

Basel, 23 July 2015

Roche delivers strong performance in the first half of 2015

- Group sales up 6% at constant exchange rates¹, 3% in Swiss francs
- Pharmaceuticals Division sales up 5%, driven by oncology (HER2-positive breast cancer medicines +21%, Avastin +9%, MabThera/Rituxan +6%) and immunology (Actemra/RoActemra +25%, Xolair +28%)
- Diagnostics Division sales up 7%, driven by Professional Diagnostics (+7%) and Molecular Diagnostics (+12%)
- Strong demand for idiopathic pulmonary fibrosis medicine Esbriet
- Positive phase III results for ocrelizumab in multiple sclerosis
- Immunotherapy candidate atezolizumab delivers positive study results in lung, breast and bladder cancers
- Core earnings per share² increased by 7% at constant exchange rates, 1% in Swiss francs
- IFRS³ net income stable at constant exchange rates, -7% in Swiss francs
- Outlook for 2015 confirmed

Key figures	In millions of CHF		% change	
	2015	2014	CER ¹	CHF
January - June				
Group sales	23,585	22,974	+6	+3
Pharmaceuticals Division	18,350	17,834	+5	+3
Diagnostics Division	5,235	5,140	+7	+2
Core operating profit excl. filgrastim ²	9,236	9,410	+2	-2
Core EPS - diluted (CHF) excl. filgrastim ²	7.22	7.57	+2	-5
IFRS net income	5,249	5,641	0	-7

¹ Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average full-year 2014).

² This increase excludes the one-time benefit of 428 million Swiss francs before tax related to the divestment of filgrastim rights in 2014.

³ IFRS: International Financial Reporting Standards.

Unless otherwise stated, all growth rates are in constant exchange rates (CER)

Commenting on the Group's results, Roche CEO Severin Schwan said: "We had continued strong sales growth in both Pharmaceuticals and Diagnostics in the first half. I am very encouraged by the strong uptake of our new medicine Esbriet, for idiopathic pulmonary fibrosis, following our acquisition of InterMune last year. We have made significant progress in cancer immunotherapy and now have over forty programmes in clinical development. I am also pleased with the very positive results of the phase III studies for ocrelizumab in multiple sclerosis. Based on the strong first half, I am confident we will reach our full-year targets for 2015."

Group results

Strong performance across both divisions

Sales increased 6% in the first half, with significant growth of sales of oncology and immunology medicines. There was also strong growth in the Diagnostics Division, driven particularly by immunodiagnostic and molecular diagnostics products.

In the Pharmaceuticals Division, 5% sales growth was driven by medicines to treat HER2-positive breast cancer (Herceptin, Perjeta, Kadcyla, combined +21%) and Avastin (+9%), which saw very strong growth in use for cervical and ovarian cancers. Avastin is now used to treat seven different types of cancer.

MabThera/Rituxan (+6%) for blood cancers and rheumatoid arthritis continued to grow solidly.

Actemra/RoActemra (+25%), which is used mainly to treat rheumatoid arthritis, also remained a significant growth contributor in the first six months. Xolair (+28%), which is now used in the treatment of chronic hives as well as asthma, continued to grow strongly. Uptake of Esbriet was very strong in the first six months (229 million Swiss francs). Sales of oral chemotherapy drug Xeloda and anti-viral medicine Valcyte declined as these medicines are no longer patent protected. Sales of hepatitis medicine Pegasys and eye medicine Lucentis were lower as a result of increased competition.

In the Diagnostics Division, sales increased 7%, driven primarily by immunodiagnostic products from the Professional Diagnostics business area (+7%). The Molecular and Tissue Diagnostics business areas also performed well, each up 12%, and sales in Diabetes Care increased 1%, despite ongoing challenging market conditions.

The Swiss franc strengthened considerably against the euro during the first half of 2015, after the Swiss National Bank lifted its exchange rate peg in January, whilst weakening against the US dollar. The Japanese yen continued to further weaken against the Swiss franc, as did most European and Latin American currencies. Overall, there was a significant negative currency impact of 3 percentage points on sales.

Core earnings per share growth ahead of sales²

Core⁴ operating profit increased 7% in the first half, excluding a one-time income from the sale of filgrastim rights in 2014. On the same basis, core earnings per share (7.22 Swiss francs) were 7% higher.

