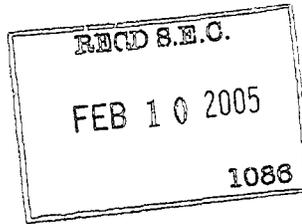
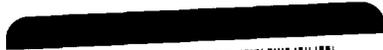


# Media release



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## Roche in 2004: Net income doubled — further significant improvement in operating profitability and financial position

### Roche Group in 2004

- Sales show double-digit increase of 12% in local currencies (9% in Swiss francs; 18% in US dollars) to 29.5 billion Swiss francs\* — growth well above the market average
- Operating profit increases 24% in local currencies (20% in Swiss francs) to nearly 7 billion Swiss francs\*\*
- Operating profit margin improves for third consecutive year: up 2.2 percentage points to 23.5%\*\*
- Net income more than doubles to 6.6 billion Swiss francs
- Board to propose 18th consecutive dividend increase, 21% to 2 Swiss francs
- Substantial increase in net liquidity, from 5.9 to 11.7 billion Swiss francs
- Sale of Consumer Health completes strategic refocusing process

### Roche Pharmaceuticals in 2004

- Sales increase 13% in local currencies (10% in Swiss francs), well ahead of the global market
- Operating profit margin (before exceptional items) up 1.9 percentage points to 25.7%
- Strong demand for Avastin and established oncology products

### Roche Diagnostics in 2004

- Market share expanded further as sales grow 8% in local currencies (6% in Swiss francs)
- Operating profit margin (before exceptional items) increases by a substantial 2.4 percentage points to 21.4%
- Roche becomes first company to launch chip-based test for broad diagnostic use

### Outlook

- Roche expects local-currency sales in both divisions to continue to outpace market growth in 2005
- Pharma: operating profit margin for 2005 (before exceptional items) expected to be broadly in line with that in 2004, despite investments in product launches (Avastin, Tarceva, Boniva) and significant development activities
- Diagnostics: additional progress towards achieving an operating profit margin of around 23% (before exceptional items) in 2006
- A balanced financial income in 2005

\* Basis: continuing businesses / \*\* Basis: continuing businesses before exceptional items

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Commenting on the full-year results for 2004, Roche Chairman and CEO Franz B. Humer said, 'We achieved — and in some cases even exceeded — our ambitious goals for the year. Our operating profit was the highest ever in Roche's history. We gained marketing approvals for two breakthrough anticancer medicines. And we intensified the focus on our core capabilities. Thanks to a very strong operating performance and the gain from the sale of our consumer health business, net income more than doubled, reaching 6.6 billion Swiss francs. Given the tremendous need for new and better medical solutions and the explosive progress of science and technology, the outlook for continued growth is good despite today's challenging marketplace. We thus expect sales in both divisions to continue to grow faster than the market this year.'

**Key figures** *in millions of CHF*

	Roche Group				Continuing businesses <sup>a)</sup>			
	2004	2003	in CHF	% change in local currencies	2004	2003	in CHF	% change in local currencies
Sales	31,273	31,220	0	3	29,522	27,190	9	12
EBITDA <sup>b)</sup>	9,566	8,609	11	15	9,231	8,038	15	19
Operating profit before exceptional items	7,254	6,268	16	20	6,950	5,793	20	24
Operating profit	8,979	5,592	61	65	6,179	5,520	12	16
Net income before exceptional items	—	—	—	—	4,343	3,371	29	—
Net income	6,641	3,069	116	—	4,339	3,074	41	—
Research and development	5,093	4,766	7	11	5,053	4,624	9	14
Additions to property, plant and equipment	2,357	2,265	4	8	2,351	2,080	13	17
Diluted earnings per share and non-voting equity security (in CHF)	7.81	3.61	116	—	5.09	3.62	41	—
Dividend per share and non-voting equity security (in CHF) <sup>c)</sup>	2.00	1.65	21	—	—	—	—	—
Employees	64,703	65,357		-1	64,594	63,267		2

- a) Continuing businesses includes the Pharmaceuticals and Diagnostics businesses, treasury and other corporate activities. Consumer Health (OTC) and Vitamins and Fine Chemicals are reported as discontinuing businesses.
- b) EBITDA: Earnings before exceptional items and before interest and other financial income, tax, depreciation and amortisation, including impairment. This corresponds to operating profit before exceptional items and before depreciation and amortisation, including impairment.
- c) 2004 dividend as proposed by the Board of Directors.

