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Media Release

Roche

SUPPL

Basel, 21 April 2004

First quarter exceeds expectations: 15% rise in sales results in further market share gains; Avastin successfully launched in United States

Roche Group

- Roche Group lifts core business sales by 15% in local currencies and 14% in Swiss francs
- Redemption of outstanding LYONs IV convertible notes further reduces debt and interest expense: transaction yields one-time after-tax gain of 613 million Swiss francs
- Outlook for the current year
  - Sales growth in both divisions to outpace global market
  - Margins in pharmaceuticals and diagnostics businesses improving as planned
  - Substantial increase in net income expected

Roche Pharmaceuticals

- Pharmaceuticals Division achieves double-digit sales growth in local currencies (+17%) and Swiss francs (+16%) - global market up 9%*
- Oncology franchise posts 27% growth. Avastin successfully launched in the United States
- Pegasys and Copegus: sales for first quarter already at 391 million Swiss francs
- Anti-anemia product CERA enters phase III clinical testing in patients with renal disease

* IMS, Moving Annual Total February 2003–January 2004.

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Roche Diagnostics

- **Diagnostics Division grows twice as fast as the market, with sales up 10% in local currencies (+11% in CHF)**
- **Above-average sales growth in diabetes care and molecular diagnostics segments (+15% and +14%, respectively, in local currencies)**
- **Igen acquisition completed — strong growth in key immunodiagnostics segment (+24% in local currencies)**

Roche recorded sales of 7.6 billion Swiss francs in the first quarter of 2004. Compared with the same period last year, this represents an increase of 15% in local currencies (+14% in CHF) for the Group's core businesses. The Pharmaceuticals Division continued to grow faster than the market, increasing its sales by 17% in local currencies (+16% in CHF). The Diagnostics Division gained additional market share on sales growth of 10% in local currencies (+11% in CHF).

Commenting on the first-quarter figures, Roche Chairman and CEO Franz B. Humer said, 'Roche has started the new year very well. Our Pharmaceuticals and Diagnostics Divisions continue to grow significantly faster than the market. The launch of Avastin in the United States makes us the only healthcare company in the world to supply four medicines that can help extend the lives of people with cancer and underscores our leadership in oncology. Barring unforeseen events, our continuing progress on the operational side and the redemption of our LYONs IV convertible notes will result in a substantial improvement in our net income this year and will also strengthen our balance sheet further.'

	2004	2003	% Change	
Sales from January to March	mCHF	mCHF	In CHF	In local currencies
Pharmaceuticals	5,646	4,888	16%	17%
Roche prescription	3,546	3,053	16%	16%
Genentech prescription	923	777	19%	29%
Chugai prescription	748	656	14%	12%
Prescription	5,217	4,486	16%	18%
OTC	429	402	7%	5%
Diagnostics	1,908	1,725	11%	10%
Core businesses (continuing businesses)	7,554	6,613	14%	15%
Vitamins and Fine Chemicals	-	743	-100%	-100%
Group	7,554	7,356	3%	3%

Finance: major step towards strengthening the Group's balance sheet

In early April Roche completed the call of its LYONs IV convertible notes. This marks a major step towards further reducing the Group's debt and strengthening its balance sheet. The notes were mainly exchanged for Genentech shares. The transaction yielded a one-time pre-tax gain of 968 million Swiss francs and an after-tax gain of 613 million Swiss francs for Roche. The transaction has reduced Roche's debt by 1.36 billion Swiss francs. The delivery of Genentech shares in exchange for the notes has decreased Roche's interest in Genentech by 2.5% to 55.3%. Roche continues to hold a majority stake in Genentech, and its successful relationship with the US biotechnology company will remain unchanged.

Pharmaceuticals Division

The Pharmaceuticals Division increased its sales by 17% in local currencies and 16% in Swiss francs in the first quarter of 2004. Sales of prescription medicines were up 18% in local currencies (+16% in CHF), with Roche, Genentech and Chugai all contributing to this strong growth with solid double-digit gains. Consumer Health also grew well ahead of the market, increasing its sales by 5%.

