and CEO Franz B. Humer said: 'Roche commenced the year with an outstanding quarter and all growth drivers continued last year's strong performance. Sales growth was primarily driven by our novel cancer medicines with proven survival benefits, and Tamiflu was also a major contributor to growth. US approval of the first rheumatoid arthritis indication for MabThera/Rituxan and the progress we have made in developing Actemra are major milestones for our emerging autoimmune disease franchise. The molecular diagnostics business and immunochemistry portfolio continued to be the main growth drivers for our Diagnostics Division. We expect sales in this division to accelerate over the next several quarters.'

## Roche Group

Sales from January to March <sup>1</sup>	2006	2005	% Change	
	mCHF	mCHF	in CHF	in local currencies
Pharmaceuticals Division	7,739	6,155	+26	+19
Roche	4,821	3,859	+25	+19
Genentech	2,056	1,341	+53	+40
Chugai	862	955	-10	-8
Diagnostics Division	2,091	1,935	+8	+3
Roche Group	9,830	8,090	+22	+15

<sup>1</sup> See attachment to this release for details on quarterly sales growth.

Roche posted sales of 9.8 billion Swiss francs in the first quarter of 2006, an increase of 15% in local currencies and 22% in Swiss francs (+11% in US dollars) over the same period last year. This continued the strong double-digit growth reported for full-year 2005. First quarter sales in the Pharmaceuticals Division increased 19% (+26% in Swiss francs). The Diagnostics Division maintained its leading market position with sales growth of 3% (+8% in Swiss francs).

### Positive outlook for 2006

Barring unforeseen events, Roche expects full-year sales and income for 2006 to be up significantly from 2005. The Group reaffirms the outlook announced at its annual media conference: Sales in both the Pharmaceuticals and the Diagnostics Division are expected to grow ahead of the market in local currencies, and we anticipate continued double-digit growth for the Pharmaceuticals Division and the Group as a whole. Sales growth rates in the second half of the year are expected to be comparable to those in the first half. Our target is for core earnings per share and non-voting equity

security to grow at least in line with sales.

## **Pharmaceuticals Division**

### **Key products continue to deliver strong growth**

In the first quarter of 2006 sales in the Pharmaceuticals Division rose 19% in local currencies (+26% in Swiss francs), again growing three times as fast as the market. Much of this growth came from the Group's oncology portfolio, which showed again a significant increase in sales for all its key products, including Herceptin, Avastin, MabThera, Tarceva and Xeloda. Overall sales of the oncology portfolio showed an outstanding growth of 52%. Pandemic stockpiling by governments of the anti-influenza drug Tamiflu was also a significant contributor to growth. Regional pharmaceutical sales growth continues to far outpace market growth in North America (+24% vs. 5%) and Europe (+24% vs. 7%). Japan experienced a sales decline (-8%), due to seasonal shifts in Tamiflu sales and trade stock adjustments in anticipation of government price cuts, which became effective on 1 April.

### **Oncology – demand up strongly for whole portfolio**

First-quarter sales of Roche's top-selling product, MabThera/Rituxan, for the treatment of non-Hodgkin's lymphoma (NHL), were up by 16%. Sales showed particularly impressive growth in Europe/Rest of World<sup>1</sup> (+30%). The European authorities are currently reviewing a marketing application to expand the product's indications to include maintenance treatment of relapsed indolent NHL filed in December 2005. Genentech received FDA approval for first-line treatment of aggressive NHL and filed for first-line treatment of the indolent form.

Worldwide sales of Herceptin, the only targeted treatment approved for use in advanced HER2-positive breast cancer, have effectively doubled in the first quarter 2006 compared with the same period last year. Strong growth was achieved in all major markets. Based on exceptionally strong data on Herceptin's benefits in early-stage HER2-positive breast cancer, US and EU filings for this indication took place in February 2006. As a result of the impressive data, Herceptin is already being used in some countries in the early-stage (adjuvant) setting.

