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Basel, 2 June 2006

MabThera recommended for approval in rheumatoid arthritis in Europe

First selective B cell therapy provides patients with a real option to tackle this debilitating disease

Roche announced today that MabThera (rituximab) has received a recommendation for approval from the Committee for Medicinal Products for Human Use (CHMP) for the treatment of rheumatoid arthritis (RA) in Europe. MabThera is now a step closer to being available for RA patients who have had an inadequate response or intolerance to current treatment options (including TNF inhibitors) and is the first and only selective B cell therapy. B cells play a key role in the chain of inflammatory events that ultimately lead to the damage of bone and cartilage in the joints, both serious outcomes characteristic of RA.

Professor Paul Emery, University of Leeds, UK, one of the lead investigators in the REFLEX¹ study commented: "This is a very exciting time – MabThera is set to make a substantial difference to people suffering from RA in Europe who do not receive sufficient relief from currently available therapy or who are not able to tolerate it. This new approach has the ability to provide long lasting clinical benefits with each short course of therapy every six to twelve months."

"This positive opinion is a major milestone for MabThera - the first treatment for RA in our autoimmune portfolio. We are delighted that MabThera will soon be available as a new therapeutic option for many people afflicted with this debilitating disease" said Eduard Holdener, Head of Roche's Global Pharma Development.

As per the CHMP positive opinion, MabThera in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs including one or more tumour necrosis factor (TNF) inhibitors. Of the RA patients treated with current biologic therapy,

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up to 40% do not have a satisfactory outcome and at present have few treatment alternatives. There is therefore a high need for novel and effective options for patients whose daily life continues to be impacted by this serious disease.

The announcement from the CHMP follows positive results from the phase III REFLEX study which showed that MabThera is a highly effective therapy for controlling symptoms in RA patients, providing lasting improvement after only two infusions per treatment course. The study showed that in particular, MabThera shows impressive results in reducing swollen and tender joints, improving fatigue and the quality of life of patients. Further analysis of the REFLEX trial including one year radiographic data and the effect of repeat treatment courses, will be presented at the European League Against Rheumatism (EULAR) in June 2006.

MabThera, marketed in the US by Genentech under the brand name Rituxan, has recently also received FDA approval for treatment of moderate to severe RA, after priority review.

RA is one of the most common forms of autoimmune disease which affects more than 21 million people worldwide, with up to 2 million sufferers in Europe alone.

MabThera is well established in the treatment of a form of lymphatic cancer called non-Hodgkin's lymphoma (NHL) where over 730,000 patients have been treated with MabThera over a seven year period without major safety concerns.

About the REFLEX study

The REFLEX study (Randomised Evaluation of Long-term Efficacy of Rituximab in RA) is a multi-centre, randomized, double-blind, placebo-controlled Phase III study. In this trial, patients who received a single course of only two infusions of MabThera with a stable dose of methotrexate (MTX) displayed a statistically significant improvement in symptoms measured at 24 weeks, compared to those receiving placebo and MTX. Most of the patients who received additional courses did so 24 weeks after the previous course. A preliminary analysis of the REFLEX data did not reveal any unexpected safety signals and the companies continue to monitor the long-term safety of MabThera in all clinical trials.

Significant improvements across all symptom parameters

The results of the six-month analysis show that MabThera in combination with methotrexate (MTX), a standard RA treatment, was highly effective, producing statistically significantly higher response rates compared to MTX plus placebo: 51% of patients achieved 20% improvement in signs and symptoms (ACR20²), compared to 18% with MTX alone. The difference in the two groups was apparent after 8 weeks and sustained for the duration of the study after only one course

of 2 infusions of MabThera, two weeks apart. Over the six-month period, more than five times as many patients in the MabThera group achieved a 50% improvement in signs and symptoms compared to MTX alone (ACR50: 27% vs 5%), and twelve times more MabThera patients achieved a 70% improvement (ACR70: 12% vs 1%). Most patients who received additional courses did so 6 months after the previous course.

About MabThera in rheumatoid arthritis

MabThera selectively targets a subset of B cells that express CD20, leaving stem, pro-B and plasma cells unaffected. This subset of B cells plays a key role in the autoimmune process of RA and MabThera aims to interrupt this process by inhibiting a series of reactions inflaming the synovia and leading to cartilage loss and bone erosion that is characteristic of the disease. More than 1000 patients with RA have been treated with MabThera in clinical trials to date. A comprehensive phase III clinical development programme is also currently underway to further investigate the potential clinical benefit of MabThera in earlier RA.

