Media Release

Basel, 24 July 2014

Roche with good half year performance

- **Group sales up 5% at constant exchange rates[1], -1% in Swiss francs**
- **Core earnings per share up 7% at constant exchange rates, 0% in Swiss francs**
- **Cancer medicine sales growing well; in particular HER2 breast cancer medicines, Herceptin, Perjeta and Kadcyla**
- **Diagnostics Division showing good growth, especially in the Professional Diagnostics business**
- **FDA Breakthrough Therapy Designation for cancer immunotherapy candidate anti-PDL1**
- **Panel recommends EU approval for Gazyvaro to treat chronic lymphocytic leukemia**
- **Full-year outlook confirmed**

Key figures January-June	**In millions of CHF**		**% change**	
	2014	2013	**CER[1]**	**CHF**
Group sales	22,974	23,295	+5	-1
Pharmaceuticals Division	17,834	18,162	+4	-2
Diagnostics Division	5,140	5,133	+6	0
Core operating profit	9,410	9,488	+7	-1
Operating free cash flow	7,869	7,445	+11	+6
IFRS net income[2]	5,641	6,047	+2	-7
Core earnings per share – diluted	7.57	7.58	+7	0

Commenting on the Group's half year results, Roche CEO Severin Schwan said: "We had a good first half, driven mainly by our cancer medicines, especially the new breast cancer medicines, Perjeta and Kadcyla, as well as by Diagnostics. We made significant progress in our product pipeline, as the FDA granted Breakthrough Therapy Designation for our cancer immunotherapy candidate anti-PDL1, as well as priority

[1] Unless otherwise stated, all growth rates in this document are in constant exchange rates CER (average full-year 2013).
[2] IFRS: International Financial Reporting Standards.

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 Fax +41 61 688 27 75 www.roche.com

reviews for Avastin in two new indications and fast track designation for a promising new antibiotic. In Diagnostics, we also gained an important FDA approval for use of our HPV test in primary screening for cervical cancer. Based on our half year performance, I am confident that we will meet our full-year targets."

Group Results

HER2 breast cancer medicines drive growth

Group sales rose to 22,974 million Swiss francs (+5%) with strong growth from HER2-positive breast cancer medicines, Herceptin, Perjeta and Kadcyla; other oncology medicines Avastin and MabThera/Rituxan; and Actemra/RoActemra for rheumatoid arthritis. Sales of Xeloda, a chemotherapy drug which is no longer patent-protected, were lower as a result of generic competition in a number of markets. In Diagnostics, demand for Professional Diagnostics' products for clinical laboratories remained strong, whilst Diabetes Care sales were unchanged.

Reported sales in Swiss francs were 1 percent lower than the first half of 2013, as the US dollar, along with a number of Latin American currencies and the Japanese yen, have weakened against the Swiss franc.

Core operating profit and cash flow increased

Group core operating profit increased 7%[3] in the first half as a result of the strong operating performance, as well as cost containment in both divisions. Core earnings per share also increased by 7% to 7.57 Swiss francs. Operating free cash flow was 7,869 million Swiss francs, up 11% in the first half. Cash generation in both divisions was strong, despite the increase in net working capital and capital investments in site development and manufacturing expansion. Net working capital was higher as a result of increased inventory levels to ensure supply to patients. IFRS net income, which includes impairment charges of 414 million Swiss francs related to intangible assets in Tissue Diagnostics, was 5,641 million Swiss francs, an increase of 2% at constant exchange rates over the first half of 2013.

Significant progress in Pharma product pipeline

The pipeline currently has 66 new molecular entities in clinical development, of which 12 are in late-stage development.

[3] Included in the Group's core operating profit were some one-time items, including the divestment gain from the sale of the filgrastim franchise rights back to Amgen and the base effect of income from changes to the Group's pension plans in 2013. In aggregate they had no material net impact on the results.