Avastin, a novel cancer therapy with demonstrated survival benefits in metastatic colorectal, breast and lung cancer, also posted strong sales growth in the US and Europe (+141%). Avastin was just filed in the US for the most common form of lung cancer. The first filing for Avastin in Japan has

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<sup>1</sup> Europe/Rest of World: Europe and other countries excluding US and Japan

also been submitted this month for the treatment of advanced colorectal cancer. Furthermore, regulatory filings in advanced NSCLC in Europe and in advanced breast cancer in Europe and the US are on track for later this year. Broadening the current label in metastatic colorectal cancer to include more chemotherapeutic options is also planned in Europe.

Tarceva, a novel targeted drug that has been shown to extend the lives of patients with advanced NSCLC and pancreatic cancer patients, achieved high sales growth of 182%. Only 12 months after the launch in first countries, sales in Europe/RoW made up already more than 30% of total sales while the roll-out in further markets is progressing on-track. The filing for advanced NSCLC in Japan has just been submitted to the authorities this month. The EU regulators are currently reviewing a filing for the treatment of advanced pancreatic cancer submitted in October 2005.

Xeloda has achieved outstanding worldwide sales resulting in a growth of 35%. All regions contributed to this strong increase, in particular the US (+40%) and Europe/RoW (+34%). Sales were positively impacted by further growth in the area of post-surgical (adjuvant) use in colon cancer patients, an indication approved and launched last year in the EU and US. Future filings include stomach cancer and a combination therapy with Avastin in first-line metastatic colorectal cancer.

#### **Anemia – good growth maintained in Europe**

Sales of Roche's NeoRecormon and Chugai's Epogin, for the treatment of anemia, achieved a combined growth of 3%, despite declining Epogin sales in Japan in anticipation of the bi-annual across-the-board price cuts there. Sales of NeoRecormon were up 6% in Europe/RoW.

#### **Transplantation – CellCept remains leading immunosuppressant**

The transplant portfolio achieved further robust growth as sales rose 14% for the quarter. CellCept, the world's top-selling branded immunosuppressant, maintained strong double digit growth (+15%), driven by good performance especially in the US (+32%).

#### **Virology – Tamiflu sales remain strong**

Sales of Tamiflu grew by 37% over last year, driven by pandemic deliveries. Japanese Tamiflu sales were down from the first quarter of 2005 because the flu season 2005/2006 started earlier with already considerable sales in the fourth quarter of 2005. More than 65 countries have already placed orders for pandemic stocks of Tamiflu. Roche has continued to ramp up production capacity for Tamiflu and will be able to produce 400 million treatment courses annually from the end of 2006 significantly exceeding orders that have been received from governments to date. This has been

achieved by using a collaborative network of Roche's facilities and those of a number of independent companies. In March an additional sub-license to manufacture oseltamivir, the active ingredient of Tamiflu, for China was granted to the HEC group. Research into the most effective utilisation of Tamiflu against the H5N1 virus, both internally and through collaborations with outside scientists and physicians and the WHO, continues.

Pegasys sales increased slightly in the first quarter, against a background of declining prescriptions for hepatitis C in the US and a number of European countries. In addition, US sales were affected by an adjustment in wholesaler inventory levels following a price increase late last year. However, Pegasys still commands a stable US market share of above 60% and remains the world's leading treatment for chronic hepatitis C. The National Institute for Clinical Excellence in the UK (NICE) has recommended Pegasys as first-line choice for the treatment of chronic hepatitis B supporting the superior efficacy and cost effectiveness of Pegasys compared to the previous standard of care. As anticipated, Copegus sales saw a marked decline, mainly due to the emergence of generic competition in the US.

The HIV medicine Fuzeon continues its consistent growth trend with sales increasing in the first quarter by 36%. Growth remains strongest in Europe/RoW (+60%).

#### **Other products – Bonviva rolling out in Europe**

Sales of once monthly oral Bonviva/Boniva for the treatment of postmenopausal osteoporosis reached 75 million Swiss francs. Sales came predominantly from the US, with product launches set to continue in a number of European markets this year. In the past quarter, Roche/GSK received FDA and EU approval for the quarterly Bonviva/Boniva injection, an alternative formulation for women for whom oral bisphosphonates are not appropriate.