About rheumatoid arthritis

Rheumatoid arthritis is a progressive, systemic autoimmune disease characterized by inflammation of the membrane lining in joints. This inflammation causes a loss of joint shape and function, resulting in pain, stiffness and swelling, ultimately leading to irreversible joint destruction and disability. Characteristics of RA include swelling, pain, and movement limitation around joints of the hands, feet, elbows, knees and neck. RA may shorten life expectancy by affecting major organ systems and after 10 years, less than 50% of patients can continue to work or function normally on a day to day basis.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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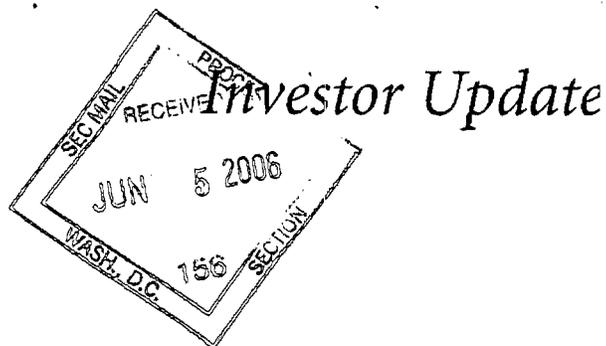
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References:

¹The REFLEX study (Randomised Evaluation of Long-term Efficacy of Rituximab in RA) is a multi-centre, randomized, double-blind, placebo-controlled Phase III study.

²The ACR response is a standard assessment used to measure patients' responses to anti-rheumatic therapies, devised by the American College of Rheumatology (ACR). It requires a patient to have a defined percentage reduction in a number of symptoms and measures of their disease. For example, a 20 or 50% level of reduction (the percentage of reduction of RA symptoms) is represented as ACR20, ACR50 or ACR70. An ACR70 response is exceptional for existing treatments and represents a significant improvement in a patient's condition.



Basel, 31 May 2006

IAS 19 (revised): effects on the Roche Group results

Effective 1 January 2006 the Roche Group is revising its accounting policies for pensions and other post-employment plans, following the implementation of IAS 19 (revised) 'Employee Benefits'.

Amongst other matters, the revised standard allows actuarial gains and losses from defined benefit plans to be recorded directly to equity with the result that the balance sheet represents the net funding status of the plans. This improves the comparability of the Groups results to those of other healthcare companies and allows readers to make a more accurate assessment of the Group's financial position.

In addition the Group now reports the expected return on plan assets and interest costs from defined benefit plans as part of financial income and financing costs, respectively. This change in presentation aligns the reporting of the Group's results more closely with its internal management and organisation structure.

The revised standard requires retrospective application, and so the previously published 2005 results will be restated to include these changes. A summary of the impacts of these changes on the Group's results is given in the table below. Roche's restated income statement for the periods Full-Year 2005 and Half-Year 2005 and the restated balance sheet for 31 December 2005 can be found in the appendix.

The application of IAS 19 (revised) does not change our guidance to the market on the underlying business.

CHF millions (unless stated)	Six months ended			Year ended		
	30 June 2005			31 December 2005		
	Previously published ¹⁾	Restated	Change	Previously published	Restated	Change
Operating profit *	4,373	4,454	81	9,025	9,189	164
- Pharmaceuticals	3,608	3,645	37	7,463	7,539	76
- Diagnostics	904	946	42	1,687	1,771	84
Operating margin *	26.3	26.8	+0.5	25.4	25.9	+0.5
- Pharmaceuticals	28.5	28.8	+0.3	27.4	27.6	+0.2
- Diagnostics	22.8	23.8	+1.0	20.5	21.5	+1.0
Net financial income	69 ¹⁾	85	16	296	328	32
Income taxes	(1,036) ¹⁾	(1,066)	(30)	(2,224)	(2,284)	(60)
Net income	3,261 ¹⁾	3,328	67	6,730	6,866	136
Diluted EPS (CHF)	3.28 ¹⁾	3.36	+0.08	6.71	6.87	+0.16
Core EPS (CHF)	3.72 ¹⁾	3.80	+0.08	7.68	7.84	+0.16

* Before exceptional items

1) Previously published 30 June 2005 figures have been restated for the changes in IFRS that were applied retrospectively in the second half of 2005 and were already included in the 2005 Annual Financial Statements.

Roche invites you to join a conference call to discuss the impact of IAS 19 (revised) on the Roche Group Financial statements. The conference call will be held on

Wednesday, June 7, 2006

2 p.m. - 3 p.m. (CET)

The conference call will consist of a short presentation, followed by a Q&A-session (with live access to the speakers). The call will be hosted by Ian Bishop, Head of External Reporting and Karl Mahler, Head of Investor Relations. Also participating will be key members of the Roche Corporate Finance Accounting and Reporting Team.