The division's oncology, virology and transplantation franchises continued to be the main drivers of growth in prescription drug sales. Sales of oncology products[1] were up 27%[2], with major contributions to growth coming from products such as MabThera (+33%), Herceptin (+27%) and Kytril (+28%). Pegasys and Copegus captured additional market share both in the United States and internationally, as combined sales of the two products reached 391 million Swiss francs in the first quarter. In the transplantation segment, CellCept and Valcyte/Cymevene continued on a growth path, with sales rising by 23% and 38%, respectively. Sales of NeoRecormon and Epogin advanced 5% in the face of intense price competition.

Sales of prescription medicines outpaced market growth[3] in all major regions. In North America sales increased by 22%, or twice as fast as the market (+11%), resulting in additional market share gains. European sales also grew at a double-digit rate (+17%), and thus substantially faster than the market average (+8%). Chugai likewise posted double-digit sales growth (+12%), despite a virtually stagnant Japanese market (+3%). In Latin America sales increased by 22% amidst an overall market recovery (+9%).

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[1] Oncology portfolio: MabThera/Rituxan, Herceptin, Xeloda, Bondronat, Kytril, Furtulon, Neupogen, NeoRecormon (25%), Roferon-A (85%), Neutrogin, Picibanil, Avastin.
[2] Unless otherwise noted, all percentage changes are based on results in local currencies.
[3] Source: IMS, Moving Annual Total February 2003 - January 2004

Oncology: US launch of Avastin contributes to accelerated growth

Sales of MabThera/Rituxan (US: +21%; Japan: +177%; Europe/RoW: +56%) continued to grow strongly, driven by increased use in the first-line treatment of aggressive and indolent non-Hodgkin's lymphoma (NHL). In Europe 60% of patients with aggressive NHL and 34% of patients with indolent NHL are already being started on MabThera as first-line therapy.

Herceptin continued to deliver strong growth (+27%), particularly in Europe/RoW (+39%) and Japan (+28%). Herceptin combined with Taxotere has been shown to significantly improve survival in patients with an aggressive form of breast cancer. The data have been submitted to the European authorities to support a label extension for this drug combination.

Xeloda, for breast and colorectal cancer, continued to make a steadily growing contribution to the oncology franchise, posting sales growth of 34% in Europe, Latin America and Asia. Sales in the United States were down 49% for the first quarter, primarily due to changing wholesaler inventory levels and buying patterns; this trend should correct itself over the course of the year, however, as US prescriptions continue to grow at a strong +19% rate.

In the supportive cancer care segment, the division has begun rolling out Bondronat across Europe for use in patients with metastatic bone disease. Kytril, Roche's anti-emetic for controlling nausea and vomiting associated with cancer therapy, continues to show strong growth (+28%) in all major markets.

The first quarter was also marked by the approval and launch of Avastin in the United States for first-line treatment with chemotherapy in patients with advanced cancer of the colon or rectum. Filings for Avastin, the first anti-angiogenesis agent for cancer, have been granted priority review status in Switzerland, Australia and Canada. An application for European marketing authorisation was filed in December 2003.

Virology: Pegasys and Copegus drive growth

Pegasys and Copegus, Roche's combination therapy for hepatitis C, continued to show dynamic growth and gain market share, with combined sales of these two products rising to 391 million Swiss francs worldwide. In the last 12 months Pegasys and Copegus have posted sales of over 1 billion Swiss francs. Pegasys strengthened its market leadership in the United States (57%) during the first quarter. Programmes to develop Pegasys for additional indications are under way. In February, for example, Roche announced the results of a large-scale trial of the product in patients co-infected with HIV and HCV. Liver disease is the leading cause of hospital admissions and death in HIV/HCV co-infected patients. The trial patients who received Pegasys plus Copegus had the highest sustained virological response rate ever achieved in this patient population.

Sales of the anti-HIV drug Fuzeon, the world's first fusion inhibitor, were up by nearly one-third from the previous quarter and are expected to increase further now that the product has also been launched in the key Spanish and Italian markets. Reimbursement negotiations in several other EU countries are ongoing, as are programmes to increase acceptance of subcutaneous self-injection of the medicine.