Xenical performed well in the first quarter with sales growth of 16%. Sales were up both in the US (+24%) and in Europe/RoW (+14%).

Overall Rocephin sales declined substantially (-69%), in line with expectations. Following its US patent expiry in July 2005 sales declined by 96% in the quarter, in Europe/RoW sales were 24% lower.

#### **Major development activities**

In 2006 Roche already received four approvals in major indications and submitted six major filings to regulatory authorities worldwide. In addition, the company's late-stage clinical development

projects showed further progress with an impressive 45 phase III projects going ahead as planned or have been successfully completed in the first quarter.

#### Autoimmune diseases

A significant milestone for MabThera/Rituxan was achieved with the approval in the US for its first rheumatoid arthritis indication. One treatment course comprising two infusions offers lasting benefit to many rheumatoid arthritis patients who have had an unsatisfactory outcome with current biological treatment options. Most patients in the trials who received additional courses did so six months after the previous course. A regulatory filing was submitted to European authorities in September 2005.

Since end 2005/early 2006, patient recruitment is ongoing in the MabThera phase III programme for patients who have had an inadequate response or who are intolerant to treatment with one or more disease-modifying antirheumatic drugs (DMARDs), including two trials specifically studying the effect of further courses. Last month Genentech announced that a next generation anti-CD20 humanised monoclonal antibody (ocrelizumab) phase II study in rheumatoid arthritis met its primary endpoint and showed clinical activity in all dose levels studied. The development of Actemra (formerly known as MRA) for rheumatoid arthritis is progressing well with more than 2,500 of the targeted 4,100 patients already recruited for the international phase III programme. The results of a second Japanese phase III study confirmed earlier results in showing significant improvements in slowing down joint damage. Chugai will submit a filing for Actemra to Japanese regulators shortly.

#### Oncology

The development programme with Avastin is investigating the medicine in a broad range of cancers, including renal cell carcinoma, pancreatic cancer, ovarian cancer and prostate cancer. Trials to expand the options for combining Avastin with other chemotherapeutic agents for the treatment of metastatic colorectal cancer, non-small cell lung cancer (NSCLC) and metastatic breast cancer are also ongoing. In addition, preparations are underway to start phase III trials in the adjuvant indication of NSCLC and breast cancer, and Genentech recently started recruiting into an adjuvant rectal cancer study. The result of the review process regarding the adjuvant colon cancer study (AVANT) is expected in May. A Xeloda trial in advanced gastric cancer has met its primary endpoint showing it to be at least as effective as current therapy. This followed positive survival data seen in a Xeloda study in pancreatic cancer. The phase III programmes of MabThera/Rituxan in Chronic Lymphocytic Leukaemia (CLL), Herceptin in gastric cancer, Xeloda in metastatic colorectal cancer and adjuvant colon and breast cancer, and Tarceva in NSCLC and glioblastoma

are on track. In addition, Roche expects data on the use of Herceptin in combination with hormonal therapy in metastatic breast cancer during 2006.

#### **Anemia**

The first filing of CERA, the first Continuous Erythropoietin Receptor Activator for the treatment of anemia in chronic kidney disease was submitted to the US authorities in April having completed the largest development programme undertaken for this indication. The programme involved four phase III studies which investigated the outcome of converting renal anaemia patients from existing erythropoietin stimulating agents to CERA at extended dosing intervals and two phase III studies which investigated the treatment (correction) of anaemia in previously untreated patients in comparison to standard treatments. The European filing for CERA is due to follow imminently. In the oncology setting, Roche has started recruiting patients for an additional dose-optimisation study.

#### **Strong R&D pipeline**

As of March 31, Roche has 59 new molecular entities (NME's) and 53 additional indications (AI) in its R&D pipeline (phase 0-3). During the first quarter of 2006, the following changes in the pipeline occurred: Phase I - one project moved in and two projects were discontinued, Phase II - two projects newly entered and two projects were discontinued, and Phase III - five projects newly entered and one project received regulatory approval. There were no discontinuations in phase III during the period. A complete overview of the Roche Pharma R&D pipeline is available on the Internet ([www.roche.com/inv\\_pipeline](http://www.roche.com/inv_pipeline)).