Analysts are invited to dial in to the conference call using the following dial-in numbers:

+41 (0) 91 610 5600 (Europe and ROW)
+1 (1) 866 291 4166 (USA Toll Free)
+44 (0) 207 107 0611 (UK)

Please dial in to the conference call 10 – 15 minutes before the call is scheduled to start.

Alternatively, a live audio webcast can be accessed via <http://ir.roche.com> (listen only, no access to speakers)

From June 6, 7:30 CET, the presentation will be available from the IR website at <http://ir.roche.com>.

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

Access is by dialling:

+41 91 612 4330 (Europe and ROW) or
+1 (1) 866 416 2558 (USA)
+44 20 7108 6233 (UK)

Listeners will be asked to enter the ID 009 followed by the # sign

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Appendix:

1. Consolidated income statement for the six months ended 30 June 2005 in millions of CHF

	Pharmaceuticals	Diagnostics	Corporate	Group
Sales	12,652	3,970	-	16,622
Royalties and other operating income	542	168	-	710
Cost of sales	(2,831)	(1,500)	-	(4,331)
Marketing and distribution	(3,354)	(998)	-	(4,352)
Research and development	(2,207)	(336)	-	(2,543)
General and administration	(825)	(192)	(137)	(1,154)
Amortisation and impairment of intangible assets	(332)	(166)	-	(498)
Operating profit before exceptional items	3,645	946	(137)	4,454
Major legal cases	-	(146)	-	(146)
Operating profit	3,645	800	(137)	4,308
Associated companies				-
Financial income				554
Financing costs				(469)
Profit before taxes				4,393
Income taxes				(1,066)
Profit from continuing businesses				3,327
Profit from discontinued businesses				1
Net income				3,328
Attributable to				
- Roche shareholders				2,884
- Minority interests				444
Earnings per share and non-voting equity security			Continuing	
			businesses	Group
Basic (CHF)			3.42	3.42
Diluted (CHF)			3.35	3.36

Core (CHF)

3.80

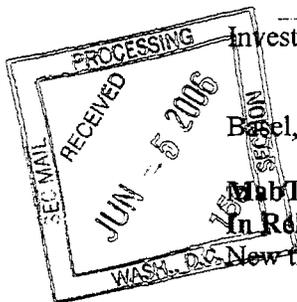
2. Consolidated income statement for year ended 31 December 2005 in millions of CHF

	Pharmaceuticals	Diagnostics	Corporate	Group
Sales	27,268	8,243	-	35,511
Royalties and other operating income	1,176	271	-	1,447
Cost of sales	(6,016)	(3,254)	-	(9,270)
Marketing and distribution	(7,458)	(2,049)	-	(9,507)
Research and development	(4,970)	(702)	-	(5,672)
General and administration	(1,785)	(403)	(121)	(2,309)
Amortisation and impairment of intangible assets	(676)	(335)	-	(1,011)
Operating profit before exceptional items	7,539	1,771	(121)	9,189
Major legal cases	(210)	(146)	-	(356)
Operating profit	7,329	1,625	(121)	8,833
Associated companies				1
Financial income				1,313
Financing costs				(985)
Profit before taxes				9,162
Income taxes				(2,284)
Profit from continuing businesses				6,878
Profit from discontinued businesses				(12)
Net income				6,866
Attributable to				
- Roche shareholders				5,923
- Minority interests				943
Earnings per share and non-voting equity security			Continuing	
			businesses	Group
Basic (CHF)			7.02	7.01
Diluted (CHF)			6.89	6.87
Core (CHF)				7.84

3. Consolidated balance sheet for year ended 31 December 2005 in millions of CHF

Non-current assets	
Property, plant and equipment	15,097
Goodwill	6,132
Intangible assets	6,256
Investments in associated companies	58
Financial long-term assets	2,190
Other long-term assets	660
Deferred income tax assets	2,551
Post-employment benefit assets	625
Total non-current assets	33,569
Current assets	
Inventories	5,041
Accounts receivable	7,698
Current income tax assets	299
Other current assets	1,703
Marketable securities	16,657
Cash and cash equivalents	4,228
Total current assets	35,626
Total assets	69,195
Non-current liabilities	
Long-term debt	(9,322)
Deferred income tax liabilities	(3,462)
Post-employment benefit liabilities	(4,408)
Provisions	(1,547)
Other non-current liabilities	(806)
Total non-current liabilities	(19,545)
Current liabilities	
Short-term debt	(348)
Current income tax liabilities	(811)
Provisions	(833)
Accounts payable	(2,373)
Accrued and other current liabilities	(5,127)
Total current liabilities	(9,492)
Total liabilities	(29,037)
Total net assets	40,158
Equity	
Capital and reserves attributable to Roche shareholders	33,334
Equity attributable to minority interests	6,824
Total equity	40,158

Roche - Investor Update



Investor Update

Basel, 2 June 2006

MabThera Receives Positive Opinion In Europe For Maintenance Therapy In Relapsed or Refractory Follicular Non-Hodgkin's Lymphoma

New treatment option dramatically improves patient survival

Roche announced today that the European Union's Committee on Human Medical Products (CHMP) has given a positive recommendation for the use of MabThera as maintenance therapy for patients with relapsed or refractory follicular Non-Hodgkin's Lymphoma (NHL). Patients will now have access to MabThera maintenance therapy that has been clinically proven to reduce the risk of death by almost half (48%) compared to standard disease management.

