

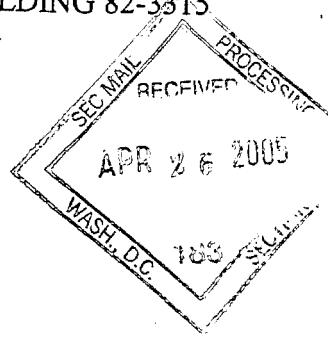
# Media Release

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Basel, 25 April 2005

## SUPPL



## FDA approves Roche's Cobas AmpliScreen Hepatitis B Test for use in screening Blood Donors

Test is first nucleic acid Hepatitis B blood screening test approved by FDA

Today, Roche Diagnostics announced that the United States Food and Drug Administration (FDA) approved the Cobas AmpliScreen HBV Test for use in a mini-pool format as a screening test for the detection of Hepatitis B (HBV) in donated whole blood, blood components, source plasma and other living donors. The test is the first nucleic acid test designed for screening whole blood for HBV to be approved by the FDA.

The approval follows a decisive vote in favour of licensure at an earlier Blood Products Advisory Committee of the FDA in 2004, at which time Roche Diagnostics presented results from their related five-center clinical study. Roche Diagnostics submitted a Biologics License Application (BLA) to the FDA, for the Cobas AmpliScreen HBV Test to screen plasma samples from donors of whole blood and blood components, source plasma and other living donor organ components.

"This is an important day for the blood screening community and concludes a successful effort by Roche Diagnostics, the blood centers and FDA to bring this important test to market" said Heino von Prondzynski, CEO Division Roche Diagnostics and Member of the Executive Committee. "Implementation of the Cobas AmpliScreen HBV test based on PCR (polymerase chain reaction) ensures that a highly sensitive and robust technology is being used to keep our precious blood supply safe."

In the clinical study, the Cobas AmpliScreen HBV identified two HBV "window cases" (cases within the time between infection and detection of infection by antigen tests) which may have gone undetected by currently licensed HBsAg tests. In these tests, conducted at five blood centers in the US, Roche Diagnostics evaluated 581,790 individual donations in pools of 24. In addition,

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F. Hoffmann-La Roche Ltd.

CH-4070 Basel

MAY 04 2005

Corporate Communications

Tel. 061 - 888 88 88

Fax 061 - 888 27 75

<http://www.roche.com>

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Roche Diagnostics presented non-clinical study data illustrating that the Cobas AmpliScreen HBV Test reduced the window period by an average of 17 days in 40 seroconversion panels when compared to the currently implemented Hepatitis B surface antigen test. Following the conclusion of the clinical study period, three of the five centers voluntarily chose to continue using Roche Diagnostics' test under a cost-recovery IND (Investigational New Drug) protocol.

Since conclusion of the clinical trial period in 2004, three additional "window cases" out of an additional one million donated blood units were identified using the Cobas AmpliScreen HBV Test.

"Memorial Blood Centers is proud to have been one of the first three centers to use the Roche Hepatitis B blood screening nucleic acid testing assay" said Jed Gorlin, M.D., Vice President of Medical and Quality Affairs, Memorial Blood Centers, Minneapolis. "The study clearly documented the necessity to be vigilant in continuing to screen the blood supply for Hepatitis B. The current Hepatitis B surface antigen assays are very sensitive, but on rare occasions, may still miss small, but potentially infectious amounts of Hepatitis B."