IFRS net income was 7% lower in Swiss francs at 5.2 billion Swiss francs as a result of the significant negative currency impact, the base effect from the one-time income from the sale of filgrastim rights and the impact from the recent acquisitions, in particular InterMune. In constant exchange rates net income was stable.

Positive data in oncology and neuroscience

In May, Roche presented highly encouraging data for cancer immunotherapy candidate atezolizumab (anti-PDL1) in non-small cell lung cancer, both in monotherapy and in combination with chemotherapy, and in recurrent advanced bladder cancer. There were also positive results for atezolizumab plus chemotherapy in triple negative breast cancer reported earlier in the year. In July, further phase II data showed that atezolizumab shrank tumours in people with locally advanced or metastatic urothelial bladder cancer.

Another oncology highlight was updated data on the MEK inhibitor cobimetinib in combination with Zelboraf, which helped people with BRAF-mutated advanced melanoma live for a year without their disease worsening. In addition, updated data from the phase II NeoSphere study provided additional evidence on the role of Perjeta in combination with Herceptin and chemotherapy, in the neoadjuvant (pre-surgical) treatment of HER2-positive early breast cancer. The results suggest that people who received the Perjeta regimen prior to surgery were 31 percent less likely to experience disease worsening, recurrence or death, compared with those who received Herceptin and chemotherapy. There was also very encouraging data presented for trials of alectinib in ALK-mutated lung cancer that will form the basis of regulatory filing in this type of lung cancer; as well as data from an independent phase III study of Avastin in mesothelioma.

In neuroscience, there was an important milestone in the first half with the readout of two phase III studies of ocrelizumab in relapsing multiple sclerosis, the most common form of the disease. The results showed a significant reduction in both relapses and disability progression compared with an interferon-based standard-of-care treatment.⁵

Investigational medicine crenezumab will move into phase III clinical development in prodromal-to-mild Alzheimer's disease. A strategy for higher dosing is being explored for gantenerumab, another candidate for the treatment of Alzheimer's disease.

⁴ The core basis excludes non-core items such as global restructuring costs, amortisation and impairment of goodwill and intangible assets and loss on major debt restructuring.

⁵ Interferon beta-1a (Rebif®)

Data for investigational biologic ACE910 for hemophilia A was presented in June and showed a reduction in bleeding rates for people on the trial. Roche is moving the ACE910 development programme forward and aims to initiate phase III trials in a subset of patients later in the year.

The FDA granted Roche three Breakthrough Therapy Designations in the first six months: for atezolizumab in PDL1 positive non-small cell lung cancer; venetoclax in a type of relapsed-refractory chronic lymphocytic leukemia; and Actemra/RoActemra in systemic sclerosis. In total, Roche investigational medicines have been granted eight Breakthrough Therapy Designations.

The Group achieved a number of marketing approvals in different markets in the first half: Avastin with chemotherapy in the EU for advanced cervical cancer; Lucentis in the US for diabetic retinopathy; and Zelboraf for advanced melanoma in Japan. In addition, the EU's Committee for Medicinal Products for Human Use recommended approval of Perjeta for use before surgery in HER2-positive early breast cancer.

Diagnostic product launches to further strengthen key growth areas

There were a number of key product launches in the first half in the Diagnostics division. In Molecular Diagnostics, the cobas DPX test and the cobas HBV quantitative nucleic acid test for use on the cobas 6800/8800 systems were introduced. The US authorities also cleared the cobas HSV1 and HSV2 test, the MRSA/SA test, the cobas Cdiff test, as well as approvals for the cobas KRAS test. In Professional Diagnostics, the improved CARDIAC point-of-care Troponin T test for the cobas h 232 system was launched. Additionally, the Elecsys HTLV-I/II immunoassay has been made available in countries that accept the CE mark (a European Economic Area standard which is used in a number of other countries worldwide). This is a diagnostic test to help detect antibodies against Human T-lymphotropic virus I or II infection in donated blood and routine diagnostic samples.

In the US, the use of the cobas Strep A test and the cobas Liat System were expanded after the CLIA (Clinical Laboratory Improvement Amendments) regulation was waived.

