

Basel, 27 April 2017

## Roche reports a good start in 2017

- Group sales increase 4%<sup>1</sup> at constant exchange rates and in Swiss francs
- Pharmaceuticals Division sales up 3%, driven mainly by Tecentriq and Perjeta
- Diagnostics Division sales grow 6%, primarily due to immunodiagnostic solutions
- US FDA approves Ocrevus to treat two forms of multiple sclerosis
- EU approves Alecensa for the treatment of a specific form of lung cancer
- Successful phase III Aphinity study of Perjeta treatment regimen in early breast cancer
- Outlook for 2017 confirmed

Sales January - March 2017	CHF millions		As % of sales		% change	
	2017	2016	2017	2016	At CER	In CHF
Group sales	12,942	12,414	100	100	+4	+4
Pharmaceuticals Division	10,177	9,800	79	79	+3	+4
United States	5,070	4,716	39	38	+6	+8
Europe	2,273	2,319	18	19	+1	-2
Japan	856	853	7	7	-2	0
International*	1,978	1,912	15	15	+1	+3
Diagnostics Division	2,765	2,614	21	21	+6	+6

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

<sup>1</sup> Unless otherwise stated, all growth rates in this document are at constant exchange rates (CER: average 2016).

Commenting on the Group's results, Roche CEO Severin Schwan said: «We have started the year with good growth in both our Pharmaceuticals and Diagnostics Divisions and with important positive clinical study results. A highlight of the first quarter was the US approval of our medicine Ocrevus for the treatment of multiple sclerosis (MS). Ocrevus is the first and only FDA approved medicine for both relapsing and primary progressive forms of MS and represents a new era for the treatment of this disease. We are well on track to meet our full-year targets.»

## Group results

### Good sales growth in both divisions

Group sales rose 4% to CHF 12.9 billion. Sales in the Pharmaceuticals Division increased 3% to CHF 10.2 billion, driven by very good early uptake of Tecentriq and continued strong growth of Perjeta and partially offset by lower sales of Tamiflu. In the US, sales advanced 6%, led by the recently launched medicines Tecentriq and Alecensa, as well as Xolair and MabThera/Rituxan. Sales of Tamiflu declined due to competition from generics. In Europe (+1%), Perjeta, Actemra/RoActemra and Herceptin were the main contributors to sales growth. In the International region, sales advanced 1%, led by the Latin America and Asia-Pacific subregions. In Japan (-2%), sales were impacted by government price reductions in April 2016.

Diagnostics Division sales increased 6% to CHF 2.8 billion. Centralised and Point of Care Solutions<sup>2</sup> was the main contributor, led by the growth of its immunodiagnostics business (+13%). In regional terms, growth was driven in particular by Asia-Pacific (+13%) and Latin America (+21%). In EMEA<sup>3</sup> (+2%) and Japan (+4%), sales increases were led by Centralised and Point of Care Solutions, and in North America (+4%) by Tissue Diagnostics.

### Important new product approvals in Pharmaceuticals

The US Food and Drug Administration (FDA) approved Ocrevus for the treatment of two forms of multiple sclerosis (MS); relapsing MS (RMS) and primary progressive MS (PPMS). Ocrevus is an important new treatment option for people with RMS, and due to the favourable benefit-risk profile has the potential to change disease course. It is also the first and only medicine approved to treat PPMS, a particularly disabling form of MS. Multiple sclerosis, for which there is currently no cure,<sup>4</sup> is a chronic disease that affects an estimated 2.3 million people around the world. The European Commission granted Alecensa a conditional marketing authorisation as monotherapy for adult patients with ALK<sup>5</sup>-positive advanced non-small cell lung cancer (NSCLC) previously treated with crizotinib.

---

<sup>2</sup> Formerly Roche Professional Diagnostics

<sup>3</sup> EMEA = Europe, Middle East and Africa

<sup>4</sup> Multiple Sclerosis International Federation. (2013). Atlas of MS 2013. Available at: <http://www.msif.org/about-us/advocacy/atlas/>.

<sup>5</sup> ALK = anaplastic lymphoma kinase

### **Clinical trial results support key new indications for Roche medicines**

Roche communicated important clinical results in the first quarter of 2017. The phase III Aphinity study with Roche's Perjeta regimen met its primary endpoint. It showed that adjuvant (after surgery) treatment with the combination of Perjeta, Herceptin and chemotherapy achieved a statistically significant reduction in the risk of recurrence of invasive disease or death in people with HER2-positive early breast cancer compared with Herceptin and chemotherapy alone. Encouraging results from the Tecentriq phase II study IMmotion 150 were presented: the study compared Tecentriq plus Avastin as well as Tecentriq monotherapy to the treatment with sunitinib in people with previously untreated, locally advanced or metastatic renal cell carcinoma.

