Roche: adapting to the changing environment

Severin Schwan, CEO Roche Group
Tokyo, 8 October 2010
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3. delay or inability in obtaining regulatory approvals or bringing products to market;
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5. uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
6. increased government pricing pressures;
7. interruptions in production;
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10. loss of key executives or other employees; and
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A position of strength

Operational Excellence – adapting to a changing environment

Continued focus on innovation
Continuous growth in sales and margin

Group sales (CHF bn)

Operating profit¹ (CHF bn) and margin

¹ before exceptional items
Limited exposure to patent expiries

% Sales Lost calculated by subtracting given year sales (‘10, ‘11, ‘12, ‘13) from full year sales from year prior to LOE. Data excludes sales lost impact of products with LOE prior to 2010.

Source: Evaluate Pharma
Biotech products drive growth in both divisions

Pharma Division

- Biotech products as % of sales: 67%

Diagnostics Division

- Biotech products as % of sales: 85%

H1’ 2010
Long patent protection
Biosimilars facing high hurdles

Long primary patent protection of our key biologics

Biosimilars outlook

<table>
<thead>
<tr>
<th>Patents</th>
<th>US</th>
<th>EU</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>ROW/EM</td>
</tr>
<tr>
<td>Avastin</td>
<td>2019</td>
<td>similar</td>
</tr>
<tr>
<td>Lucentis</td>
<td>2019</td>
<td>marketed by Novartis</td>
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<tr>
<td>Rituxan/MabThera</td>
<td>2018</td>
<td>earlier</td>
</tr>
<tr>
<td>Herceptin</td>
<td>2019</td>
<td>earlier</td>
</tr>
<tr>
<td>Pegasys</td>
<td>2018</td>
<td>similar</td>
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US: recent healthcare legislation opens pathway for biosimilars
FDA in the process of developing guidelines
Data exclusivity for biologics 12 years

EU: legal and regulatory hurdles likely to remain high for biosimilars

ROW/EM: investment in countries with strong IP regulations (China)
Brand awareness important
Key Pharmaceuticals & Diagnostics products
A risk-diversified portfolio of drugs and BUs

- Avastin
- MabThera/Rituxan
- Herceptin
- Diabetes Care
- Pegasys
- Immunochemistry
- CellCept
- NeoRecormon
- Tarceva
- Clinical Chemistry
- Xeloda
- Lucentis
- Molecular Dx
- Boniva/Bonviva

* Sales 2009

- 2 with > than CHF 6 bn
- 1 with > than CHF 5 bn
- 11 with > than CHF 1 bn

Sales (CHF bn)

'03 '04 '05 '06 '07 '08 '09

>CHF 6bn*
>CHF 5bn*
>CHF 1bn*
Avastin: Portfolio within a portfolio
Key treatment option in multiple tumor types

- Ovarian: Superior PFS front line
- Metastatic Breast: Superior PFS in multiple 1st line trials, Superior PFS in 2nd line
- Renal: Superior PFS in 1st line
- Recurrent Glioblastoma: Unsurpassed PFS and OS
- Advanced Non-Small Cell Lung Cancer: Superior OS 1st line, Superior PFS 1st and 2nd line
- Metastatic Colorectal: Superior OS 1st and 2nd line, Superior PFS 1st and 2nd line

2009 Sales
- 75%-80%
- 20%-25%
**Actemra/RoActemra**

**Building new pillar**

- Launched in ~50 countries so far
- Uptake in Japan remains strong
- In US after only 5 months, Actemra already prescribed by more than 50% of rheumatologists
- US patient share constantly increasing (currently 3-6% following anti-TNFs)

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**Actemra vs Humira H2H trial**

Enrolling patients
Roche in Emerging Markets
Gaining in significance

**United States**
- 35% Group sales, +3%
- 38% Pharma sales
- 23% Dia sales

**Western Europe**
- 29% Group sales, +3%
- 26% Pharma sales
- 41% Dia sales

**International**
- 27% sales Group, +15%
- 25% Pharma sales
- 31% Dia sales

**Japan**
- 9% sales Group, -5%
- 11% Pharma sales
- 5% Dia sales

H1’ 2010: All growth in local currencies
Roche in Emerging Markets
Oncology leading the trend

International region as % of Oncology sales

Herceptin

MabThera/Rituxan

Roche in Emerging Markets
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International region as % of Oncology sales

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International region as % of Oncology sales

Herceptin

MabThera/Rituxan
Roche

Acting from a position of strength

- Protection of current portfolio:
  - long patent protection
  - hurdles for biosimilars