Outlook for 2015

Roche continues to expect sales to grow low- to mid-single digit at constant exchange rates in 2015. Core earnings per share are targeted to grow ahead of sales at constant exchange rates.⁶ Roche expects to further increase its dividend in Swiss francs.

⁶ This outlook excludes the one-time benefit of 428 million Swiss francs before tax related to the divestment of filgrastim rights in 2014.

Pharmaceuticals Division

Sales increased 5% in the Pharmaceuticals Division to 18,350 million Swiss francs in the first six months, with oncology continuing to perform strongly, in particular medicines for HER2-positive breast cancer (Herceptin, Perjeta, Kadcyla, combined +21%). Avastin (+9%) grew in its new indications for ovarian and cervical cancers, whilst MabThera/Rituxan (+6%) also grew strongly, in both oncology and immunology. Sales of immunology medicines also showed strong growth, with Actemra/RoActemra up 25% and Xolair +28%.

Esbriet for idiopathic pulmonary fibrosis, which was acquired with InterMune in 2014, made a significant contribution to growth with 229 million Swiss francs of sales. Sales of Xeloda and Valcyte, which are no longer patent protected, declined. Pegasys and Lucentis sales were also lower, as a result of increased competition.

In the US (+7%), sales of medicines for HER2-positive breast cancer (+22%) continued to drive growth, as demand increased for Herceptin in combination with Perjeta, both in pre-surgical use and in metastatic breast cancer. MabThera/Rituxan and Avastin grew strongly (both +9%). There was also strong uptake of Esbriet (148 million Swiss francs), which was approved for idiopathic pulmonary fibrosis in 2014, as well as Xolair (+28%), which is now used to treat chronic hives as well as allergic asthma.

In Europe, sales were 2% higher driven by Perjeta and Kadcyla in the treatment of HER2-positive breast cancer and strong demand for Esbriet (69 million Swiss francs) and Actemra/RoActemra (+23%). Pricing pressure continued in some markets, however demand remained high. Lower Tamiflu sales in the first half reflected a base effect from UK government stockpiling in early 2014.

In the International region (+7%), strong sales were driven by Latin America (+12%), particularly Brazil and Argentina. There was also strong growth in Turkey and South Korea, mainly from oncology medicines. In China, sales were 1% higher, with continued strong demand for Herceptin and MabThera/Rituxan. Sales of mature products Xeloda, Pegasys and Tarceva were impacted by competition.

In Japan (+7%), there was strong demand for Avastin (+16%) in all indications, HER2-positive breast cancer medicines (+20%) and MabThera/Rituxan (+14%). Newly-approved Alecensa (alectinib) for ALK-positive lung cancer continued to grow strongly, as did Actemra/RoActemra (+14%), with additional growth from the subcutaneous dosage form. Edirol and Bonviva/Boniva, both used in osteoporosis treatment, also made a significant contribution to growth.

Key pharmaceutical products in the first half of 2015

Top-selling pharmaceuticals and recent new launches January - June 2015	Total		United States		Europe		Japan		International**	
	CHF m	%*	CHF m	%*	CHF m	%*	CHF m	%*	CHF m	%*
MabThera/Rituxan	3,496	6	1,875	9	895	0	107	14	619	7
Herceptin	3,265	11	1,176	18	998	0	125	6	966	18
Avastin	3,263	9	1,502	9	891	3	349	16	521	19
Lucentis	769	-13	769	-13	-	-	-	-	-	-
Actemra/RoActemra	675	25	253	32	224	23	103	14	95	28
Perjeta	659	72	379	50	188	132	39	17	53	160
Tarceva	602	-7	319	-8	114	-15	43	-2	126	3
Xolair	593	28	593	28	-	-	-	-	-	-
Activase/TNKase	437	15	416	17	-	-	-	-	21	-6
Tamiflu	417	10	308	54	12	-81	53	-5	44	-9

Recent new launches										
Kadcyla	362	65	150	-1	152	171	27	231	33	196
Esbriet	229	-	148	-	69	-	-	-	12	-
Zelboraf	106	-25	23	-41	62	-30	1	-	20	22
Erivedge	72	27	50	35	16	-5	-	-	6	126
Gazyva/Gazyvaro	63	237	35	81	9	***	-	-	19	***