Anemia: NeoRecormon and Epogin maintain their market position

NeoRecormon and Epogin, the leading treatments for anemia in patients with renal disease and cancer, posted 5% growth. Sales were affected by price erosion, which has resulted in flattening growth rates in the anti-anemia market, and by slow growth in the oncology segment early in the quarter. However, NeoRecormon sales in the oncology segment are expected to improve further thanks to the recent approval and launch of a more convenient and cost-effective pre-filled syringe for once-weekly dosing in patients with lymphoid cancers.

An extensive programme of phase III clinical trials with the newly developed anemia treatment CERA in patients with renal disease has commenced in Europe and the United States.

Transplantation: strong double-digit growth

CellCept (+23%), Roche's low-toxicity immunosuppressant for kidney, liver and heart transplantation and the top-selling branded immunosuppressant in the United States, continued to achieve impressive sales increases in the United States and all other key markets.

Combined sales of Valcyte and Cymevene were up 38%. This strong growth was driven primarily by the launch of Valcyte in a number of countries, following EU and US approval of the product in 2003 for the prevention of CMV disease in transplant patients.

Other major products

Sales of Xenical have stabilised (+1%). In March the European authorities approved an extension to Xenical's prescribing label based on the XENDOS study. The label now includes information on Xenical's ability to reduce the risk of developing type 2 diabetes. In addition, Sweden's reinstatement of reimbursement for the product has helped stimulate sales in Europe.

Tamiflu sales remained strong in Japan in the first quarter. Growing concerns about the avian flu and the potential for a pandemic in the coming years have led to intense discussions with the WHO and a number of government agencies.

A once-daily oral formulation of Bonviva/Boniva, a medicine for the prevention and treatment of osteoporosis, was approved by the European authorities in February 2004. Moreover, results from a new phase III trial indicate that once-monthly oral dosing of the drug is at least as effective as a once-a-day regimen, while at the same time promising to increase patient acceptance and enhance

treatment compliance. Publication of the final results and submission of approval applications to the European and US regulatory authorities are planned for this year.
Rocephin sales grew 4% in the first quarter. Strong sales were reported in North America because of the flu outbreak there. Sales erosion in Europe/RoW was less than anticipated due to the absence of generic competition in Italy.

Consumer Health: above-market growth

In the first quarter of 2004 sales of non-prescription (OTC) medicines, including sales by Chugai in Japan, grew 5% in local currencies (+7% in CHF) to 429 million Swiss francs. Excluding Chugai, the Group's consumer health sales grew by 8% in local currencies, significantly outpacing the market as a whole. This strong growth was fuelled by sales of the Group's most important OTC brands, which were up 10% in local currencies, and particularly by increased sales in the core markets of Spain (+19%), the United Kingdom (+14%), Brazil (+30%) and Turkey (+25%).
As previously announced, Roche is reviewing various strategic options for Roche Consumer Health. A decision is expected in the course of this year.

Diagnostics Division

Roche Diagnostics continued to grow significantly faster than the market in the first quarter of 2004. Divisional sales totalled 1.9 billion Swiss francs, a 10% increase over last year's first quarter results in local currencies (+11% in CHF). The first-quarter sales figures are substantially better than those of other leading diagnostics companies.

All regions once again contributed to growth. Double-digit sales gains were posted in Asia–Pacific, Latin America, Iberia and Japan. In Latin America sales benefited from the region's economic recovery. The market slowdown seen last year in the United States continued in the first quarter of 2004. After adjusting for special items (sale of product lines), however, Roche Diagnostics once again outpaced the US market by a significant margin. Worldwide sales growth was driven primarily by insulin pump sales, diabetes monitoring products, immunodiagnostics and the molecular diagnostics business. Sales gains in Europe were in the high single-digit range despite the cost containment measures implemented in a number of countries.