#### **About Roche Diagnostics' blood screening business**

Roche Diagnostics' PCR-based tests are used to screen more units of blood worldwide than any other nucleic acid tests. Roche Diagnostics' Cobas AmpliScreen Tests for the detection of HIV-1 and Hepatitis C have been approved for use in the US and abroad for screening whole blood, source plasma, and potential organ donors. The Cobas AmpliScreen HBV Test is approved for use in the EU and is currently the only HBV nucleic acid test to have been approved by the FDA. The Cobas AmpliScreen Tests are also used in other countries. Roche's Amplinat multiplex assay - the first single-tube assay to test for HIV-1, Hepatitis C, and Hepatitis B in a single triplex reaction - has been used exclusively by the Japanese Red Cross (JRC) since 1999 to screen 100% of Japan's blood supply. In 2004, the JRC renewed their agreement with Roche Diagnostics for a four year period. Roche Diagnostics' TaqScreen West Nile Virus Test, the first in North America to fully automate the extraction, amplification, and detection steps of PCR, is currently in clinical trials in the US and Canada. Roche Diagnostics is also actively engaged in developing next-generation instrument systems and assays to further integrate and automate the blood screening process. Additional information about Roche Diagnostics' blood screening business is available on the Internet ([www.rocche-diagnostics.com/press\\_lounge/blood\\_screening.html](http://www.rocche-diagnostics.com/press_lounge/blood_screening.html)).

#### **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)).

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#### **Additional information**

- Roche Diagnostics: [www.roche-diagnostics.com](http://www.roche-diagnostics.com)

#### **Media Office contacts**

Phone: +41 61 688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Baschi Dürr
- Alexander Klausner
- Daniel Piller (Head of Group Media Office)
- Katja Prowald (Head of Science Communications)
- Martina Rupp



## Investor Update

April 19, 2005

Roche files supplemental new drug application to extend prophylaxis indication for Tamiflu to patients between one to 12 years of age. Leading prescription antiviral medication plays key role in influenza prevention and treatment.

Roche has filed a supplemental new drug application (sNDA) with the U.S. Food and Drug Administration (FDA), requesting an extension of the prophylaxis indication for Tamiflu (oseltamivir phosphate) to include children ages one through 12. Currently, Tamiflu is indicated for the prophylaxis of influenza in adult patients and adolescents 13 years and older. Tamiflu is also indicated for the treatment of uncomplicated acute illness due to influenza type A or type B infection in patients one year and older who have been symptomatic for no more than two days. Roche is optimistic that FDA will complete their review of the sNDA before the next flu season.

The sNDA was filed based on results from a subset of pediatric patients in a clinical study where Tamiflu was used for the management of influenza in households. The study enrolled over 1000 patients in total (including adults and children). The study overall showed that post-exposure prophylaxis is effective in preventing secondary spread of influenza infection and illness in households and that the protective efficacy of Tamiflu was the same in children aged one through 12 as the whole population. Gastrointestinal events, particularly vomiting, were the most frequently reported adverse events in pediatric patients.

Tamiflu is the leading prescription antiviral medication for influenza. It works by targeting one of the two major surface structures of the influenza virus, the neuraminidase protein. The neuraminidase site is virtually the same in the most common strains of influenza, types A and B. Tamiflu attacks the influenza virus and is thought to work by stopping it from spreading inside the body. Tamiflu treats flu at its source, by attacking the virus that causes the flu, rather than simply masking symptoms.

### Flu's Impact on Children

According to the U.S. Centers for Disease Control, an average of 36,000 people in the United States die from influenza each year while more than 200,000 people are hospitalized due to flu-related illnesses. Children younger than two years old are as likely as those over age 65 to be hospitalized because of the flu. It is estimated that children are three times more likely to get sick with the flu - on average, one in 10 adults is affected by influenza annually, compared with one in three children. Therefore, prevention of influenza in children can have a significant impact on the spread of influenza in the household and the whole community.

### About Tamiflu

Tamiflu, co-developed by Gilead Sciences, Inc. is a systemic treatment for the most common strains of influenza (types A and B).

Tamiflu is generally well tolerated. In treatment studies in adults, the most frequently reported adverse events were mild-to-moderate transient nausea and vomiting. Other events reported more frequently than with placebo were bronchitis, insomnia and vertigo. In prophylaxis studies in patients aged 13 and older, adverse events were qualitatively similar to those seen in the treatment studies despite a longer duration of dosing. Events reported more frequently in subjects receiving Tamiflu compared to subjects receiving placebo in prophylaxis studies included nausea, vomiting, diarrhea, abdominal pain, dizziness, insomnia, headache, vertigo and fatigue.

