Media Release

Basel, 16 October 2014

Roche delivers solid sales growth for the first nine months of 2014

- **Group sales up 5% at CER[1], stable in Swiss francs**
- **4% higher sales in Pharmaceuticals Division, with strong growth of oncology portfolio, as well as Actemra for rheumatoid arthritis and Xolair for asthma and chronic hives**
- **6% higher sales in Diagnostics Division, driven by strong Professional Diagnostics' performance**
- **Acquisition of InterMune completed, FDA approval of Esbriet**
- **New generation of fully-automated PCR testing systems launched**
- **Full year outlook confirmed**

Nine months' sales Jan–Sept	In millions of CHF		As % of sales		% change	
	2014	2013	2014	2013	At CER[1]	In CHF
Group Sales	34,757	34,867	100	100	5	0
Pharmaceuticals Division	26,965	27,190	78	78	4	-1
US	11,528	11,429	33	33	5	1
Europe	7,070	6,952	20	20	3	2
Japan	2,406	2,492	7	7	7	-3
International*	5,961	6,317	18	18	3	-6
Diagnostics Division	7,792	7,677	22	22	6	1

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

Commenting on the nine month results, Roche CEO Severin Schwan said: "Demand for our products is strong in both divisions and we are well on track to reach our full-year targets. We have had positive news from our product pipeline, including study results for Perjeta in breast cancer and a new combination

[1] Unless otherwise stated, all growth rates in this document are in constant exchange rates CER (average full-year 2013).

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therapy with Zelboraf in melanoma. The InterMune acquisition has also strengthened our portfolio with a new medicine, Esbriet for idiopathic pulmonary fibrosis, which has now been approved by the FDA. In Diagnostics, growth continues to be driven by the immunodiagnostics business and we have strengthened our molecular diagnostics portfolio with a new generation of testing systems."

Group nine months overview

Group sales were 34.8 billion Swiss francs, 5% higher at constant exchange rates and stable in Swiss francs for the nine months ended 30 September 2014. A number of currencies remained weaker against the Swiss franc throughout the year, most notably the US dollar, as well as all Latin American currencies and the Japanese yen.

Both divisions saw good sales growth for the nine months, with Pharmaceuticals up 4% and Diagnostics up 6%. Growth in the Pharmaceuticals Division was driven by the oncology portfolio, in particular the medicines for HER2-positive breast cancer, Herceptin, Perjeta and Kadcyla, whilst growth in Diagnostics mainly stemmed from a continued strong performance in Professional Diagnostics.

Recent highlights included new approvals for Avastin in cervical cancer in the United States and platinum-resistant ovarian cancer in Europe, and of Gazyvaro in Europe for chronic lymphocytic leukemia. In Diagnostics, the cobas 6800 and cobas 8800 integrated laboratory testing instruments were launched. The Diagnostics division also launched a global access programme for HIV viral load testing in resource constrained countries, in partnership with a number of organisations, including UNAIDS, the Clinton Access Initiative and the President's Emergency Plan for AIDS relief. Another achievement was Roche being named the Group Leader for the Pharmaceuticals, Biotechnology and Life Sciences Industry in the Dow Jones Sustainability Indices for the sixth year running.

Acquisition of InterMune

The acquisition of InterMune was completed in September, adding a new medicine for idiopathic pulmonary fibrosis, Esbriet which was approved by the FDA in October 2014. Idiopathic pulmonary fibrosis is a progressive disease, which causes scarring of the lungs and has a survival rate of 2 to 3 years from diagnosis. Esbriet has the potential to make a considerable difference to the treatment of patients with this debilitating disease. Roche has successfully issued bonds to the value of 5.75 billion US dollars to finance the transaction.

Pipeline update

At the European Society for Medical Oncology (ESMO) annual congress in September, Roche presented final overall survival data from the Phase III CLEOPATRA study of Perjeta in HER2-positive metastatic breast cancer. The results showed that in combination with Herceptin and chemotherapy, Perjeta extended overall survival by 15.7 months, compared with Herceptin and chemotherapy alone. Results of the Phase III coBRIM study, testing the combination of Zelboraf and the Roche investigational MEK inhibitor, cobimetinib, in patients with malignant melanoma were also presented. The data showed that treatment with the combination halved the risk of the disease worsening. Other highlights at ESMO included encouraging data from early phase trials of an investigational cancer immunotherapy medicine, anti-PDL1 (MPDL3280A) in bladder cancer, a disease for which the drug has received FDA Breakthrough Therapy Designation. There was also positive early data for anti-PDL1 in combination with Avastin in renal cell carcinoma and other solid tumours. Cancer immunotherapy is a new approach that aims to enable the body's immune system to fight cancer.

Other positive pipeline news came in two Phase III studies (IMELDA and TANIA) for Avastin in treatment for HER2-negative breast cancer, the most common form of breast cancer, showing significant improvements in progression-free survival. Phase III trials for lampalizumab, the first potential treatment for geographic atrophy, were initiated in September. Geographic atrophy is an advanced form of age-related macular degeneration, a progressive condition that can lead to blindness. In Japan, Alecensa (alectinib) was approved for the treatment of ALK-positive non-small cell lung cancer in July, based on the results of a Japanese trial. The FDA has granted Breakthrough Therapy Designation for alectinib and global studies are ongoing.