Diabetes Care: new products well received in the marketplace

Roche Diabetes Care extended its market leadership as sales rose 15% (+15 in CHF) compared with the very strong results posted a year earlier. Roche Diabetes Care is confident of its ability to maintain above-market growth worldwide.

The Accu-Chek Compact system is expected to continue delivering steady growth. In the first quarter Accu-Chek Go was launched in France and Austria, and Accu-Chek Advantage III was rolled out on schedule in the United States and Germany. Both devices offer users enhanced convenience.
The FDA is expected to conduct a re-inspection of Disetronic's Burgdorf facility in the third quarter of 2004, after issuing an advisory letter last year regarding production processes and documentation at the site.

Near Patient Testing: Urisys launched in United States; OMNI S available worldwide
While Roche Near Patient Testing posted a 1% decline in overall sales for the quarter (+0% in CHF), revenues in this business area show a 3% gain (+4% in CHF) if special items (sale of the OPTI product line and drugs-of-abuse testing business) are taken into account. In the primary care and patient self-testing segments, sales of coagulation meters and Accutrend cholesterol testing products showed double-digit growth. As part of a global market rollout, the Urisys 1100 was launched in the United States, strengthening Roche Diagnostics' position in the automated urinalysis segment. The global rollout of the OMNI S blood gas and electrolyte analyser continues and is making a major contribution to consolidating Roche's leading position in this segment.
The launch of Cobas IT 1000, an innovative data management software package for use at the point of care, is planned for the second quarter of 2004. This Internet-based solution will create additional incentives for customers to draw on the broad portfolio of products supplied by Near Patient Testing and will help Roche Diagnostics to extend its lead in the hospital point of care segment.
A contract signed in the first quarter of this year with Novation, one of the largest healthcare group purchasing organisations in the United States, will generate additional sales momentum.

Centralized Diagnostics: immunochemistry drives growth
Overall, sales by Roche Centralized Diagnostics increased 5% (+8% in CHF). Sales of immunodiagnostic products grew well ahead of the market, increasing by 24% (+27% in CHF). The completed acquisition of Igen has created additional potential for growth in the immunodiagnostics market, the single largest diagnostics segment, currently worth over 8 billion Swiss francs. Mounting demand for tools designed to optimise laboratory workflow is expected to provide an additional stimulus for growth. Systems like Modular Pre-Analytics open up additional growth opportunities for Roche Centralized Diagnostics, the leading supplier of integrated analytical systems. The business area expanded its broad menu of cardiac diagnostic tests by licensing in a highly sensitive immunoassay.

Molecular Diagnostics: women's health and blood screening the most important growth segments

Roche Molecular Systems increased its sales by 14% in the first quarter (+13% in CHF). The blood screening and women's health segments were the biggest contributors to growth.

Sales of screening tests to ensure the safety of blood products were fuelled by the signing of new contracts in expanding markets and by the introduction of additional tests. Roche Diagnostics strengthened its leading position in the Asia–Pacific region and Japan, for example, by expanding its partnership with Asian blood banks. The Cobas AmpliScreen HIV-1 Test was approved in the United States for testing blood plasma and donor organs. Preparations for filing an application for AmpliChip CYP 450 as an in vitro diagnostic are moving ahead as planned. Roche intends to submit applications to the US and European authorities this year. European approval is expected in the middle of 2004.

The European launch of an HPV test in April of this year is an important landmark in the development of Roche's women's health portfolio. It is the first PCR-based test for detecting HPV and is capable of identifying all 13 high-risk subtypes of the virus.

Following a decline in 2003, sales to industrial customers were up 14% (+5% in CHF) for the first quarter.

Applied Science: return to growth

Following last year's noticeable downturn, the biotechnology market returned to healthy growth, with Roche Applied Science posting a 10% rise in sales in this segment (+9% in CHF). The introduction of additional components for the LightCycler 2.0 system, offering an even wider range of applications for PCR technology, and a focus on genomics and life science research will contribute to further growth.