## Roche Group

Sales revenues from the Group's continuing businesses rose to 29.5 billion Swiss francs in 2004, an increase of 12% in local currencies (9% in Swiss francs) and 18% in US dollars; these results exclude the

consumer health (OTC) businesses and the vitamins and fine chemicals business, which was sold in 2003. Both Roche divisions, Pharmaceuticals and Diagnostics, grew significantly faster than the global market. Prescription drug sales advanced 13% in local currencies (10% in Swiss francs), with positive contributions to growth coming from the Roche Prescription subdivision (+8% in local currencies) and from the strategic alliances with Genentech in the United States (+45% in US dollars) and Chugai in Japan (+3% in Japanese yen). In the Diagnostics Division sales rose 8% in local currencies (6% in Swiss francs), led by the division's diabetes care, molecular diagnostics and immunochemistry businesses, which grew significantly ahead of their markets.

#### **Significant improvement in operating profit and operating margins**

Operating profit from continuing businesses was up substantially for the year, advancing 24% in local currencies (20% in Swiss francs) to nearly 7 billion Swiss francs (before exceptional items). The operating profit margins in both divisions again increased sharply. In the Pharmaceuticals Division it rose 1.9 percentage points to 25.7%, while the margin in the Diagnostics Division gained 2.4 percentage points to reach 21.4%. Strong sales growth, productivity improvements and the gains realised on the disposal of non-core products and technologies as Roche continued to realign its product portfolio were major contributors to the Group's improved profitability. Together these factors more than offset increased costs for new product launches, investments in the Group's R&D pipeline and expenditures on in-licensing agreements for products and technologies. Even excluding gains from the disposal of products, the operating margin improved significantly.

#### **Significant increase in net liquidity and equity-to-assets ratio**

Thanks to the strong operating performances of the Group's continuing businesses, EBITDA from these businesses increased 15% to 9.2 billion Swiss francs. The EBITDA margin in the Pharmaceuticals Division reached 32.6%, compared with 31.5% the year before, and in the Diagnostics Division it advanced 2.7 percentage points to 31.2%. The Group's net liquidity nearly doubled, from 5.9 to 11.7 billion Swiss francs, thanks to the strong positive cash flows from the divisions, the sale of the consumer health (OTC) businesses and the conversion of the 'LYONs IV' notes. The ratio of equity to total assets rose significantly, from 49% to 57%. The sale of the OTC businesses (Roche and Chugai) resulted in an exceptional pre-tax gain totalling 2.3 billion Swiss francs. The Group also completed a major acquisition during the year, purchasing Igen in the United States in early 2004 for a total consideration of 1.6 billion Swiss francs.

#### **Further improvement in financial income**

Financial income showed further improvement compared with the previous year, with the Group recording a net financial expense of 359 million Swiss francs for 2004 (after an expense of 667 million

Swiss francs in 2003). Group debt was reduced by a further 6.3 billion Swiss francs, to 9 billion Swiss francs, resulting in a decrease in interest expense. The conditions are thus now in place for a balanced financial income in 2005. The conversion and redemption of debt instruments yielded an exceptional pre-tax gain of 908 million Swiss francs. Including this exceptional gain, financial income for 2004 was positive.

#### Net income doubled

Net income increased 116% (or 3.6 billion Swiss francs) to 6.6 billion Swiss francs thanks to the further improvement in the Group's operating results and the gains from the sale of the OTC businesses and the conversion and redemption of debt instruments. Even excluding exceptional items and the Group's discontinuing businesses, net income showed an increase of 972 million Swiss francs, or 29%.

#### Outlook positive

In 2005 the results in the Pharmaceuticals Division will be influenced by the expiry of the US patent for Rocephin and by costs for product launches in key markets and significant development activities. As an overall outcome the division anticipates local-currency sales growth above the world market and an operating profit margin (before exceptional items) broadly in line with that for 2004. In 2005 Roche Diagnostics expects to outgrow the world market again in terms of local-currency sales. The division also expects further progress towards its goal of an operating profit margin (before exceptional items) of around 23% in 2006. In addition, Roche expects a balanced financial income in 2005.