In pediatric treatment studies, the most frequently reported adverse event was vomiting. Other events reported more frequently by pediatric patients treated with Tamiflu included abdominal pain, epistaxis, ear disorder and conjunctivitis. These events generally occurred once and resolved despite continued dosing. In a prophylaxis study which included pediatric patients aged one to 12 years, gastrointestinal events were most frequently reported, particularly vomiting.

Efficacy of Tamiflu in the treatment of subjects with chronic cardiac disease and/or respiratory disease has not been established.

Tamiflu was approved by the U.S. Food and Drug Administration (FDA) for the treatment of uncomplicated acute illness due to influenza infection in adults in October 1999.

The FDA granted marketing approval for the prevention of naturally occurring influenza A and B in adults and adolescents 13 years and older in November 2000. The FDA granted marketing approval of the oral suspension for use in the treatment of influenza A and B in children one year and older in December 2000. Tamiflu oral suspension is used for pediatric patients one year and older or adult patients who cannot swallow a capsule. Tamiflu is the first and only liquid suspension to treat influenza A and B. Vaccination is considered the first line of defense against influenza.

Tamiflu is available for the treatment of influenza in more than 40 countries worldwide. For more information visit [www.Tamiflu.com](http://www.Tamiflu.com)

#### About 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 2003, the Pharmaceuticals Division generated 19.8 billion Swiss francs in prescription drug sales, while the Diagnostics Division posted sales of 7.4 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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#### Roche IR contacts:

Dr. Karl Mahler

Phone: +41 (61) 687 85 03

e-mail: [karl.mahler@roche.com](mailto:karl.mahler@roche.com)

Eva-Maria Schäfer

Phone: +41 (61) 688 66 36

e-mail: [eva-maria.schaefer@roche.com](mailto:eva-maria.schaefer@roche.com)

Dianne Young

Phone: +41 (61) 688 93 56

e-mail: [dianne.young@roche.com](mailto:dianne.young@roche.com)

Dr. Zuzana Dobbie

Phone: +41 (0)61 688 80 27

e-mail: [zuzana.dobbie@roche.com](mailto:zuzana.dobbie@roche.com)

#### North American investors please contact:

Richard Simpson

Tel: +1 (973) 235 36 55

email: [richard.simpson@roche.com](mailto:richard.simpson@roche.com)

With best regards,

Your Roche Investor Relations Team

F. Hoffmann-La Roche Ltd

Investor Relations

Grenzacherstrasse 68 / Postfach

4070 Basel

<http://ir.roche.com>/email: [investor.relations@roche.com](mailto:investor.relations@roche.com)/phone: ++41 61 688 88 80/fax: ++41 61 691 00 14



Basel, 19 April 2005

## **Roche leads off in 2005 with impressive first quarter — pharmaceutical sales grow three times as fast as the global market**

### **Roche Group**

- Group sales for the first quarter up by 17%\* (14% in Swiss francs)
- Both divisions successfully launch a number of products
- Outlook raised for 2005: despite significant expenditures and expiry of the Rocephin patent, the Pharmaceuticals Division expects its operating profit margin to be in line with or better than last year's margin

### **Roche Pharmaceuticals**

- Pharmaceuticals Division posts strong sales growth of 22%\* (18% in Swiss francs)
- Avastin successfully launched in Europe for colorectal cancer
- Study shows Avastin also improves survival in lung cancer patients
- Positive data of Avastin also in first-line metastatic breast cancer
- Strong market uptake for Tarceva in the US and Switzerland — EU market authorisation expected in the fourth quarter of 2005
- Study demonstrates that Tarceva also prolongs life in pancreatic cancer patients
- Boniva/Bonviva becomes first and only FDA-approved once-monthly tablet for osteoporosis — market launch successfully under way

### **Roche Diagnostics**

- Diagnostics Division opens year with 4%\* sales growth (1% in Swiss francs), in line with market growth
- Solid gains for diabetes care and molecular diagnostics, including women's health and blood screening products; immunodiagnostics sales also up substantially for the quarter
- AmpliChip CYP450 Test successfully launched; rollout of next generation of Accu-Chek products off to a good start in selected markets
- Roche Diagnostics expects sales growth to accelerate, particularly in the second half, following new product launches in major markets

\* Unless otherwise stated, all percentage changes are changes from the first quarter of 2004 and are based on results in local currencies.