This media release, including a full set of tables, can be found at

http://www.roche.com/med-corp-detail-2004?id=1167&media-language=e

Disclaimer

This release contains certain forward-looking statements. These forward-looking statements may be identified by words such as "believes", "expects", "anticipates", "projects", "intends", "should", "seeks", "estimates", "future" or similar expressions or by discussion of strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation among others: (1) pricing and product initiatives of competitors; (2) legislative and regulatory developments and economic conditions; (3) delay or inability in obtaining regulatory approvals or bringing products to market; (4) fluctuations in currency exchange rates and general financial market onditions; (5) uncertainties in the discovery, development or marketing of new products or new uses of existing 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.

Media release

Basel, 19 April 2004

Amplicor HPV, new diagnostic test to detect cancer causing viruses, launched in Europe

Amplicor HPV, first PCR-based test kit, detects all 13 high-risk DNA genotypes of human papillomavirus (HPV), the leading cause of cervical cancer

Roche today announced the launch of its Amplicor Human Papillomavirus (HPV) test kit in the European Union, an important landmark in the development of its global women's health portfolio. The new Amplicor HPV kit with CE marking ("Conformité Européene") for in-vitro diagnostics is the first PCR-based (polymerase chain reaction) reagent for the detection of HPV. This new test identifies all 13 high-risk genotypes of HPV, which is the leading cause of cervical cancer affecting more than 500,000 women worldwide every year.

"There is a large unmet medical need to enhance diagnosis of cervical cancer through the use of an HPV PCR test," said Heino von Prondzynski, Head of Roche Diagnostics and Member of the Roche Executive Committee. "The Pap test alone is only about 80% effective in detecting the precursors of cervical cancer. Furthermore, the presence of a cervical precancer is unclear in a significant percentage of 'inconclusive' Pap tests. HPV PCR tests can help resolve these inconclusive tests. Women in Europe can benefit from this innovative test as of now."

Roche Diagnostics is also developing a PCR-based linear array HPV product, based on a proven format used by more than 30 laboratories globally. The linear array identifies 37 HPV genotypes, including all high- and low-risk genotypes in the anogenital region. Potential clinical applications for the linear array HPV product include confirmation of positive screening results, follow-up of positive results, and providing subtype (genotype) information that will assist physicians with choosing the next steps for treatment. Discoveries about HPV and cervical cancer conducted with the aid of Roche's linear array HPV product have been published in many leading peer-reviewed

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medical and scientific journals, including "The Lancet" and "Cancer".

About Cervical Cancer Screening and HPV

According to the World Health Organization, cervical cancer is the second biggest cause of female cancer mortality worldwide with close to 300,000 deaths yearly. In the absence of screening programs (routine Pap smear), cervical cancer may be detected at later stages, with poor prognosis. Almost all (99.8%) cervical cancers are caused by specific types of a sexually-transmitted DNA tumor virus called human papillomavirus (HPV). To screen for cervical cancer, 160 million Pap tests are performed each year worldwide. Through the approval of reimbursement initiatives for HPV screening, governments in European countries are now recognizing the importance of HPV screening in preventing cervical cancer.

About Roche and Roche Diagnostics

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of 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 employs roughly 65,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Diagnostics Division, the world leader in in-vitro diagnostics with a uniquely broad product portfolio, supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories worldwide.

Additional information

- Roche Diagnostics: www.roche-diagnostics.com
- Roche Diagnostics & Women's health:
  www.roche-diagnostics.com/ba_rmd/rmd_products_womens_health.html
- Polymerase Chain Reaction (PCR): www.roche.com/pages/facets/pcr_e.pdf
- Background on HPV / cervical cancer: www.who.int/vaccine_research/diseases/hpv/en/

Media Release

Basel, 22 April 2004

CellCept's cardioprotective profile reinforced

Data further strengthens CellCept's unique benefits for heart transplant patients

Data presented today[1] at the International Society for Heart and Lung Transplantation (ISHLT) annual meeting strengthens the body of evidence that CellCept (mycophenolate mofetil, MMF) has unique benefits for heart transplant patients as the only immunosuppressant that offers:

- superior survival benefits[2]
- reduced coronary artery disease[3]
- the least toxic side effect profile[4]

The new set of data, compiled by means of state of the art technology, has shown that heart transplant patients treated with CellCept have significantly less coronary artery disease than those treated with azathioprine (AZA) in the first year after heart transplantation ($p \leq 0.005$). This finding could further explain the superior survival benefits of CellCept.