During the first half, Roche presented data on 27 different medicines at the 50th American Society of Clinical Oncology meeting, most notably the results of a Phase I study that showed that the investigational cancer immunotherapy anti-PDL1 (MPDL3280A) shrank tumours in advanced bladder cancer. This medicine has now been granted Breakthrough Therapy Designation by the FDA. Anti-PDL1 moved into Phase III for lung cancer earlier in the year and a broad programme of development in a number of other indications and combinations is ongoing.

There was positive regulatory newsflow throughout the first half, with both the subcutaneous formulations of MabThera/Rituxan for blood cancer and Actemra/RoActemra for rheumatoid arthritis approved in the EU. The EU's committee on medicinal products (CHMP) also recommended that Gazyvaro (known as Gazyva outside the EU) be approved for the treatment of chronic lymphocytic leukemia and Avastin be approved for platinum-resistant recurrent ovarian cancer. In the United States, the FDA has given Avastin filings priority review in treatment for cervical cancer, as well as platinum-resistant ovarian cancer and a fast track designation for LptD, a new antibiotic currently in Phase II trials. In Japan, Alecensa (alectinib) was approved for the treatment of ALK-positive non-small cell lung cancer in July based on a Japanese trial. The FDA has granted Breakthrough Therapy Designation for alectinib and further global studies are ongoing.

The FDA approved a new indication for Xolair, which can now be used to treat chronic idiopathic urticaria, a form of chronic skin hives. This is in addition to its current use in allergic asthma. Phase II data for lebrikizumab, an experimental medicine for severe asthma showed good results for a sub-group of patients who can be identified using a companion diagnostic test. Another investigational medicine, cobimetinib, used in combination with skin cancer medicine Zelboraf, also showed positive top line results in advanced melanoma.

Full-year outlook confirmed

For the full year 2014, Roche expects low- to mid-single digit growth in Group sales at constant exchange rates. Core EPS is targeted to grow ahead of sales. Roche expects to further increase its dividend.

Pharmaceuticals Division

Sales in the Pharmaceuticals Division rose by 4%. In the United States (+5%), growth was driven by sales of medicines for HER2-positive breast cancer, which were 30% higher and Avastin for treatment of colorectal and lung cancer. Sales of Xolair, which was approved for a new indication to treat chronic skin hives, were also higher; as were sales of eye medicine Lucentis. Sales of Xeloda, a chemotherapy drug, were lower, as it is

no longer patent protected in the United States and has generic competition.

In Europe (+3%), sales were also driven by HER2 breast cancer medicines; as well as cancer medicines MabThera/Rituxan and Avastin; and Tamiflu in the United Kingdom.

In Japan (+7%) higher sales reflected strong growth of HER2 breast cancer medicines, as well as increased demand for Avastin in breast and lung cancer and Actemra/RoActemra for rheumatoid arthritis.

In the International Region (+2%), sales growth was driven by Latin America (+11%), in particular in Brazil, Argentina and Venezuela, however political unrest had a negative impact on sales in the Middle East. Sales in China fell by 1%, primarily as a result of lower sales of Tamiflu. Sales of HER2 breast cancer medicines, as well as MabThera/Rituxan, Avastin and Actemra/RoActemra remained solid in China.

Demand for oncology medicines continues to increase

The oncology portfolio continued to drive growth in all regions. Sales of HER2 breast cancer medicines (+20%) were higher, with strong demand for new products Perjeta and Kadcyla, as well as for Herceptin in combination with Perjeta. Avastin (+6%) also showed good growth across the regions, in particular for treatment of colorectal and ovarian cancers. MabThera/Rituxan (+4%), which is now available in a subcutaneous formulation in Europe, delivered solid growth in most regions.

Immunology and ophthalmology performing well

Sales of Actemra/RoActemra (+22%) a medicine for rheumatoid arthritis, increased significantly in all major markets. There was good uptake of the new subcutaneous formulation of the medicine in the United States and this formulation has now also been approved in Europe. Sales of eye medicine Lucentis (+6%), which Roche sells in the United States, continued to grow with increased adoption in the treatment of diabetic macular edema.