* At constant exchange rates

** Asia-Pacific, EEMEA (Eastern Europe, Middle East and Africa), Latin America, Canada, Others

*** Over 500%

Herceptin, **Perjeta**, and **Kadcyla** (combined +21%) for HER2-positive breast cancer and HER2-positive metastatic gastric cancer drove growth in the first half. **Herceptin** (+11%) sales grew strongly in the US (+18%) associated with a longer duration of treatment in combination with Perjeta in advanced breast cancer, as well as in pre-surgical use. Increasing demand was also seen in the International region (+18%), notably in China and Brazil, as well as in Japan (+6%), with increased use in combination with Perjeta. **Perjeta** (659 million Swiss francs) also saw strong growth, particularly in the US and Europe, with rising demand in both early (pre-surgical) and advanced breast cancer settings. In June, Perjeta was recommended for approval in the EU for pre-surgical use in HER2-positive early breast cancer. **Kadcyla** (362 million Swiss francs) sales were driven by launches in a number of key markets in Europe and Brazil.

MabThera/Rituxan (+6%) for common forms of blood cancers, including non-Hodgkin's lymphoma (NHL), follicular lymphoma and chronic lymphocytic leukemia (CLL); and for rheumatoid arthritis and certain types of ANCA-associated vasculitis, performed well. Sales growth was driven primarily by the US (+9%), as demand continued to increase in oncology and immunology. Sales in the International region were

up 7%, with increasing demand in Brazil and in China, where new patient access programmes have been initiated.

Avastin (+9%) for advanced colorectal, breast, lung, kidney, cervical and ovarian cancer and glioblastoma (a type of brain tumour) had good sales growth. Increased sales were seen across all regions, with rising demand in ovarian and cervical indications in the US (+9%), and strong growth in the International region (+19%), especially in Latin America (+30%). Growth in Japan (+16%) was driven by demand in all approved indications; and sales were up in Europe (+3%). In July, Avastin received approval for the treatment of lung cancer in China.

Lucentis (-13%, US only) for eye conditions, including wet age-related macular degeneration (wAMD), macular edema following retinal vein occlusion (RVO) and diabetic macular edema (DME) was impacted by competitive pressure in the wAMD and DME segments. In February, the FDA approved Lucentis for an additional indication, diabetic retinopathy in people with DME.

Actemra/RoActemra (+25%) for rheumatoid arthritis, systemic juvenile idiopathic arthritis and polyarticular juvenile idiopathic arthritis, recorded strong growth in the first half. Sales increased across all regions, driven by strong demand for the subcutaneous formulation, particularly in the US (+32%), Europe (+23%), International (+28%), and Japan (+14%). Additionally, the FDA granted Breakthrough Therapy Designation for Actemra in systemic sclerosis.

Esbriet (229 million Swiss francs) for idiopathic pulmonary fibrosis, a fatal lung disease, was another key contributor to half-year sales growth. Approved by the FDA last year, Esbriet sales reached 148 million Swiss francs in the US and 69 million Swiss francs in Europe, where it was approved in 2011. Roche acquired InterMune, the company which developed Esbriet, in 2014.

Zelboraf (-25%), for BRAF V600 mutation-positive metastatic melanoma, has been under intense competitive pressure as the standard of care moves from monotherapy to targeted combinations. Updated phase III study results presented in May demonstrated that Roche's investigational regimen of Zelboraf combined with cobimetinib helped people with BRAF-mutated metastatic melanoma live for a year without their disease worsening. Marketing authorisation decisions are expected from the FDA and the European Medical Agency (EMA) by the end of 2015.

Gazyva/Gazyvaro (63 million Swiss francs) for the treatment of chronic lymphocytic leukemia had good sales growth in the first half. Sales in the US benefited from a label update in late 2014, whilst there was good uptake in the International region and Europe. Phase III study results presented in May showed that Gazyva/Gazyvaro extended the time people lived with refractory indolent NHL without their disease worsening. Roche will submit these data to the FDA and EMA for approval.