#### Eighteenth consecutive annual dividend increase

In view of the strong increases in operating profit and net income, the Board of Directors will propose a dividend increase of 21%, to 2 Swiss francs per share and non-voting equity security, at the Annual General Meeting on 28 February 2005. If approved, this will be Roche's eighteenth consecutive dividend increase.

## Pharmaceuticals Division

### Growth well above the market average

Key figures	In millions of CHF	% change in CHF	% change in local currencies	As % of sales
Sales	21,695	10	13	100
EBITDA	7,079	14	18	32.6
Operating profit*	5,573	19	23	25.7
Research and development	4,355	12	17	20.1

\* Before exceptional items

Roche Pharmaceuticals — including Genentech and Chugai — continued to deliver strong performance in 2004, recording total sales of 21,695 million Swiss francs. This represents an increase over the previous year of 13% in local currencies, well ahead of the global market. Once again, growth was driven by the Group's oncology, virology and transplantation franchises. Operating profit (before exceptional items) increased further, advancing 23% in local currencies and 19% in Swiss francs to 5,573 million Swiss francs. Despite a sustained high level of investment in R&D and product launch activities, the division posted another significant increase in profitability, recording an operating profit margin (before exceptional items) of 25.7%, compared with 23.8% in 2003. EBITDA totalled 7,079 million Swiss francs or 32.6% of sales, compared with 31.5% the previous year.

#### **Market share gains in the United States**

All regions contributed to growth in 2004. Sales growth weakened slightly during the fourth quarter of 2004 compared with the record highs of the prior-year period. This was primarily due to the late start of the 2004/2005 influenza season. Excluding this effect, fourth-quarter sales growth was in the double digits.

Sales by Roche and Genentech in North America were up 20% (all growth rates are based on local currencies) in 2004, well ahead of the market (8%), fuelled primarily by strong demand for Avastin, established oncology brands and the hepatitis combination Pegasys and Copegus. The oncology and hepatitis franchises were also the main contributors to above-market growth in Europe (12% vs a 7% market average). Sales by Chugai in Japan rose 3%, compared with local market growth of 2%. In Latin America the division recorded double-digit sales growth against a background of steady market recovery. Growth in the markets of the Asia-Pacific region was strong, while in the Middle East and Africa it held up well despite political and economic turbulence.

#### **Oncology — further innovative products launched**

In 2004 the Roche Group's oncology portfolio earned revenues of 7.7 billion Swiss francs and posted a gain of 32%. Roche is the only pharmaceuticals group offering five anticancer medicines that can help extend the lives of cancer patients.

MabThera/Rituxan, the world's first therapeutic monoclonal antibody for indolent and aggressive forms of non-Hodgkin's lymphoma (NHL), delivered strong growth in 2004, particularly in Europe and Japan. Sales of the product benefited from its approval last August in Europe for first-line use in indolent NHL; new data show a survival benefit for this group of patients. In addition, two large clinical trials have shown that maintenance treatment with MabThera/Rituxan over two years is highly effective in patients with indolent NHL.

Herceptin, a monoclonal antibody for the targeted treatment of breast cancer, generated sales of almost 1.5 billion Swiss francs, with solid gains in all major markets. Adoption of the drug as first-line therapy received a major boost in June 2004, when the combination of Herceptin plus Taxotere was approved for this indication in the European Union.

Total sales of Xeloda, for colorectal and breast cancer, rose 7% in 2004, with growth outside the United States an impressive 31%. Although sales growth in the United States was impacted in the first half of the year by a number of important changes in the marketplace, prescription figures continued to show increasing adoption of the product. In August Roche filed applications with the EU and US authorities for approval of Xeloda in a new indication, adjuvant treatment of colon cancer patients following surgery.

In February Genentech received approval for Avastin in the United States for use in combination with chemotherapy in patients with previously untreated metastatic cancer of the colon or rectum. After an extremely successful launch, demand for the product in its first market has been strong, resulting in sales of almost 700 million Swiss francs in less than 12 months. In January 2005 Avastin also received marketing approval in the European Union. In December Avastin was approved in Switzerland, which also opens the way to registration of the medicine in over 90 countries. Clinical trials have repeatedly demonstrated that Avastin, when added to chemotherapy, significantly prolongs survival in patients with metastatic colorectal cancer, regardless of the chemotherapy used.