Commenting on the first quarter of 2005, Roche Chairman and CEO Franz B. Humer said, 'Sales advanced by a very strong 17%, extending the record of success our Group has sustained in recent years. And at the same time our product development activities are setting the stage for future growth. Avastin is now approved in Europe as well as the United States for the treatment of colorectal cancer. In addition, recent data show that Avastin extends the lives of lung cancer patients and significantly improves progression-free survival in patients with breast cancer. Moreover, the FDA recently approved Boniva/Bonviva as the first and only once-monthly tablet for osteoporosis. At Roche Diagnostics the launch of the first AmpliChip test got off to a strong start, and the division successfully began rolling out its next generation of Accu-Chek products. Although we anticipate generic competition to Rocephin, we remain confident about the outlook for 2005 and beyond.'

## Roche Group

Sales from January to March	2005	2004	% Change	
	mCHF	mCHF	in CHF	in local currencies
<b>Pharmaceuticals</b>	6,155	5,217	+18	+22
Roche	3,859	3,546	+9	+11
Genentech	1,341	923	+45	+54
Chugai	955	748	+28	+32
<b>Diagnostics</b>	1,935	1,908	+1	+4
<b>Group</b>	8,090	7,125	+14	+17

Roche recorded sales of 8.1 billion Swiss francs in the first quarter of 2005, an increase of 17% (14% in Swiss francs; 21% in US dollars) over the year-earlier period. Sales in the Pharmaceuticals Division increased 22% (18% in Swiss francs), three times as fast as the global market average. The Diagnostics Division maintained its strong market position with sales growth of 4% (1% in Swiss francs).

### Full-year outlook reaffirmed for Diagnostics and raised for Pharma

Roche reaffirms the outlook for full-year 2005 announced at its Annual Media Conference in early February, and now expects results in the Pharmaceuticals Division to be even better than previously indicated (all statements are based on the Group's previous accounting policies and exclude the

effects of changes in International Financial Reporting Standards): The Pharmaceuticals Division expects sales in local currencies to grow at a double-digit rate above the global market average. Similarly, Roche Diagnostics expects sales for 2005 to show another above-market increase, with growth in the single-digit range. The Pharmaceuticals Division now expects its operating profit margin (before exceptional items) to be in line with or better than the margin for 2004. Roche Diagnostics anticipates the margin development to continue towards its goal of achieving an operating profit margin of around 23% (before exceptional items) in 2006. Roche also continues to anticipate a balanced financial income in 2005.

## **Pharmaceuticals Division**

### **Dynamic sales growth significantly above the market average**

The Pharmaceuticals Division posted extremely strong growth in the first three months of 2005 as sales for the period rose 22% (18% in Swiss francs; 25% in US dollars). This was three times the global market growth rate of roughly 7%, resulting in significant market share gains for Roche. Growth was driven primarily by strong demand for the division's oncology products, including the new cancer treatments Avastin and Tarceva, and by the anti-influenza drug Tamiflu, which saw sales quadruple during the quarter. Overall, sales were up 28% in North America, 14% in Europe and 32% in Japan — advancing faster than the market average in all three regions.

### **Oncology — key products Avastin, Tarceva, MabThera, Xeloda and Herceptin all deliver strong growth**

Avastin, for the treatment of colorectal cancer, posted first-quarter sales of 260 million Swiss francs, bringing to roughly 1 billion Swiss francs the total sales generated by the product since its US launch by Genentech about one year ago. In January the European Commission approved Avastin for the first-line treatment of patients with advanced colorectal cancer, and the drug is already available in key European markets, including Germany, Switzerland and the United Kingdom. A large-scale study has additionally shown that first-line treatment with Avastin significantly improves survival in patients with advanced non-small cell lung cancer (NSCLC); NSCLC is the most common form of lung cancer. Roche expects to file Avastin for NSCLC in the United States and Europe in the first half of 2006. Further on, interim analysis of a study demonstrated significantly improved progression-free survival with Avastin, in combination with chemotherapy, for patients with previously untreated metastatic breast cancer — the third cancer to show benefit with Avastin. Avastin is also being investigated in other cancers.