Major clinical and regulatory news flow in the first half of 2015

Compound	Indication	Milestone	
Cobimetinib + Zelboraf	BRAF V600 mutation-positive metastatic melanoma	FDA Priority Review	Q1✓
Avastin + chemotherapy	advanced cervical cancer	EU approval	Q1✓
Lucentis	diabetic retinopathy	FDA approval	Q1✓
Atezolizumab (anti PD-L1)	PD-L1 positive non-small cell lung cancer	FDA Breakthrough Therapy Designation	Q1✓
Gazyva/Gazyvaro	refractory indolent non-Hodgkin's lymphoma	Phase III results (GADOLIN)	Q1✓
Venetoclax	17p deletion relapsed-refractory chronic lymphocytic leukemia	FDA Breakthrough Therapy Designation	Q2✓
Avastin	mesothelioma	Phase III results (MAPS, independent study)	Q2✓
Atezolizumab + chemotherapy	non-small cell lung cancer	Phase Ib results	Q2✓
Atezolizumab	non-small cell lung cancer	Phase II interim results (POPLAR)	Q2✓
Alectinib	ALK-positive non-small cell lung cancer	Pivotal phase I/II results	Q2✓
ACE 910	hemophilia A	Phase I results	Q2✓
Cobimetinib + Zelboraf	BRAF V600 mutation-positive metastatic melanoma	Phase III results (coBRIM)	Q2✓
Actemra/RoActemra	systemic sclerosis	FDA Breakthrough Therapy Designation	Q2✓
Perjeta	early HER2-positive breast cancer, neoadjuvant (pre-surgical) treatment	CHMP recommendation for EU approval	Q2✓
Ocrelizumab	relapsing forms of multiple sclerosis	Phase III results (OPERA I and OPERA II)	Q2✓
Atezolizumab	urothelial bladder cancer	Pivotal phase II results	Q3✓

Diagnostics Division

Diagnostics Division Sales January - June 2015		In millions of CHF	% change		As % of sales
			At CER*	In CHF	
Sales - Diagnostics Division		5,235	+7	+2	100
Business Areas	Professional Diagnostics	2,972	+7	+2	57
	Diabetes Care	1,057	+1	-7	20
	Molecular Diagnostics	832	+12	+9	16
	Tissue Diagnostics	374	+12	+12	7
Regions	Europe, Middle East, Africa	2,260	+5	-7	43
	North America	1,394	+4	+10	27
	Asia-Pacific	1,037	+15	+18	19
	Latin America	355	+14	+3	7
	Japan	189	-6	-15	4

* At constant exchange rates

In Diagnostics, sales increased (+7%) in the first six months, with Professional Diagnostics (+7%) driving growth through its immunodiagnosics business. Sales were up 12% in Molecular Diagnostics as well as in Tissue Diagnostics and in Diabetes Care (1%). Asia-Pacific (+15%) and EMEA (Europe, Middle East, Africa, +5%) were the main contributors to growth, whilst in North America sales increased 4% and in Latin America 14%. In Japan, sales declined 6%, mainly as a result of the non-renewal of a tender from 2013. Sales in China were up 24%.

The Division also announced an expansion of the HIV Global Access Program to cover infant testing in low and middle income countries. The programme is a partnership with a number of organisations including UNAIDS to improve access to HIV testing.

Professional Diagnostics

Growth in Professional Diagnostics was driven by the immunodiagnosics business (+12%), along with the coagulation monitoring business (+11%). The cobas 8100 V2 automated workflow series was launched, a fully automated system covering all operational pre-analytical and integrated post-analytical steps in a laboratory, as well as sample transport. It is designed for high-throughput laboratories and has a capacity of 1,100 samples per hour. Strong growth was reported in infectious diseases driven by the menu completion with the hepatitis tests.

Introduction of the improved CARDIAC point-of-care Troponin T test for the cobas h 232 system was initiated in countries accepting the CE mark. The Elecsys® HTLV-I/II immunoassay has also now been made available in CE markets. It is a diagnostic test to help detect antibodies against Human T-lymphotropic virus I or II infection in donated blood and routine diagnostic samples.

There was continued good growth in all regions, especially in Asia–Pacific, with continued strong sales increases in China.