Tarceva, a breakthrough anticancer drug developed by Genentech, OSI Pharmaceuticals and Roche, was approved by the US Food and Drug Administration (FDA) in November as monotherapy for advanced non-small cell lung cancer (NSCLC). Approval, which followed a priority review, was based on the results of a phase III trial showing that the drug extends overall survival in patients with pretreated lung cancer. An application for marketing authorisation is being evaluated by the EU authorities. Data from another phase III study showed that Tarceva increases the survival of patients with metastatic pancreatic cancer when added to chemotherapy. Tarceva is currently being investigated in a variety of malignant diseases.

Kytril, used to control nausea and vomiting in patients receiving chemo- or radiation therapy or who have undergone surgery, continued to perform well in a highly competitive marketplace.

#### **Anemia – new pre-filled syringe for NeoRecormon patients**

Against a background of continued price pressure in the anemia market as a whole, Roche's NeoRecormon and Chugai's Epogin posted combined sales of 2.1 billion Swiss francs. Sales of NeoRecormon in cancer-related anemia grew by 14%, driven by the successful launch and penetration of

a new once-weekly 30,000 IU pre-filled syringe that offers patients high efficacy plus convenient dosing.

#### **Transplantation — global market leadership achieved**

Roche is now the global market leader in transplantation medicines. In 2004 the Group's transplantation portfolio posted sales of 1.8 billion Swiss francs, an increase of 11%, with Roche's flagship transplantation drug CellCept showing solid growth. While CellCept remains the leading branded immunosuppressant in the United States, with total prescriptions up by 24%, US sales were negatively impacted in the second half of the year by changes in wholesaler buying patterns, the effects of which are expected to disappear during the first half of 2005.

Combined sales of Valcyte and Cymevene showed solid growth of 22% in 2004 as Valcyte became the global market leader for the prevention of cytomegalovirus infection (CMV).

#### **Virology — Pegasys gains additional market share**

In 2004 Roche enhanced its leadership position in hepatitis C, with sales of its combination therapy Pegasys plus Copegus advancing to over 1.5 billion Swiss francs. At year end Pegasys accounted for over 60% of both the US and global pegylated interferon markets. During the year new data demonstrated the significant benefits of Pegasys plus Copegus in two hepatitis C patient subgroups: patients co-infected with HIV, and patients with persistently normal liver enzymes (normal ALT), a subgroup that would traditionally not be considered for treatment. Roche received marketing authorisation in Europe for the normal ALT indication in November. Regulatory filings for approval of the combination in HIV-HCV co-infection were submitted in mid-2004 in the European Union and in the United States. Roche received a positive opinion from the EU authorities in December, and the US filing has been granted priority review. Roche has completed its development programme for Pegasys in chronic hepatitis B, with extensive clinical trial data supporting its use as a first-line treatment of the disease. Marketing applications have now been filed in Europe, the United States and elsewhere. In January 2005 the EU authorities recommended approval.

Sales of Fuzeon, for the treatment of HIV, improved steadily in 2004, reaching 168 million Swiss francs at year end. Roche and Trimeris are working to accelerate the uptake of Fuzeon through major physician and patient education initiatives.

#### **Other major products — Rocephin sales remain stable**

Global sales of Xenical were down slightly in a market that is still in overall decline. While US sales fell significantly, the product experienced steady growth elsewhere.

Rocephin remained the world's leading injectable antibiotic in 2004, posting total sales of over 1 billion Swiss francs. Rocephin had a strong year in the United States, with sales growing 8%.