For heart transplant patients, cardiovascular disease is the predominant cause of post-transplant death.[3] The body's own immune response to the transplanted organ, and the cocktail of drugs taken by the patient cause an increase in coronary artery disease and other risk factors such as hypertension, diabetes and hyperlipidaemia.[5] However, unlike other immunosuppressants, CellCept is NOT associated with these risk factors.[6,7,8]

"These results add to the body of evidence demonstrating the superior efficacy, low-toxicity and cardioprotective profile of CellCept. They show CellCept to offer real long-term benefits to patients, both in terms of overall patient survival and health of the graft," comments William M. Burns, Head of

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Roche's Pharmaceuticals Division. "CellCept has boosted prescriber confidence and is the ideal cornerstone immunosuppressive agent for 'heart healthy' treatment regimens."

About the study

A total of 650 heart transplant patients from 28 centres were enrolled in the pivotal trial. Patients were then randomly assigned to receive CellCept (3000mg/day) or azathioprine (1.5-3.0 mg/kg/day), in addition to cyclosporine and corticosteroids.

IVUS[a] results, including an increase in MIT[b] (measures the thickening of the wall of the coronary artery) of at least 0.3mm from baseline to one-year, are widely considered to be a marker for poor long-term outcome after heart transplantation. The analysis showed that a significantly larger number of patients treated with azathioprine had first year MIT of ≥0.3 mm compared to those treated with MMF.

About CellCept

CellCept is the cornerstone of low toxicity immunosuppressant therapy. It has been available to patients for 10 years, initially through clinical trials and more widely since 1995, following licence approval as a key component of the maintenance immunosuppression used in patients at risk of organ rejection following kidney transplant. CellCept has also been approved for prevention of rejection in heart, liver and paediatric kidney transplant in 1998, 2000 and 2001 respectively.

Over this time, CellCept has become one of the world's most widely studied immunosuppressant and with more than 275,000 patients having received the drug worldwide, it is the largest selling branded immunosuppressive in North America today.

For CellCept, this therapeutic success represents a decade of patient experience, built on a foundation of rigorous and landmark clinical trials that have set the standards for clinical research in solid organ transplant. Data from these trials and long term follow up show that CellCept prolongs organ graft and patient survival, is safe with a low toxicity profile and is also associated with a reduced risk of post transplant malignancy.

CellCept's innovative clinical trials programme continues to offer therapeutic solutions to unmet clinical needs. Research is ongoing in organ transplantation and autoimmune disease, to help provide clinical benefit to a wider range of patients and reduce their reliance on more toxic agents.

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[a] IntraVascular UltraSound

[b] Maximal Intimal Thickness

Roche in transplantation

Roche is strongly committed to improving the long-term outcomes of transplantation and enhancing the quality of life of transplant recipients. Roche has developed innovative therapies that improve graft and post-transplant health: CellCept is the cornerstone of low toxicity immunosuppressant therapies. CellCept is the largest selling branded immunosuppressive in North America, offers both physicians and patients the possibility of an effective long term immunosuppressive regimen with low toxicity, Zenapax prevents the acute rejection of the newly transplanted organ, and Valcyte developed for the prevention of cytomegalovirus, a dangerous viral infection associated with transplantation. In addition, Roche supports basic research in transplantation with its funding of the independent Roche Organ Transplantation Research Fund (ROTRF), which directly supports innovative research projects attracting new researchers with innovative and novel scientific ideas to meet unmet medical needs in solid organ transplantation.