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

Top-selling pharmaceuticals and recent launches Jan–Sept 2014	Total		US		Europe		Japan		International**	
	CHF m	%*	CHF m	%*	CHF m	%*	CHF m	%*	CHF m	%*
MabThera/Rituxan	5,124	3%	2,483	0%	1,517	6%	165	2%	959	6%
Avastin	4,749	6%	2,002	5%	1,472	3%	519	11%	756	10%
Herceptin	4,679	7%	1,451	10%	1,696	3%	200	4%	1,332	9%
Lucentis	1,260	5%	1,260	5%	-	-	-	-	-	-
Tarceva	971	0%	486	7%	229	-11%	73	17%	183	-10%
Actemra/RoActemra	897	24%	292	31%	320	22%	156	23%	129	17%
Pegasys	811	-17%	167	-34%	194	-29%	49	37%	401	-4%
Xolair	701	24%	701	24%	-	-	-	-	-	-
Perjeta	633	255%	380	190%	157	319%	58	***	38	***
Xeloda	623	-43%	171	-63%	76	-68%	67	-8%	309	-8%
Recent launches										
Kadcyla	371	148%	213	46%	111	***	21	-	26	***
Zelboraf	230	-8%	53	-42%	145	2%	-	-	32	69%
Erivedge	90	93%	57	29%	29	***	-	-	4	***
Gazyva/Gazyvaro	32	-	30	-	1	-	-	-	1	-

* At constant exchange rates (CER) ** Asia–Pacific, EEMEA (Eastern Europe, Middle East, Africa), Latin America, Canada, Others *** >500%

Sales in the Pharmaceuticals Division grew 4%, with a significant contribution from medicines to treat HER2-positive breast cancer, Herceptin, Perjeta and Kadcyla, which together increased 21%. This more than outweighed lower sales of oral chemotherapy drug Xeloda following the entry of generic competitors in key markets.

In the **United States**, sales were 5% higher, with medicines for HER2-positive breast cancer, as well as Avastin driving growth. This more than offset declines in sales of Xeloda and Pegasys, a medicine for hepatitis B and C, which is facing competition from a new generation of hepatitis C treatment. Demand for Xolair increased after FDA approval of the medicine for a form of chronic hives, in addition to its existing use in allergic asthma.

In **Europe** 3% higher sales were driven by strong growth in Germany, particularly in sales of HER2 breast cancer medicines, as well as MabThera/Rituxan; and in the UK with sales of HER2 breast cancer medicines and stockpiling of Tamiflu. These increases were partially offset by on-going pricing pressure in a number of markets. There were significantly lower sales of Xeloda.

Following a further acceleration of growth in the third quarter, sales for the **International** region were 3% higher, with strong growth in Latin America, in particular Argentina, Venezuela and Brazil. In the Middle East, sales were impacted by political unrest, whilst in China sales were stable, with continued strong growth for key products such as the HER2 breast cancer medicine portfolio, MabThera/Rituxan and Actemra/RoActemra. Sales of a number of mature products including Tarceva, Xeloda and Madopar, were lower in China, mainly as a result of increased competition. Sales of Tamiflu in China were significantly lower.

In **Japan,** 7% higher sales were driven by strong demand for HER2 breast cancer medicines, as well as Avastin and Actemra/RoActemra. In the osteoporosis segment, there was solid sales growth for Edirol, as well as Bonviva.

Key products

- **Herceptin, Perjeta, Kadcyla** (+21%), for HER2-positive breast cancer and Herceptin for HER2-positive metastatic (advanced) gastric cancer. **Herceptin** (+7%) sales growth was driven mainly by the United States (+10%), with increased use in breast cancer treatment in combination with Perjeta. There was also strong growth in the International region (+9%), with significant increases in China and Brazil. In Europe, sales increased 3%, with strong demand in Germany, Spain and the UK. In Japan, sales were 4% higher, with increased usage in combination with Perjeta in breast cancer, as well as in gastric cancer. **Perjeta** (633 million Swiss francs) showed continued strong growth in the United States and in Europe, especially in France and the UK. **Kadcyla** (371 million Swiss francs) is an antibody-drug conjugate that can attach to HER2-positive cancer cells and deliver potent chemotherapy directly to the cancer cell. This helps patients avoid some of the side effects of conventional chemotherapy. Uptake of this medicine has been very strong in the United States and Europe, in particular Germany and UK.
- **MabThera/Rituxan** (+3%), for common forms of blood cancers, non-Hodgkin's lymphoma and chronic lymphocytic leukemia; and for rheumatoid arthritis and certain types of ANCA-associated vasculitis. Sales grew strongly in Europe (+6%), driven by increased market share in follicular lymphoma, as well as first line treatment for chronic lymphocytic leukemia. Sales were stable in the United States. In

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