Due to a relatively mild influenza season, sales of Tamiflu declined despite initial orders of pandemic

readiness supplies. Preclinical tests have shown Tamiflu to be effective against the highly pathogenic human and avian H5N1 influenza virus, considered the most likely source of a pandemic strain. Boniva/Bonviva is being developed as the first once-monthly oral treatment for postmenopausal osteoporosis. One-year data from a two-year multinational study show that once-monthly oral Boniva is an effective, well-tolerated and convenient alternative to current daily and weekly oral bisphosphonate regimens and has the potential to improve long-term treatment adherence. In addition, new data from a multinational study of injectable Boniva have shown it to be the first injectable bisphosphonate that is effective when administered once every two or three months. The once-monthly oral formulation has already been filed in the United States, the European Union and Switzerland. A marketing application for Boniva two-monthly or three-monthly intravenous injection was submitted to the US FDA at the end of 2004.

#### **Research and development — 64 new molecular entities**

Roche Pharmaceuticals invested 4.4 billion Swiss francs in R&D in 2004. At 20.1% of sales, this again puts Roche above the industry average and shows its strong commitment to innovation.

The Pharmaceuticals Division R&D pipeline currently includes 64 new molecular entities (NMEs), of which 13 are in phase 0, 30 in phase I, 13 in phase II and eight in phase III or filed.

In the division's main growth area, oncology, Roche Research and Development increased the number of projects to 60, twelve more than at the end of 2003. Roche currently has 107 research projects across seven therapeutic areas and 79 development projects in eight therapeutic areas.

Development of CERA, the first continuous erythropoietin receptor activator, for the treatment of renal and cancer-related anemia is progressing on track. CERA represents a major advance in anemia management. Recruitment into global phase III renal anemia studies is advancing well, and phase III studies in cancer-related anemia are scheduled to begin in the second half of 2005. Roche plans to file marketing applications in the United States and elsewhere in 2006.

Roche, Genentech and Biogen Idec are developing MabThera/Rituxan for the treatment of rheumatoid arthritis (RA). It is the first B-cell depleting agent to be studied in this disease. Development is progressing on track and global filings for an initial indication — in patients with an inadequate response to currently prescribed biologics — are planned for the second half of 2005. Development of MRA for the treatment of RA is also progressing on track. Phase III studies of this novel biopharmaceutical in RA commenced in Europe and the United States at the end of 2004.

Work is continuing on development of the insulin sensitiser R483 in the treatment of type 2 diabetes. Following new guidance by the FDA on data requirements for the class of drugs to which R483 belongs, Roche has decided to wait for the results of ongoing long-term toxicity studies before starting phase III clinical trials. The toxicity studies will be completed in the first half of 2005.

## Diagnostics Division

Above-market growth in all business areas

Key figures	In millions of CHF	% change in CHF	% change in local currency sales	As % of sales
Sales	7,827	6	8	100
- Diabetes Care	2,895	7	10	37
- Near Patient Testing	554	1	3	7
- Centralized Diagnostics	2,743	4	5	35
- Molecular Diagnostics	1,104	8	11	14
- Applied Science	531	5	7	7
EBITDA	2,444	16	17	31.2
Operating profit*	1,675	19	21	21.4
Research and development	698	-4	-2	8.9

\*Before exceptional items

Roche Diagnostics remained on the growth track, with sales advancing 8% in local currencies and 6% in Swiss francs. Sales grew significantly faster than the market in all five of the division's business areas, led by particularly strong gains in the diabetes care, molecular diagnostics and immunochemistry segments. As a result, the division reinforced its position as the global market leader. Profitability also improved further. The division's operating profit margin (before exceptional items) reached 21.4%, and the EBITDA margin climbed 2.7 percentage points to 31.2%. These figures set a new industry benchmark. Operating profit (before exceptional items) increased 19% to 1,675 million Swiss francs, while the division's EBITDA rose 16% to 2,444 million Swiss francs.

Roche Diagnostics invested 698 million Swiss francs in research and development, significantly more than any competitor. The division is concentrating its research efforts primarily on its three fastest-growing segments — molecular diagnostics, diabetes and immunochemistry.

### Double-digit growth rates sustained in Asia

Roche Diagnostics outpaced the market in all regions. Once again, sales advanced at double-digit rates in Iberia/Latin America (14%) and the Asia-Pacific region (13%). The division continued to expand its market leadership in both these regions. Sales increased 11% in Japan, helped by the success of the division's diabetes care, blood screening and immunochemistry businesses. After adjusting for the sale of several product lines in 2003, North American sales rose 6% on a comparable basis, an increase well above the market growth rate. Diabetes management products, molecular diagnostics and immunochemistry were the biggest growth segments in Europe. Sales in this market region (which includes the Middle East and Africa) advanced 7% for the year, and thus also grew significantly faster than the market.