Acquisition of Seragon Pharmaceuticals

On 2 July 2014 the Group announced an agreement to acquire a 100% controlling interest in Seragon Pharmaceuticals, Inc., a US private company based in San Diego, California. The closing of the transaction is expected in the third quarter of 2014. With the acquisition, the Group will obtain rights to Seragon's entire portfolio of selective estrogen receptor degraders (SERDs) for the potential treatment of hormone receptor-positive cancers. Seragon's lead product candidate, ARN-810, is a next-generation SERD that is currently in

Phase I clinical trials for patients who have hormone receptor-positive breast cancer and have failed current hormonal agents. The purchase consideration will be 725 million US dollars in cash and up to 1 billion US dollars from a contingent consideration arrangement.

Key products

HER2 breast cancer medicines, Herceptin, Perjeta, Kadcyla (+20%), for HER2-positive breast cancer and HER2-positive metastatic (advanced) gastric cancer. **Herceptin** (+6%) sales growth was driven by the United States (+10%), with increased use in breast cancer in combination with Perjeta. There was also strong growth in the International region (+6%), with significant sales growth in Brazil and China. In Europe, sales increased 3% with higher volumes. The subcutaneous formulation, which was approved in 2013, showed good uptake and is now available in 20 markets, including Germany and the UK. Sales were 4% higher in Japan, with increased usage in combination with the recently launched Perjeta. **Perjeta** (CHF 388 m) is combined with Herceptin to treat first-line metastatic HER2-positive breast cancer and has also been approved in the United States for neo-adjuvant (pre-surgical) treatment in breast cancer. Demand in the United States remains high in both settings. In Europe, uptake was strong in first line metastatic breast cancer, especially in Germany, France and the United Kingdom. **Kadcyla** (CHF 227m) is an antibody-drug conjugate that attaches to HER2-positive cancer cells and delivers chemotherapy directly to them, resulting in a highly potent treatment with fewer adverse side effects. It is now approved in many major markets including the United States and Europe, where adoption of Kadcyla is high and demand remains strong. Reimbursement has also now been agreed in Japan and Brazil, following their respective approvals in late 2013 and early 2014.

MabThera/Rituxan (+4%), for common forms of blood cancers, non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia (CLL); and for rheumatoid arthritis (RA). It is also used to treat granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), which are two types of ANCA (anti-neutrophil cytoplasmic antibody) associated vasculitis. Sales were 4% higher, with strong growth in Europe (+7%), where sales were driven by increased market share in both follicular lymphoma, as well as first line treatment for CLL. Sales were 3% higher in the United States. In International markets, sales rose by 5%, driven by Latin America. The subcutaneous formulation of MabThera in NHL was approved in Europe, as well as in Australia.

Avastin (+6%), for advanced colorectal, breast, lung, kidney and ovarian cancer, and glioblastoma (a type of brain tumour). Sales in the United States rose by 6% with steady demand in colorectal and lung cancer

treatment. In Europe, 5% higher sales were driven by increased use in ovarian cancer. In the International region, sales were 8% higher driven by launches for ovarian cancer and colorectal cancer. In Japan (+10%) demand increased in lung and breast cancer.

Lucentis (+6%, United States only), for eye conditions specifically wet age-related macular degeneration (wAMD), macular edema following retinal vein occlusion (RVO) and diabetic macular edema (DME). Growth was driven largely by increased adoption of Lucentis in treating DME.

Actemra/RoActemra (+22%), for rheumatoid arthritis (RA), systemic juvenile idiopathic arthritis and polyarticular juvenile idiopathic arthritis. Sales growth was strong in all major markets (United States +26%; Europe +20%; International region +15%; Japan +24%) driven by strong demand for monotherapy in rheumatoid arthritis. A new subcutaneous formulation of the medicine was launched in the United States in late 2013 and sales are growing well. This formulation was subsequently approved in Europe and Canada and initial uptake has been positive.