Molecular Diagnostics

Sales increased 12%, driven by strong growth in the underlying molecular business (+9%) and the sequencing business. Major contributions to sales growth came from virology (+13%) and HPV screening (+28%).

The cobas DPX test for parvovirus B19 and hepatitis A virus and the cobas HBV quantitative nucleic acid test (HBV: hepatitis B virus) were launched in CE mark countries; both tests are for use on the cobas 6800/8800 systems. The US health authorities granted clearances for the cobas HSV1 and 2 test (HSV: herpes simplex virus), the next generation cobas MRSA/SA test, the cobas Cdiff test to detect *Clostridium difficile* as well as the approval for the cobas KRAS mutation test for use on the cobas 4800 system. A major tender for blood screening was won in the UK. Authorities in the US also granted the CLIA (Clinical Laboratory Improvement Amendments) waiver for the cobas Liat system as well as the cobas Strep A test. This test uses throat swabs and is the first CLIA-waived PCR test to detect the bacterium *Streptococcus pyogenes* (Strep A). The CLIA waiver allows for broad use of the test by healthcare providers in non-traditional laboratory sites.

In the sequencing business, the non-invasive prenatal Harmony test drove sales growth. This product was added to Roche's portfolio following the acquisition of Ariosa Diagnostics.

Sales grew strongly in EMEA and North America, whilst in Japan a decline of sales resulted from the non-renewal of a tender in blood screening in 2013.

Tissue Diagnostics

Sales rose 12% overall, driven by 12% growth in the advanced staining portfolio, which includes immunohistochemistry reagents (+10%). The CINtec franchise for cervical cancer diagnosis grew by 22% and there was continued strong growth for external personalised healthcare services, driven by development agreements with external partners.

All regions contributed to the strong growth, with North America and EMEA as the main growth drivers.

Diabetes Care

Sales increased by 1%, despite continuing challenging market conditions for blood glucose monitoring portfolio especially in the US. Sales of Accu-Chek Mobile grew by 6% and Accu-Chek Aviva/Performa and lancing devices sales were up 4% each. This sales growth outweighed the negative impact of the phase out of older products such as Accu-Chek Advantage and Accu-Chek Compact. The insulin delivery systems (IDS) business grew by 12%, driven by infusion systems and the newly launched Accu-Chek Insight system.

Diabetes Care sales increased in Latin America and Asia–Pacific, strengthening the business unit's global market leadership position in blood glucose monitoring. Sales were stable in EMEA but declined in North

America and Japan. Overall, business efficiencies were gained with the implementation of specific measures that were initiated in 2013 to streamline processes.

Key product launches planned for 2015

Area	Product name	Description	Market
Instruments/devices			
Laboratories	cobas c 513	Dedicated HbA1C analyzer	EU
	cobas t 411	Core laboratory coagulation analyzer	EU
	cobas 8100 V2	Integrated pre- and post-analytical solution	WW* ✓
	cobas 6800/8800	Next-generation molecular (PCR) system	US
	VENTANA HE 600	Automated H&E staining platform	WW
Point of Care	CoaguChek Pro II	Professional system for PT** and a PTT*** testing	EU
Diabetes Care	Accu-Chek Active no-code	Next-generation blood glucose meter, no coding of test strips	WW
	Accu-Chek Connect	Blood glucose meter with connectivity to smartphones, mobile applications and cloud	US
Tests			
Blood screening	cobas MPX test	Multiplex blood screening test for cobas 6800/8800 systems	US
Infectious diseases	Influenza A/B + RSV test	Point-of-care detection on cobas LIAT	US
	HTLV test	Human T-lymphotropic virus test	EU ✓
Virology	cobas HBV test	Quantitative HBV viral load test for cobas 6800/8800	EU ✓
	cobas HIV-1 test	Quantitative HIV-1 viral load test for cobas 4800	EU
	cobas HCV test	Quantitative HCV viral load test for cobas 4800	EU
	cobas HBV test	Quantitative HBV viral load test for cobas 4800	EU
Genomics and Oncology	cobas EGFR test V2	Detection of EGFR mutations in plasma	EU
Cardiology	cobas h 232 Troponin T test	Quantitative point-of-care troponin T test	EU ✓

* Worldwide

** Prothrombin time

*** Activated partial prothrombin time

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In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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