#### **Diabetes Care — new and established products on the success track**

Roche Diabetes Care remained the leading provider of solutions for better diabetes management, with sales growing 10% in local currencies. Once again, the Accu-Chek Advantage and Accu-Chek Compact blood glucose meters were among the top-selling products. The state-of-the-art Accu-Chek D-TRONplus insulin pump — the first pump to carry the Accu-Chek name — was launched in 2004. Also new is Accu-Chek Pocket Compass 2.0, a diabetes management software package for personal digital assistants that completes the 'circle of care' by allowing users to record and track data from both a blood glucose meter and an insulin pump.

2004 also saw the launch of Accu-Chek Multiclix, the world's first lancing device to use an integrated lancet drum. Multiclix offers enhanced hygiene and safety because lancets automatically retract into the six-lancet drum immediately after use.

In mid-2003 the FDA issued a letter citing certain deficiencies in manufacturing processes and documentation at Disetronic, the insulin pump manufacturer acquired by Roche earlier that same year. The procedures and processes in question have since been modified to conform to the Roche Group's worldwide quality standards. Roche is working closely with FDA officials in preparation for the pending FDA re-audit of the Burgdorf production site in Switzerland. Following successful completion of the re-audit, Roche will move quickly to start sales of its new-generation insulin pumps in the United States.

#### **Near Patient Testing — coagulation portfolio posts strong results**

Sales in this business area grew 3% in local currencies in 2004. Sales of coagulation monitoring products — a segment in which Roche has by far the largest market share — grew by more than 16%, with demand fuelled mainly by the continuing trend to systematic anticoagulation management. More and more European health insurers have begun reimbursing the costs of patient self-monitoring now that the benefits have been documented in several international clinical trials. Self-monitoring has been shown, for example, to significantly reduce the risk of thrombosis in patients with artificial heart valves.

Roche Diagnostics is also the leader in the hospital point-of-care segment (rapid testing products for use in hospitals and at accident scenes). Placements of OMNI S multifunctional blood gas analysers showed a fourfold increase over 2003.

#### **Centralized Diagnostics — moving towards leadership in immunochemistry**

Roche Centralized Diagnostics reported above-market sales growth of 5% in local currencies.

Performance in this business area was largely driven by a strong rise in immunochemistry sales, with the acquisition of Igen providing an important additional stimulus to growth. Completed in February 2004, this strategic transaction secures Roche's rights to the electrochemiluminescence (ECL) technology underlying the Elecsys line of immunochemistry products. From 2001 to 2003 this product line consistently achieved sales growth above 20%. In 2004 new placements of Elecsys systems reached a

record high, and sales rose another 21%. In the medium term Roche Diagnostics aims to become the leader in immunochemistry, a growth market currently valued at 8.6 billion Swiss francs.

In the cardiovascular testing segment, Centralized Diagnostics has increased the availability of NT-proBNP — a key marker for heart failure — through out-licensing agreements, and last year also expanded its own product portfolio further by in-licensing the marker hsCRP (high sensitivity C-reactive protein).

#### **Molecular Diagnostics — first AmpliChip test launched**

Sales of diagnostic products were up 12% in local currencies, while sales of enzymes to industrial customers, which account for a smaller percentage of revenues, showed a gain of 8%. Blood screening and women's health products were the main growth drivers. Sales in the blood screening segment advanced by an impressive 32%. Roche's viral tests are used to screen more units of blood worldwide than any other nucleic acid-based (NAT) testing system. 2004 saw the signing of three major agreements in this area. One of the agreements extends Roche's exclusive contract with the Japanese Red Cross for an additional four years, while another provides for the Korean Red Cross to use Roche tests to screen 70% of its blood donations. The third agreement, with the German Red Cross, marks Roche's entry into the German blood screening market.

In addition, an application for clearance of Cobas AmpliScreen HBV Test for screening donor blood for the hepatitis B virus was submitted to the FDA. Filings have also been submitted to the FDA for expanded indications of the Cobas AmpliScreen HIV and HCV products for NAT testing of cadaveric fluid for HIV and hepatitis C virus. Clearance of the products for these indications will help increase the safety of organ and tissue donations.