"We have not seen such a remarkable improvement in survival for indolent NHL in the last 30 years. The trial demonstrated that MabThera maintenance therapy is well tolerated and highly beneficial for all patients, including those who have already received MabThera as part of their initial therapy," said Professor Marinus van Oers M.D. from the Academic Medical Center of the University of Amsterdam and lead investigator of the pivotal study. "Maintenance therapy with MabThera may well become the new standard of care for these patients."

"The positive opinion is an important step forward leading towards the availability of MabThera maintenance therapy for all patients who could benefit from it," said Ed Holdener, Head of Roche's Global Pharma Development. "The dramatic benefit observed with MabThera maintenance therapy as demonstrated by the prolongation of progression-free survival and overall survival provides hope and confidence for the future in this difficult to cure disease."

The label extension is based on the impressive results of the EORTC (European Organisation for Research and Treatment of Cancer) 20981 study, performed in 18 countries worldwide, that was presented at the 47th annual conference of the American Society of Hematology in Atlanta in December 2005.

In Western Europe alone, 20'000 people are newly diagnosed with indolent NHL every year, and around 40,000 are being treated for this disease. NHL is one of the fastest growing cancers and has grown in incidence by 80% since the early 1970s.¹

About the pivotal study

In the EORTC 20981 (European Organisation for Research and Treatment of Cancer) trial, 465 patients with relapsed or refractory follicular NHL were randomised to receive either 3-weekly cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) chemotherapy or MabThera plus CHOP as induction therapy. Responding patients were then again randomised to either MabThera maintenance therapy, or observation (no further treatment).

MabThera maintenance therapy was applied as a single infusion of 375 mg/m² every three months over a period of two years. The primary endpoints were

response rates and progression-free survival for the initial treatment phase and the maintenance phase of the study, respectively. The trial was performed in 130 centres in Canada, Australia, Netherlands, UK, Norway, Slovenia, Slovakia, Belgium, Hungary, South Africa, Sweden, New Zealand, Denmark, Egypt, France, Switzerland, Italy and Poland.

Results of the induction phase

The results of the induction phase of the trial showed that patients who received MabThera and CHOP (R-CHOP) had a significantly higher rate of complete remission than patients who received CHOP chemotherapy alone (29% vs. 16%, p value <0.0001). Furthermore, MabThera and CHOP chemotherapy significantly increased progression free survival compared to CHOP chemotherapy alone (median progression-free survival of 33 months vs. 20 months, p value =0.0003).

Results of the maintenance phase

Overall survival (% of patients alive at 3 years)

	No maintenance	Maintenance	p value	Risk reduction ^a
All patients	77%	85%	0.011	48%
CHOP subgroup	71%	82%	0.073	48%
R-CHOP subgroup	81%	88%	0.059	50%

^a Treatment effect of maintenance therapy – reduction in the risk of death

Median progression-free survival

	No maintenance	Maintenance	p value	Risk reduction ^b
All patients	15 months	52 months	<0.0001	60%
CHOP subgroup	12 months	42 months	<0.0001	70%
R-CHOP subgroup	23 months	52 months	0.0043	46%

^b Treatment effect of maintenance therapy – reduction in the risk of progression of the disease, relapse or death

About Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphoma (NHL) affects 1 million people worldwide. Indolent NHL, representing about 45% of NHL patients, is a slow developing but serious cancer of the lymphatic system. It is currently considered incurable.

About MabThera

MabThera is a therapeutic antibody that binds to a particular protein - the CD20 antigen - on the surface of normal and malignant B-cells. It then recruits the body's natural defences to attack and kill the marked B-cells. Stem cells (B-cell progenitors) in bone marrow lack the CD20 antigen, allowing healthy B-cells to regenerate after treatment and return to normal levels within several months.

MabThera is indicated for the treatment of indolent and aggressive Non-Hodgkin's Lymphoma. More than 730,000 patients have been treated with MabThera worldwide to date.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes

on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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Further Information

- [Roche in Oncology](#)
- [Lymphoma](#)
- [The Lymphoma Coalition](#)
- [Cancer](#)
- [World Health Organization](#)

References:

1 World Health Report 2000, World Health Organization, www.who.int.

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