Tarceva, a novel cancer drug with a proven survival benefit in advanced NSCLC, was approved in the United States in November last year and generated first-quarter sales totalling 57 million Swiss



francs. The product was approved by the Swiss regulatory authorities in March. An application for marketing authorisation in the European Union is currently undergoing regulatory review, with a decision expected in the fourth quarter of this year. In January new data also showed significant improvement in overall survival of pancreatic cancer patients when Tarceva is added to chemotherapy.

Sales of MabThera/Rituxan, for non-Hodgkin's lymphoma (NHL), were up 24%. Following positive data from clinical trials showing that maintenance treatment with MabThera/Rituxan improves progression-free survival in patients with indolent NHL, Roche is preparing to file a marketing application for this indication in Europe in the second half of 2005. Results from a recently published pivotal phase III study show that MabThera/Rituxan significantly improves symptoms in rheumatoid arthritis patients, indicating that the product has the potential to play a major role in the future treatment of many patients with this disease.

Xeloda sales continued their upward trend, advancing by a strong 48% for the quarter. At the end of March the European authorities approved Xeloda for the treatment of colon cancer after surgery. Roche anticipates FDA approval of this indication later this year. The new indication will double the number of patients eligible for treatment with Xeloda. The breast cancer medicine Herceptin achieved double-digit growth in key markets.

#### **Influenza — late flu season and orders for pandemic readiness supplies spur unexpectedly strong increase in Tamiflu sales**

First-quarter sales of Tamiflu totalled 424 million Swiss francs. This impressive increase was driven by seasonal sales and by early orders for some pandemic readiness supplies. Although it started late, the 2004/2005 flu season has been severe, with unexpectedly serious outbreaks occurring particularly in Japan. In Japan alone, Tamiflu sales totalled 260 million Swiss francs. Following experts' warnings of an imminent influenza pandemic, an increasing number of countries have begun ordering stockpiles of Tamiflu, with some countries — including France, the United Kingdom, New Zealand and Norway — planning to purchase enough to treat 20% to 25% of their populations. The large orders received to date will be delivered in phases over the next two years and then recorded as sales.

#### **Anemia — strong uptake of NeoRecormon pre-filled syringe**

Sales of the anti-anemia products NeoRecormon and Epogin, prescribed in patients with kidney disease and cancer, grew steadily despite price pressure in the anemia market as a whole. Combined sales of the two drugs were up 7%. NeoRecormon remained the leading product for renal anemia in its markets. The new pre-filled syringe successfully launched last year is now the top-selling NeoRecormon dosage form for cancer-related anemia.

#### **Transplantation — global market leadership maintained**

Sales of CellCept increased 4%, helped by double-digit growth outside the United States. While wholesaler buying patterns led to an 8% decline in US sales of CellCept, new prescriptions in the United States rose 13% for the quarter, demonstrating the underlying strong demand for the product in this market.

#### **Virology — Pegasys gains additional indications**

Pegasys, which was approved for several new indications early this year, maintained its market leadership with sales growth of 15%. While the US market experienced a decline in 2004, the market now appears to be stabilising again. Pegasys plus ribavirin became the first and only pegylated interferon combination therapy to be approved by both the FDA and the European Commission for the treatment of hepatitis C in patients co-infected with HIV. In addition, Pegasys received EU approval in February for the treatment of hepatitis B. FDA approval of the hepatitis B indication is anticipated later this year. These new indications, combined with initiatives to increase the detection rate for hepatitis C infections, will further enhance the potential of Pegasys. Sales of Fuzeon, for HIV, increased steadily both in the United States and in key European markets.