In 2004 the division added another important test to its women's health portfolio with the successful European rollout of Amplicor HPV Test. HPV (human papillomavirus) infection is recognised as the leading cause of cervical cancer. Tests for chlamydial infections and gonorrhoea, which are among the most common sexually transmitted diseases, posted double-digit sales growth. In 2004 Roche Molecular Diagnostics maintained its leading position in the fiercely competitive virology market. The business area's quantitative test for hepatitis B and qualitative test for hepatitis C were two of the major growth drivers.

Sales in the genomics segment showed double-digit growth. This strong gain was due in part to AmpliChip CYP450 Test — the world's first microarray-based test for clinical diagnostic use — which was launched during the year in Europe. Since January 2005 it has also been cleared for marketing in the United States. This novel test provides valuable information for assessing the body's ability to metabolise medications, which can vary greatly between individuals.

### **Applied Science — LightCycler instruments on growth track**

Sales in this business rose 7% in local currencies. Growth was led by sales of LightCycler reagents and by Applied Science's industrial business, with a major contribution coming from new placements of LightCycler instruments. Placements of this DNA amplification system continue to increase steadily, particularly in high-growth markets in the Asia-Pacific region.

### **Additional information**

- Media release including a full set of tables: [www.roche.com/med-cqr-2005-02-02.htm](http://www.roche.com/med-cqr-2005-02-02.htm)
- Annual Report 2004: [www.roche.com/fig-annualrep-2004.htm](http://www.roche.com/fig-annualrep-2004.htm)
- Presentations / live media conference broadcast (starting at 10 am CET):  
[www.roche.com/med\\_events\\_bmk05.htm](http://www.roche.com/med_events_bmk05.htm)
- Photographs of the media conference (starting at 2:00 pm CET):  
[www.roche.com/pages/downloads/photosel/050202/](http://www.roche.com/pages/downloads/photosel/050202/)
- First-quarter sales 2005: 19 April (tentative)
- First-half results 2005: 20 July (tentative)
- Nine-month sales 2005: 19 October (tentative)

### **Media Office contacts**

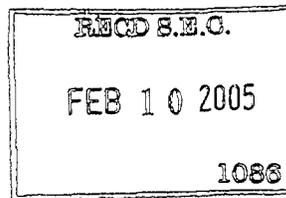
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# Media Release



Basel, 3. February, 2005

## **Pegasys combination therapy approved for the treatment of hepatitis C and HIV co-infection in Europe**

**Pegasys becomes the first and only hepatitis C treatment indicated for patients suffering from both HIV and HCV**

The European Commission has approved Pegasys (peginterferon alfa-2a (40KD)) in combination with ribavirin for the treatment of chronic hepatitis C (HCV) in clinically stable patients co-infected with HIV. This Commission Decision comes only one month after the Positive Opinion was granted by the European Medicines Agency (EMA), and it is now the first hepatitis C treatment to be indicated in HIV-HCV co-infected patients in the European Union. Co-infection has emerged as a major public health concern with data suggesting that globally 30% of patients with HIV infection are also infected with HCV<sup>I,II,III</sup>.

"This new indication represents a major breakthrough in the treatment of patients infected with both HIV and HCV in Europe," said William M. Burns, CEO of Roche's Pharmaceutical Division. "Roche has a strong heritage of developing anti-viral medications for hepatitis, and this new indication further reinforces our commitment to finding innovative solutions for patients with unmet medical needs."

The approval of Pegasys combination therapy for the treatment of HIV-HCV co-infected patients follows the recent European Commission approval of Pegasys for the treatment of hepatitis C patients with persistently 'normal' liver enzymes, as well as several approvals worldwide for Pegasys in the treatment of chronic hepatitis B with additional milestones expected for this leading hepatitis treatment throughout 2005.

### **The study on which the approval has been granted**

The extension of the current label is based on the results of APRICOT (AIDS Pegasys Ribavirin International CO-infection Trial). APRICOT is the first and only international multi-centre

prospective study evaluating the efficacy and safety of pegylated interferon combination therapy in HIV-HCV co-infected patients. Results from the trial were recently published in the peer-reviewed *New England Journal of Medicine*<sup>1</sup>.