Zelboraf (-5%), for BRAF V600 mutation-positive metastatic melanoma, launched in 2011 and is approved in over 80 countries. Zelboraf is currently facing significant competition from an alternative combination therapy in the US (-43%), whilst in Europe sales were 10% higher. Top line results from a pivotal trial coBRIM, to compare the combination of cobimetinib (a MEK inhibitor) with Zelboraf, against Zelboraf alone were announced in July and the study has met its primary endpoints. Full data will be presented later in the year.

Gazyva/Gazyvaro (CHF 18 m), for frontline treatment of chronic lymphocytic leukemia (CLL). Gazyva was approved in the United States in November 2013 with an FDA Breakthrough Therapy Designation and is included in the CLL treatment guidelines of the National Comprehensive Cancer Network. In May, the EU's advisory committee CHMP, recommended that Gazyva (which will be sold as Gazyvaro in Europe) be approved for CLL in Europe in patients who cannot tolerate aggressive chemotherapy. It is approved in Switzerland and is expected to be approved in a number of key markets later in 2014.

Top-selling pharmaceuticals and recent launches Jan–June 2014	Total		US		Europe		Japan		International**	
	CHF m	%*	CHF m	%*	CHF m	%*	CHF m	%*	CHF m	%*
MabThera/Rituxan	3,360	+4	1, 624	+3	1,018	+7	104	0	614	+5
Avastin	3,097	+6	1,300	+6	983	+5	332	+10	482	+8
Herceptin	3,082	+6	937	+10	1,138	+3	130	+4	877	+6
Lucentis	828	+6	828	+6	-	-	-	-	-	-
Tarceva	651	-1	325	+5	154	-12	49	+22	123	-8
Pegasys	582	-15	137	-28	144	-26	32	+31	269	-2
Actemra/RoActemra	568	+22	180	+26	207	+20	100	+24	81	+15
Xeloda	474	-34	159	-47	58	-64	44	-9	213	-3
Xolair	437	+19	437	+19	-	-	-	-	-	-
CellCept	413	-6	95	-6	110	-7	28	-5	180	-6
Recent launches										
Perjeta	388	+276	237	+183	92	+423	37	-	22	***
Kadcyla	227	+188	143	+83	63	***	9	-	12	***
Zelboraf	155	-5	36	-43	100	+10	-	-	19	+73
Erivedge	57	+111	35	+33	19	***	-	-	3	***
Gazyva	18	-	18	-	-	-	-	-	-	-

* At constant exchange rates (CER)

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

*** >500%

Major clinical and regulatory news flow to 24 July 2014

Compound	Indication	Milestone	
MabThera (subcutaneous formulation)	NHL (follicular lymphoma and diffuse large B-cell lymphoma)	EU approval	Q1 ✓
Xolair	chronic idiopathic urticaria	FDA approval	Q1 ✓
Bitopertin	negative symptoms of schizophrenia	Phase III	Q1 ×
Lebrikizumab	severe uncontrolled asthma	Phase IIb study results (LUTE, VERSE)	Q1 ✓
Onartuzumab and Tarceva	non-small cell lung cancer	Phase III study results (MetLung)	Q1 ×
RoActemra (subcutaneous formulation)	rheumatoid arthritis	EU approval	Q2✓
Anti-PDL1	metastatic bladder cancer	Phase I study results led to FDA Breakthrough Therapy Designation	Q2✓
Gazyvaro	chronic lymphocytic leukemia (CLL)	CHMP recommendation for EU approval	Q2✓
Avastin	platinum-resistant recurrent ovarian cancer	CHMP recommendation for EU approval FDA priority review	Q2✓
Avastin	cervical cancer	FDA priority review	Q2✓
LptD	antibiotic	FDA fast track designation	Q2✓
Alectinib	non-small cell lung cancer	Japanese approval	Q3✓