#### **Osteoporosis — Boniva/Bonviva approved in the United States**

Boniva, the first once-monthly oral bisphosphonate for the effective treatment and prevention of osteoporosis, was approved by the FDA in March. Filings for approval of this once-monthly oral formulation for the treatment of osteoporosis have also been submitted in the European Union and Switzerland, where the product will be marketed as Bonviva; approvals are anticipated later this year. Along with the established efficacy of its class, Boniva/Bonviva can offer greater convenience for the patient with the possibility of improved adherence to treatment.

### **Roche Diagnostics**

#### **Sales growth in line with the market**

In the first three months of 2005 Roche Diagnostics recorded sales of 1.9 billion Swiss francs, an increase of 4% (1% in Swiss francs; 8% in US dollars) over the previous year's very strong first quarter. The division's molecular diagnostics business, which includes women's health and blood screening products, and the diabetes care and immunodiagnostics portfolios all made major contributions to growth. Sales grew significantly faster than the market in the Asia-Pacific region, Japan and Latin America. In Eastern Europe sales showed double-digit gains, while elsewhere in Europe and in Africa growth was in the single digits. In the United States divisional sales kept pace

with market growth. Roche Diagnostics is currently launching new diabetes care products in selected markets in Europe and expects to see accelerated sales growth from mid-year on as these products are rolled out in major European markets and in the United States.

**Diabetes Care — two innovative products ready for launch worldwide**

Roche Diabetes Care increased its sales by 4% during the quarter and anticipates above-market growth going forward this year. Two innovative new products launched in their first markets during the quarter — the Accu-Chek Aviva blood glucose meter and the Accu-Chek Spirit insulin pump — will help build additional sales momentum. Accu-Chek Aviva is now on the market in the Netherlands and Scandinavia, and Accu-Chek Spirit is available in Germany and the Netherlands. The global rollout of these products will continue in the months ahead.

**Near Patient Testing — strong quarter for coagulation monitoring and glucose testing products**

Roche Near Patient Testing posted a 15% increase in sales of its coagulation monitoring products. Total sales revenues in this business area were down 1%, however, primarily as a result of weaker sales of blood gas and electrolyte analysers in Europe and the United States. With the Omni S now available worldwide, Roche expects to see a return to dynamic growth in this segment before the end of the year. Sales of the Accutrend GC/GCT meters, used for cholesterol testing in doctors' offices, experienced double-digit growth. Cardiac markers also contributed to growth, with sales showing a high single-digit increase for the quarter. Recent clinical trials confirming the benefits of patient self-monitoring contributed to a double-digit increase in sales of the CoaguChek S meter. The rollout of a new coagulation monitoring device in the second half of this year will fuel additional growth.

**Centralized Diagnostics — immunodiagnostics drives growth**

Roche Centralized Diagnostics grew in line with the market at 4%. Immunodiagnostics was a major growth driver, with placements of Elecsys instruments increasing by 28% for the quarter which will fuel future, highly profitable reagent sales. Clinical chemistry placements of Cobas Integra and Modular Analytics increased 14%, which will further strengthen Roche's position in the market. This year Roche Centralized Diagnostics is focusing on expanding and strengthening its lead in the serum work area segment and on developing new immunoassays for cancer, rheumatoid arthritis and cardiovascular disease.

**Molecular Diagnostics — blood screening products a key growth driver**

Diagnostics sales in this business area rose 8%. Roche Molecular Diagnostics received FDA approval to market its Cobas AmpliScreen HIV-1 and hepatitis C blood screening tests for use in screening

organ and tissue donations. In the virology segment, the business area obtained CE certification for the first fully automated real-time PCR tests for hepatitis C, hepatitis B and HIV-1 on its Cobas AmpliPrep/Cobas TaqMan system. US clearance of the AmpliChip CYP450 Test represents a major step towards personalised medicine. This new test provides doctors with information that can help them in selecting the most appropriate medications and dosages for their patients.

#### **Applied Science — outlook good for full-year 2005**

Roche Applied Science posted 2% growth compared with a very strong first quarter in 2004. The business area expects growth to increase significantly in the course of 2005 as a result of additions to its portfolio of PCR systems — particularly the launch of a new, high-throughput LightCycler system — and increased reagent sales.