According to Dr. Francesca Torriani, Associate Professor of Medicine, Antiviral Research Centre, University of California and the lead author of the APRICOT study, "It is clearly important that we treat these patients as we now know that the leading cause of death in HIV-HCV co-infected patients is liver disease as a result of hepatitis C. With great strides being made in potent antiretroviral therapy, allowing HIV-infected patients to live longer, we don't want to see those benefits disappear by the emergence of fatal liver disease."

#### **APRICOT Results**

Investigators randomized 868 patients from 19 countries into APRICOT. Patients co-infected with HIV-HCV were randomized to receive either Pegasys 180 µg once weekly plus ribavirin 800 mg daily; Pegasys 180 µg monotherapy once weekly (plus placebo), or conventional interferon alfa-2a (Roferon® A) 3MIU three times a week in combination with ribavirin 800 mg daily, all for 48 weeks.

The key results of APRICOT were:

- 40% of patients treated with Pegasys plus ribavirin achieved a sustained virological response (SVR, which is indicative of a cure) compared with 20% of patients treated with Pegasys monotherapy and 12% of patients treated with conventional interferon/ribavirin.
- Genotype 1 patients, those with the most difficult to treat type of the virus, treated with Pegasys plus ribavirin achieved a four-fold increase in SVR compared with conventional interferon/ribavirin (29% vs 7%).
- 62% of genotype 2/3 patients treated with Pegasys plus ribavirin combination therapy achieved an SVR compared to 20% with conventional interferon/ribavirin.
- Pegasys plus ribavirin therapy effectively treated hepatitis C in patients with HIV-HCV co-infection being compatible with antiviral treatment and had a positive effect on the virological control of HIV infection.
- In APRICOT, treatment with Pegasys plus ribavirin was associated with the greatest overall histological improvement, even in patients who do not achieve an SVR.

#### **About Pegasys**

Pegasys, the market leader worldwide in hepatitis C therapy, provides significant benefit over conventional combination interferon therapy in HCV patients of all genotypes. The benefits of

Pegasys are derived from its large 40 kilodalton (KD) branched-chain polyethylene glycol (PEG) construction, which allows for sustained drug levels over the course of a full week. Pegasys also distributes more readily to the liver (the primary site of infection) than conventional interferon. Pegasys is the only pegylated interferon available as a ready-to-administer solution. Each weekly subcutaneous injection contains 180mcg of pegylated interferon alfa-2a (40KD), which is the approved dose for all patients, regardless of body weight.

### **Roche in Virology**

Roche is committed to the field of virology, having introduced effective treatments for hepatitis C as well as having a range of medications for HIV. Roche introduced Roferon-A, followed by Pegasys in hepatitis C and now Pegasys is demonstrating similar superior efficacy over conventional interferon in hepatitis B. Roche also has its own brand of ribavirin, Copegus, to be used in conjunction with Roferon-A or Pegasys for HCV. Since 1986, Roche has been at the forefront of groundbreaking research and development of new drugs and technologies for care of patients with HIV. Medications developed by Roche for HIV include Fortovase and Invirase (two formulations of saquinavir), administered in combination with zidovudine, and Viracept (nelfinavir). Viracept, introduced in 1997, has proven efficacy and safety in the treatment of HIV infection, is widely used in early treatment and has a unique cross-resistance profile. Most recently, Roche introduced Fuzeon (enfuvirtide), the world's first HIV fusion inhibitor and the first innovation in HIV treatment since 1996. Roche manufactures HIV, HBV and HCV diagnostic systems under the tradename AMPLICOR to detect the presence of, and quantity of HIV RNA, HCV RNA, or HBV DNA in a person's blood.

### **Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-intensive healthcare groups. Its core businesses are pharmaceuticals and diagnostics. As a supplier of innovative products and services for the 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, the Pharmaceuticals Division generated 21.7 billion Swiss francs in prescription drug sales, 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.

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**Further information:**

About Hepatitis C: [http://www.health-kiosk.ch/start\\_hepa](http://www.health-kiosk.ch/start_hepa)

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