Upcoming clinical news flow

Compound	Indication	Milestone
Gazyvaro	chronic lymphocytic leukemia (first line)	EU approval
Cobimetinib and Zelboraf	BRAF V600 mutation-positive metastatic melanoma	Phase III study results (co-BRIM)
Kadcyla with Perjeta	metastatic HER2-positive breast cancer (first line)	Phase III study results (MARIANNE)
Anti-PDL1	multiple solid tumours	Update from Phase II programme
Perjeta	metastatic HER2-positive breast cancer (first line)	Final overall survival data from Phase III (CLEOPATRA)

Diagnostics Division

Strong growth in the first six months

The Diagnostics Division continued to increase sales with strong growth of 6% to 5.1 billion Swiss francs. Professional Diagnostics, with 9% sales growth, was the main contributor led by the immunodiagnostics business (+12%). Molecular Diagnostics sales increased 4%. Diabetes Care sales were stable as this unit continues to operate within a challenging and volatile market environment. Tissue Diagnostics sales grew by 9%.

All regions contributed to growth, which was primarily driven by Asia–Pacific (+15%) and North America (+6%). In the EMEA region, the division's largest market, sales increased by 2%, whilst Latin America was up 11% and Japan 4%. Professional Diagnostics was the main contributor to sales increases in all regions.

Six key products were launched in the first half and sales of companion tests for personalised healthcare and revenues from external development agreements for such tests grew strongly.

The FDA approved the cobas HPV Test (human papilloma virus) for use as a first-line primary screening test for cervical cancer in women aged 25 and older, making this test the first and only HPV test in the United States approved for first-line primary screening. Approval for this usage was also granted in Canada. These decisions represent important steps for patients, as they support the detection of this cancer-causing infection early and enable faster treatment.

Diagnostics Division: Sales Jan–Jun 2014		**In millions of CHF**	**% change at CER***	**% change in CHF**	**As % of sales**
Sales - Diagnostics Division		5,140	+6	0	100
Business Areas	Professional Diagnostics	2,904	+9	+3	56
	Diabetes Care	1,140	0	-5	23
	Molecular Diagnostics	762	+4	-2	15
	Tissue Diagnostics	334	+9	+4	6
Regions	Europe, Middle East, Africa	2,423	+2	0	47
	North America	1,272	+6	0	25
	Asia–Pacific	877	+15	+7	17
	Latin America	346	+11	-6	7
	Japan	222	+4	-8	4

* Constant exchange rates

Professional Diagnostics (+9%), grew faster than its market, with growth primarily driven by the immunodiagnostics business (+12%), which now represents 26% of divisional sales. Growth was supported by the clinical chemistry business (+9%). The Professional Diagnostics business grew in all regions, in Asia-Pacific (+17%), especially China, as well as North America (+9%). The EMEA region also saw strong growth in immunodiagnostics (+7%) and clinical chemistry (+5%).

Roche launched the cobas 6500 urine analyser series, a fully automated urine testing system that consists of two modular analysers combining urine strip testing and digital urinary microscopy. The system tests for 23 different parameters to help diagnose diseases such as urinary tract infection, kidney disease, and diabetes. A new Elecsys Syphilis immunoassay was launched to identify infections with the syphilis-causing bacterium *Treponema pallidum* in routine clinical practice and in donated blood. Worldwide approximately 12 million people are infected annually with syphilis, which can be treated more effectively if detected at an early stage. This launch represents an important addition to Roche's existing and leading test menu.

Diabetes Care (0%). Sales were stable in a challenging market environment. The premium product Accu-Chek Mobile generated a sales increase of 22% and Accu-Chek Aviva/ Performa sales were up 2%; however declining sales for products approaching the late stage of their life-cycle impacted overall sales performance. Sales of insulin delivery systems grew by 6% and Roche launched the Accu-Chek Insight system, its next generation insulin pump and pump remote control in Europe.