The phase III Alur study met its primary endpoint, showing that Alecensa significantly improved progression-free survival (PFS) in people with ALK-positive advanced NSCLC who had progressed following treatment with platinum-based chemotherapy and crizotinib, compared with chemotherapy. In addition, in early April Roche announced that the phase III Alex study met its primary endpoint, showing that Alecensa as initial (first-line) treatment significantly improved PFS compared with crizotinib in people with ALK-positive NSCLC.

The US FDA accepted Roche's supplemental Biologics License Application and granted priority review for Actemra/RoActemra for giant cell arteritis (GCA), a form of vasculitis. The FDA also granted breakthrough therapy designation for MabThera/Rituxan, in pemphigus vulgaris, a rare skin disease.

### **New generation of diagnostics products**

The cobas HPV DNA test for cobas 6800/8800 systems was launched in the EU and other markets accepting the CE-mark, and the US FDA cleared the CINtec Histology test to aid in the diagnosis of cervical pre-cancer. These tests are a key part of Roche's cervical cancer prevention portfolio. Human papillomavirus (HPV) is the cause of almost all cases of cervical cancer, a leading cause of death in women.

The cobas Liat PCR system was launched in markets accepting the CE-mark. This real-time PCR system covers four assays, including a test for the rapid detection of *Clostridium difficile*. Timely and accurate diagnosis of this infection is important because it can quickly become life-threatening. In the US, the FDA approved Roche's cobas e 801 module for high-volume immunology testing. The Accu-Chek Instant system for effortless, reliable and affordable blood glucose monitoring was introduced in various markets in the EU.

## Outlook for 2017 confirmed

In 2017, Roche expects sales to grow low- to mid-single digit, at constant exchange rates. Core earnings per share are targeted to grow broadly in line with sales, at constant exchange rates. Roche expects to further increase its dividend in Swiss francs.

## Pharmaceuticals Division

Top-selling Pharmaceuticals January - March 2017	Total		United States		Europe		Japan		International*	
	CHFm	%	CHFm	%	CHFm	%	CHFm	%	CHFm	%
MabThera/Rituxan	1,899	4	1,045	6	465	1	62	-3	327	4
Herceptin	1,756	2	680	3	522	3	67	-4	487	0
Avastin	1,684	-2	765	-2	446	-3	181	-8	292	7
Perjeta	524	19	257	14	176	21	26	7	65	47
Actemra/RoActemra	445	15	177	21	147	17	64	4	57	7
Xolair	437	22	437	22	0	0	0	0	0	0
Lucentis	392	9	392	9	0	0	0	0	0	0
Activase/TNKase	316	13	305	14	0	0	0	0	11	0
Tamiflu	270	-27	156	-39	13	-30	65	5	36	-4
Kadcyla	222	11	89	11	84	5	16	-9	33	49

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

### Key pharmaceutical products in 2017

**Herceptin, Perjeta and Kadcyla** (combined +6%). For HER2-positive breast cancer and HER2-positive metastatic gastric cancer (Herceptin only). **Herceptin** sales were up 2%, led by growth in Brazil and the US and helped by additional reimbursement approvals and broader use in China. **Perjeta** (+19%) experienced strong sales growth in Europe and the US. Sales of **Kadcyla** (+11%) were fuelled by increasing uptake in International region countries where the medicine was recently launched and in the US.

**MabThera/Rituxan** (+4%). For common forms of blood cancer, rheumatoid arthritis and certain types of vasculitis. Sales continued to rise despite competitive pressure. Increasing sales were seen mainly in the US and the International region. Growth in China was supported by additional reimbursement approvals and expanded regional access, mainly in diffuse large B cell lymphoma.

**Avastin** (-2%). For advanced colorectal, breast, lung, kidney, cervical and ovarian cancer, and relapsed glioblastoma (a type of brain tumour). Sales continued to grow in the International region (+7%). In the US, where Avastin is already broadly used in its approved indications, sales declined 2%, largely due to growing use of new cancer immunotherapy agents in lung cancer.

**Actemra/RoActemra** (+15%). For rheumatoid arthritis and forms of juvenile idiopathic arthritis. Increasing use of Actemra/RoActemra as a single agent (monotherapy) and of the subcutaneous formulation of the medicine remained a key growth driver globally. Actemra/RoActemra remains the leader in monotherapy in the five largest EU markets.

**Esbriet** (+13%). For idiopathic pulmonary fibrosis (IPF). Sales continued to expand, mostly due to increasing use in people with moderate and progressive disease.

**Gazyva/Gazyvaro** (+48%). For chronic lymphocytic leukaemia (CLL) and rituximab-refractory follicular lymphoma. Sales expanded in all regions where this product has been launched, despite increasing competition in CLL.

Recently launched Roche medicines recorded good sales performance in the first quarter. **Tecentriq sales totalled** CHF 113 million; following FDA approval of the medicine in bladder and lung cancer in 2016, market uptake in the US has been very good. **Alecensa** (CHF 68 million), for people with ALK-positive advanced NSCLC whose disease has progressed on, or who are intolerant to crizotinib, showed very good uptake in the US and sales growth remained strong in Japan.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.