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#### **Additional information**

- Media release including a full set of tables: [www.roche.com/med-cor-2005-04-19](http://www.roche.com/med-cor-2005-04-19)
- First-half results 2005: 20 July (tentative)
- Nine-month sales 2005: 19 October (tentative)

#### **Media Office contacts**

Phone: +41 61 688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Baschi Dürr
- Alexander Klauser
- Daniel Filler (Head of Roche Group Media Office)
- Katja Prowald (Head of Science Communications)
- Martina Rupp

#### **Disclaimer**

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products; (6) increased government pricing pressures; (7) interruptions in production; (8) loss of or inability to obtain adequate protection for intellectual property rights; (9) litigation; (10) loss of key executives or other employees; and (11) adverse publicity or news coverage.



Basel, 18 April 2005

## **Coagulation Self-Management with Roche's CoaguChek S System can save lives**

**Study shows that CoaguChek S diagnostics system substantially reduces bleeding complications and mortality rate after mechanical heart valve replacement**

Patient self management with the CoaguChek S system from Roche Diagnostics reduces the risk of major complications and minor hemorrhages by up 70% and the event of mortality by up to 60%. This was demonstrated by a new study comparing self-management of oral anticoagulant therapy with clinic management<sup>1</sup>.

"CoaguChek S system can help to give patients independence and – even more significant – safety and peace of mind, in short, real improvement quality of life" said Heino von Frondzynski, CEO Division Roche Diagnostics and Member of Roche's Corporate Executive Committee. "Additionally, patient self management is cost-effective and demonstrates that modern diagnostics may reduce the cost of the healthcare system. The authors of the ACOA study estimate that at least 50% of patients on anticoagulant therapy could safely use patient self-management to monitor their treatment."

Oral anticoagulation is well established in many fields of medicine including secondary prevention of cardiovascular thromboembolic events. It is important to monitor the therapeutic effect and to keep possible risks at the lowest possible level. Scheduling the dose of anticoagulants in an optimal way can reduce the incidence of bleeding complications without increasing thromboembolic events. Self testing with the CoaguChek S system gives patients information about their level of anticoagulation and allows them to adjust the doses of medication if necessary.

### **About the ACOA study**

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<sup>1</sup> (Comparing Self-Management of Oral Anticoagulant Therapy with Clinic Management; *Annals of Internal Medicine*. 2005;142:1-10; ACOA study).

ACOA was a randomized, controlled trial involving 737 patients with indications for anticoagulant treatment. It compared a conventional management group for oral anticoagulant therapy with a self-management group. The study demonstrates a risk-reduction of nearly 70% for the self-management group concerning major complications. The authors of the study suggest that the ideal way to provide access to self-management for as many patients as possible would be patient self-management supported by a specialized clinic. The major complication rate was 7.3% in the conventional management group and 2.2% in the self-management group, which corresponds to a risk reduction of 69.8%. Minor hemorrhages also occurred less frequently (36.4% vs. 14.9%) and there was a mortality reduction of 60% (4.1% vs. 1.6%).

#### **About CoaguChek S**

The portable CoaguChek S System quantitatively determines the thromboplastin time on the spot within one minute using capillary blood from the fingertip or untreated venous whole blood. This means fast information for patients about their required doses of anticoagulant medication. The immediate availability of results significantly improves the workflow of healthcare professionals. The simplicity of operation makes it easy and convenient for patients to monitor and even manage their therapy. Sales of Roche Diagnostic's CoaguChek S System in 2004 reached more than 150 million Swiss francs, continuing the double digit annual growth shown over the past 3 years. For more information: [www.coagucheck.com](http://www.coagucheck.com)

The CoaguChek System is not approved for self testing or self-management in the United States

#### **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)).

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**Additional information**

- Roche Diagnostics: [www.roche-diagnostics.com](http://www.roche-diagnostics.com)

**Media Office contacts**

Phone: +41 61 688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Baschi Dürr
- Alexander Klausner
- Daniel Piller (Head of Group Media Office)
- Katja Prowald (Head of Science Communications)
- Martina Rupp