Roche Diabetes Care continued implementing its restructuring programme which will enable the business to focus on the market changes and drive efficiencies.

Molecular Diagnostics (+4%)**.** Sales increased by 6% in the underlying molecular businesses (without genome sequencing), driven by tests for viral infections (+5%), the blood screening business (+7%) and cervical cancer screening HPV tests (+59%). Further growth came from nucleic acid purification (NAP)/real-time PCR (qPCR) reagents (+4%). This sales growth was partly offset by a decline in the genome sequencing business. The business area launched three tests in Europe: the *Herpes-simplex*-virus (HSV), MRSA/SA (MRSA/SA: methicillin-resistant *Staphylococcus aureus* and *Staphylococcus aureus*) *and* C-difficile *(Clostridium difficile)* tests*;* the MRSA/SA and C-difficile tests identify hospital acquired infections.

Roche acquired IQuum, Inc., which is focused on developing point-of-care products for the molecular diagnostics market and Genia Technologies, Inc., which is developing the next generation of sequencing technology, a single-molecule, semi-conductor based DNA sequencing platform using nanopore technology.

Tissue Diagnostics (+9%). Sales were driven by an 8% growth in advanced staining. The CINtec Histology and CINtec PLUS Cytology tests grew by 11% and 31% respectively showing a continued good uptake and adoption of the Roche portfolio of cervical cancer screening products. Revenues from partnerships with external pharmaceutical companies continued to grow. Regionally, growth was driven by EMEA (+14%), North America (+5%) and Asia-Pacific (+24%). In North America sales were adversely impacted by reimbursement changes.

Impairment charges were incurred in Tissue Diagnostics for goodwill (CHF 259m) and intangible assets (CHF 155m). These impairments were mainly due to reimbursement cuts in the United States.

Key product launches planned for 2014

Area	Product name	Description	Market
Laboratories	cobas 6800/8800	next-generation molecular (PCR) system	WW*
	cobas m511	fully integrated/ automated hematology system	EU
	cobas 6500	automated urinalysis work area	EU✓
	Ventana Connect (formerly Connect-V)	middleware providing connectivity to laboratory information systems	WW*
Diabetes care	Accu-Chek Insight	next-generation insulin pump and blood glucose monitoring system	EU✓
	Accu-Chek Connect	Blood glucose meter with connectivity to smartphones, mobile applications and cloud	EU
Tests/ assays			
Blood screening / infectious diseases	MPX 2.0	next-generation blood screening multiplex test	US
	MPX (HIV, HCV, HBV), HEV, DPX[1], WNV[2]	full NAT blood screening menu for cobas 6800/8800	WW*
	HIV, HCV, HBV	virology tests for cobas 6800/8800	WW*
	HSV	herpes simplex virus detection for cobas 4800	EU✓
	Syphilis	*Treponema pallidum* detection (immunoassay)	EU✓
	MRSA/SA	next-generation assay for cobas 4800	EU✓

Microbiology	C-difficile	diagnosis of infections and associated diarrhea for cobas 4800	EU✓
Women's health	AMH	assessment of ovarian reserve for fertility	EU
	PE Prognosis	short-term prediction of pre-eclampsia in pregnancy (claim extension)	EU

[1] Parvovirus B19 and hepatitis A virus.
[2] West Nile virus.
*Excluding the United States.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 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 roche.com.

Additional information

- Media Release including full set of tables: http://www.roche.com/med-cor-2014-07-24.htm
- Sustainable Development at Roche: www.roche.com/corporate_responsibility
- Roche Annual Report 2013 (includes Corporate Responsibility Report): www.roche.com/annual_reports
- Dow Jones Sustainability Indexes: www.sustainability-indexes.com
- SAM: www.sam-group.com

Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: roche.mediarelations@roche.com

- Nicolas Dunant (Head)
- Ulrike Engels-Lange
- Štěpán Kráčala
- Claudia Schmitt
- Nina Schwab-Hautzinger