About Roche

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Further information

Roche in transplantation: http://www.roche.com/home/healthcare/healthcare-therapy/healthcare-therapy-indications/healthcare-therapy-indications-transplan.htm

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Roche

Investor Update

April 22, 2004 8:52 AM

European CPMP issues positive opinion for Herceptin plus Taxotere as first-line therapy in metastatic breast cancer

Roche announced today that the European Union's Committee for Proprietary Medicinal Products (CPMP) has given a positive recommendation for the use of Herceptin plus Taxotere as first-line therapy in HER2-positive metastatic breast cancer.

The decision is based on study results(1) which showed that for women with an aggressive form of breast cancer, known as HER2-positive, the addition of Herceptin to Taxotere significantly improved median life expectancy by more than one-third (31 months with Herceptin plus Taxotere vs. 22 months for Taxotere alone). The study also showed that 61% of patients treated with Herceptin plus Taxotere responded to treatment, compared to 34% of patients who received Taxotere alone.

"Following on from the pivotal trial of Herceptin plus Taxol as first-line therapy for metastatic breast cancer, this study confirms Herceptin's survival benefit in combination with taxanes, and establishes a new standard of care in breast cancer management," said Dr. Stefan Manth, Head of Roche's Oncology Division.

The CPMP's positive opinion will now be proposed for approval by the European Commission. The approval will allow for the earlier use of Herceptin in combination with taxanes by patients with HER2-positive metastatic breast cancer.

HER2-positive breast cancer
HER2-positive breast cancer refers to a type of breast cancer in which increased quantities of the HER2 (Human Epidermal growth factor Receptor 2) protein are present on the surface of the tumour cells. This is known as 'HER2 overexpression'. High levels of HER2 overexpression are present in a particularly aggressive form of breast cancer which responds poorly to chemotherapy.

Editor's Notes

About the study
188 patients were recruited into the study (M77001). 94 patients randomised to receive Herceptin plus Taxotere and 94 randomised to receive Taxotere alone. Two patients in the combination arm did not receive study drug and were excluded from the final analysis. Taxotere was scheduled at a dose of 100 mg/m2 every 3 weeks for at least 6 cycles. Herceptin was administered in 2mg/kg weekly doses until disease progression (after an initial loading dose of 4mg/kg). Patients in the Taxotere arm of the study were given the option to cross over to receive Herceptin, following disease progression.

About breast cancer
Eight to nine percent of women will develop breast cancer during their lifetime, making it one of the most common types of cancer in women. Each year more than one million new cases of breast cancer are diagnosed worldwide, with a death rate of nearly 400,000 people per year(2).

About Herceptin
Herceptin is a targeted humanised antibody treatment that received approval in the European Union in 2000 for use in patients with metastatic breast cancer, whose tumours overexpress the HER2 protein. It is indicated for treatment of patients both as first-line therapy in combination with Taxol and as a single agent in second- and third-line therapy. Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche.

About Roche in oncology
Within the last five years the Roche Group has become the world's leading provider of anti-cancer treatments, supportive care products and diagnostics. Its oncology business includes an unprecedented four marketed products with survival benefit: Herceptin, MabThera, Xeloda and Avastin, which has been launched in the US recently, treat a range of malignancies such as breast cancer, non-Hodgkin's lymphoma and colorectal cancer. Other key products include NeoRecormon (anaemia in various cancer settings), Bondronat (prevention of skeletal events in breast cancer and bone metastases patients, hypercalcemia of malignancy), Kytril (chemotherapy and radiotherapy-induced nausea and vomiting) and Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma). Roche's cancer medicines generated sales of more than 6 billion Swiss francs in 2003.

Roche is developing new tests which will have a significant impact on disease management for cancer patients in the future. With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreas and lung cancer, as well as a range of molecular oncology tests, Roche will continue to be the leaders in providing cancer focused treatments and diagnostics.

Roche Oncology has four research sites (two in the US, Germany and Japan) and four Headquarter Development sites (two in the US, UK and Switzerland).

About Roche
Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of 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 employs roughly 65,000 people in 150 countries. The Group has alliances and R&D agreements with numerous partners, including majority ownership interests in Genentech and Chugai.

(1) M77001 12-month update results, presented at the European Breast Cancer Conference in March 2004
(2) World Health Organization, 2000

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With best regards,
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