### **Diagnostics Division**

#### **Above market sales in Europe, Asia and Latin America**

The Diagnostics Division increased its sales by 3% in local currencies (8% in Swiss francs) in the first quarter of 2006. The division's molecular diagnostics business and immunodiagnosics portfolio continued to be the main growth factors, with Applied Science and Near Patient Testing also delivering solid performances. Double-digit sales gains were posted in Asia Pacific and Iberia/Latin America, and above-market growth in the high single digits was recorded in the EMEA region (Europe, Middle East and Africa). In the relatively flat market environment in Japan, Roche Diagnostics continued to grow ahead of the market. In the US, revenues were down owing to erosion of Accu-Chek Advantage sales.

#### **Diabetes Care – new Accu-Chek generation gaining momentum**

Sales of Diabetes Care (-5%) were affected by the performance of the Accu-Chek Advantage in the US. The recent launch of the successor product, Accu-Chek Aviva, has so far only partially made up for declining US sales of the Advantage system. The launch of the integrated test strip system, Accu-Chek Compact Plus, in the US and Canada will help to further expand Roche's market leadership position in this fast growing segment. High placements of Accu-Chek Aviva in North America, EMEA, and now also in Japan, are contributing to regaining market share and compensating for the decline in Accu-Chek Advantage sales. The Accu-Chek Smart Pix Device Reader has been launched globally. It allows people with diabetes and Health Care Professionals to view blood glucose readings and insulin doses. With this, Accu-Chek products further cover overall diabetes care management.

#### **Centralized Diagnostics –immunochemistry sales up strongly**

Maintaining its leading market position sales of Centralized Diagnostics grew by 7%. The immunochemistry business continued to be the main growth driver, with Elecsys products posting an impressive 16% increase in sales. Continued rising demand for the Elecsys proBNP cardiac assay was just one of the factors contributing to increased Elecsys sales.

In 2006 the business area is focused on rolling out its cobas 6000 series, the first of the next generation of modular analytical systems for medium-sized laboratories.

#### **Molecular Diagnostics – new sepsis test available in Europe**

This business area increased its sales by 7%. The major focus for 2006 will be the EU launch and US FDA filing for the new automated cobas s 201 modular blood screening system and more comprehensive cobas TaqScreen MPX test which simultaneously detects HIV and hepatitis C and B viruses in donated blood. This test received the CE Mark ("Conformité Européenne") in March. The LightCycler SeptiFast Test was launched in Europe in January and can rapidly and reliably detect and identify 25 different sepsis-causing pathogens - including bacteria and fungi - which cause approximately 90 percent of all sepsis cases. This new test opens up a whole new dimension in the management of "blood poisoning" as rapid initiation of targeted treatment is crucial in this condition.

#### **Near Patient Testing – new coagulation monitoring system on the market**

Significant sales growth (+9%) was achieved by the Near Patient Testing business. The newest coagulation monitoring system - CoaguChek XS - commenced its European roll-out in January. This instrument allows more patients on long-term oral anticoagulation therapy to have access to the advantages of self-monitoring and gives them information about their coagulation status

directly on the spot, virtually pain-free from one drop of blood. Sales of the Cardiac product line rebounded in growth, primarily driven by the roll-out of Cardiac proBNP in the EMEA region, Latin America and Asia Pacific.

#### **Applied Science – remain strong player in life science research**

With sales advancing by 10%, Applied Science posted solid growth. This is based on the introduction of the Light Cycler 480 which provided a very competitive platform for high throughput real-time PCR applications in the research market. The introduction of the innovative and fast Genome Sequencer 20 marked the entry into the attractive sequencing research market. This system is the first product out of the strategic alliance with 454 Life Sciences and has been very well accepted in all global markets.

#### **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 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet ([www.roche.com](http://www.roche.com)).

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#### **Additional information**

- Media release with sales tables: [www.roche.com/med-cor-2006-04-26](http://www.roche.com/med-cor-2006-04-26)
- Half-year results 2006: July 20 (tentative)
- Nine months sales 2006: October 17 (tentative)

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