- Diversified portfolio; 14 franchises with >CHF 1 bn sales

- Significant opportunities for Avastin based on approved indications

- Growth in emerging markets
A position of strength

Operational Excellence – adapting to a changing environment

Continued focus on innovation
Roche’s response to new environment

Pre-2010

2010

Price pressure
US, Europe

Negative pipeline news
Avastin GC/PC
ocrelizumab RA

taspoglutide

Increasing regulatory requirements

2011

2012

Post-2012

Operational excellence
improve efficiency
prioritize portfolio

Pipeline roll-out
~10 NMEs in late stage development

Sales
Roche’s response to new environment
Operational excellence initiative

Objectives

- protect our profitability and safeguard financial flexibility
- adapt cost structure while sustaining innovation leadership
- focus our resources towards investments that will drive innovation

Scope and timeline

- Group-wide
- measures decided before end of the year
- implementation in 2011 and 2012
Roche’s response to new environment
Adapting to evolving regulatory environment (T-DM1 trial)

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<tbody>
<tr>
<td>Phase/Study</td>
<td>Phase III EMILIA (TDM4370g)</td>
<td># of Patients</td>
<td>N=580</td>
</tr>
<tr>
<td># of Patients</td>
<td>N=580</td>
<td>Design</td>
<td>• ARM A: T-DM1</td>
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<tr>
<td>Design</td>
<td>• ARM A: T-DM1</td>
<td></td>
<td>• ARM B: Xeloda plus lapatinib</td>
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<tr>
<td>Primary Endpoint</td>
<td>• Progression-free survival</td>
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<td>• Progression-free survival</td>
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<tr>
<td>Status</td>
<td>• FPI Q1 2009</td>
<td></td>
<td>• Overall survival</td>
</tr>
<tr>
<td></td>
<td>• Expect data early 2012</td>
<td></td>
<td>• FPI Q1 2009</td>
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Trial recruiting well.
Filing for accelerated approval expected in mid-2012, with mature PFS data. OS data to be provided within 3 years thereafter.

*subject to agreement with FDA
A position of strength

Operational Excellence – adapting to a changing environment

Continued focus on innovation
Late-stage pipeline continues to build up
Expanding into new therapeutic areas

Number of NMEs

- Virology
- CNS
- Metabolic
- Inflammation
- Oncology

- 2007
  - ocrelizumab
  - Actemra

- 2008
  - ocrelizumab
  - pertuzumab

- 2009
  - ocrelizumab
  - pertuzumab
  - RG7159 (CLL)
  - T-DM1

- 2010E
  - ocrelizumab MS
  - GlyT-1 inh
  - SGLT2 inh
  - aleglitazar
  - taspoglutide
  - dalcetrapib
  - lebrikizumab

- up to 13
  - HCV pol inh
  - ocrolizumab
  - GlyT-1 inh
  - SGLT2 inh
  - aleglitazar
  - taspoglutide
  - dalcetrapib
  - lebrikizumab

- 2007
  - Recruitment completed
  - Expect data in BCC in H1 2011
  - Expect ph II data in H2 2010
  - Filing planned for 2012
  - NHL phase III initiated

- 2008
  - Delay of a minimum 12-18 months
  - Recruitment on track
  - Phase II ongoing
  - Phase II data available

- 2009
  - Recruitment completed
  - Expect data in BCC in H1 2011
  - Expect ph II data in H2 2010
  - Filing planned for 2012

- 2010E
  - Phase III start by year-end
  - Delay of a minimum 12-18 months
  - Recruitment on track
  - Phase II ongoing

* LIP or phase III decision pending
Diagnostics

Continued high growth driven by need for medical value

Potential to improve healthcare efficiency

*IVD <2 % total worldwide healthcare spend*
*Influences >60 % of critical decision making*

Innovative tests in areas of medical need

- **Testing efficiency**
  - Patch pump
    - diabetes care
  - Digital Pathology
    - tissue analysis

- **Diagnosis**
  - MRSA screening
  - HPV early diagnosis
  - dual HER2 protein & gene

- **Companion Diagnostics**
  - BRAF test
    - patient selection
Personalised Healthcare to deliver medical value
Leveraging Pharma & Diagnostics from discovery to commercialisation

- Molecular biology foundation
- Unrestricted knowhow & IP exchange

- Prospective biomarker analysis
- Correct sample collection and patient consent

- Defined label on launch
- Potential companion diagnostic

Improved target selection
More targeted clinical trials
Safer, more efficacious medicine
We Innovate Healthcare