Committed to innovation and growth

Dr. Karl Mahler
Head of Investor Relations

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2. legislative and regulatory developments and economic conditions;
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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;
8. loss of or inability to obtain adequate protection for intellectual property rights;
9. litigation;
10. loss of key executives or other employees; and
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Our strategy

R&D and market dynamics
Changing the standard of care
Expanding in Emerging markets
Summary
An increasingly challenging environment
Where do we go from here?

Regulators
Medical benefit-risk ratio
• Efficacy (clinical endpoints)
• Safety (‘zero’ tolerance)

Payers
Economic benefit-cost ratio
• Constrained funding capacity
• Demanding real outcome evidence

Investors
Economic risk-return ratio
• Declining Returns
• Declining Growth
Roche strategy: Focused on medically differentiated therapies

Regulators:
Optimised benefit / risk ratio

Payors:
Optimised benefit / cost ratio
Our strategy

R&D and market dynamics

Changing the standard of care

Expanding in Emerging markets

Summary
R&D productivity differs substantially among players

Average annual NME peak sales (2001-10)¹
US$ bn

$ 710 m Peak Sales (per $1 bn R&D)

Average annual R&D investment (1997-2006)¹
US$ bn

$ 165 m Peak Sales (per $1 bn R&D)

1 Peak sales and R&D calculated pro forma to account for major M&A
Source: EvaluatePharma; BCG analysis; Roche analysis
Implications of R&D productivity challenge

Segregation will continue as only true innovation will be rewarded.

- Willingness to pay for added value
- Medical differentiation
  - Low differentiation: Generics
  - High differentiation: True innovators, ‘Me-too’ players, ??

No / limited differentiation

High differentiation

Willingness to pay for added value
Upcoming patent expiries in developed markets improve affordability of innovative drugs

Source: IMS Institute for Healthcare Informatics, Apr 2011.
Established market countries are US, Japan, Germany, France, Italy, Spain, Canada, United Kingdom and South Korea.
Our strategy
R&D and market dynamics
Changing the standard of care
Expanding in Emerging markets
Summary
Roche: R&D well balanced from a risk & disease point of view

Industry average probability of success – Phase 0 to Registration

Source: Bernstein Equity Research, Tufts University and Roche analysis
### Hematological cancers

**Different mechanisms of action**

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2014</th>
<th>2016</th>
<th>2018</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MabThera</strong>&lt;br&gt;<strong>Rituxan</strong>*</td>
<td>🟥</td>
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</tr>
<tr>
<td><strong>GA 101</strong></td>
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<td><strong>Bcl-2</strong></td>
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<td>🅰️</td>
<td>🅰️</td>
<td>🅰️</td>
</tr>
<tr>
<td><strong>Anti-CD22 ADC</strong></td>
<td>🅰️</td>
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<td>🅰️</td>
<td>🅰️</td>
<td>🅰️</td>
</tr>
</tbody>
</table>

* Patent expiry in the US: 2018

Potential filing of first indication
Our strategy
R&D and market dynamics
Changing the standard of care
Expanding in Emerging markets
Summary
Roche growth in E7 countries is largely exceeding the market

<table>
<thead>
<tr>
<th>Country</th>
<th>Market rank</th>
<th>2011 growth</th>
<th>Roche</th>
<th>Market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>2</td>
<td>10%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>3</td>
<td>34%</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td>Russia</td>
<td>3</td>
<td>11%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Mexico</td>
<td>5</td>
<td>3%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Turkey</td>
<td>11</td>
<td>-1%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>S. Korea</td>
<td>16</td>
<td>17%</td>
<td>6%</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>28</td>
<td>17%</td>
<td>12%</td>
<td></td>
</tr>
</tbody>
</table>

Source: Roche growth reflects in-market sales; Russia by Pharmexpert; India Roche in-market sales from internal data; All others IMS. Roche sales exclude Tamiflu & effect of divestments in Mexico & Turkey. Turkey 1Q 2012 in-market growth: Roche 15%, market -8%.
Increasing polarisation in emerging markets
Growth in patented medicines and unbranded generics

Example: Brazil market showing evidence of polarisation

Source: IMS
Growing segments in Emerging markets

Objective:
Maintain high share in private segment – expand to public segment

Roche to maintain high share

Growing segment:
We are testing various models to increase access to medicines

Illustrative for emerging markets
Our strategy
R&D and market dynamics
Changing the standard of care
Expanding in Emerging markets

Summary
The P&L reflects Roche’s innovation based strategy
Low on Marketing, General and Administration

R&D % sales

- Eli Lilly: 21%
- Amgen: 20%
- Roche: 19%
- BMS: 18%
- Merck: 17%
- Novartis: 16%
- Astra: 15%
- Sanofi: 14%
- GSK: 14%
- Pfizer: 13%
- Abbott: 10%
- Bayer: 8%

M&D+G&A % sales

- Eli Lilly: 33%
- Novartis: 32%
- Pfizer: 29%
- Bayer: 29%
- Merck: 29%
- GSK: 29%
- Astra: 28%
- Abbott: 26%
- BMS: 24%
- Sanofi: 24%
- Roche: 23%
- Amgen: 18%

Core operating profit margin % sales

- Pfizer: 43%
- Astra: 39%
- Amgen: 37%
- Roche: 36%
- Sanofi: 34%
- Merck: 34%
- BMS: 33%
- GSK: 31%
- Novartis: 27%
- Eli Lilly: 27%
- Abbott: 23%
- Bayer: 17%

Source: Company reports, Roche analysis; Figures based on fiscal year 2011 financials
# Pipeline: 71 NMEs supporting long-term growth

## Phase I (36 NMEs)
- MDM2 ant- solid & hem tumors
- HER3 MAb- solid tumors
- CSF-1R MAb- solid tumors
- GIF/MEK inh- solid tumors
- Tweak MAb- oncology
- Raf & MEK dual inh- solid tumors
- CD44 MAb- solid tumors
- MEK inh- solid tumors
- MEK inh- solid tumors
- MDM2 ant- solid & hem tumors
- AKT inhibitor- solid tumors
- PD-L1 MAb- solid tumors
- Steap 1ADC- prostate ca.
- ADC- ovarian ca.
- ADC- heme tumors
- ADC- multiple myeloma
- ADC- oncology
- Bcl-2 inh- CLL and NHL
- Chk1 inh- solid tum & lymphoma
- PI3K inh- solid tumors
- ADC- metastatic melanoma
- PI3K inh- glioblastoma 2L
- Chk1 inh(2)- solid tumors
- ALK inhibitor- NSCLC
- PI3K inh- solid tumors
- WT-1 peptide- cancer vaccine
- IL-17 MAb- autoimmune diseases
- IL-6 MAb- RA
- Cim331RA- atopic dermatitis
- TLR7 agonist- HBV
- GIP/GLP-1 dual ago- type 2 diabetes
- GABRA5 NAM- cogn. disorders
- V1 receptor antag- autism
- BACE inh- Alzheimer’s
- ACE910- hemophilia A

## Phase II (24 NMEs)
- EGFR MAb- solid tumors
- PI3K MAb- solid tumors
- PI3K/mTOR inh- solid & hem tumors
- EGFL7 MAb- solid tumors
- CD22 ADC- heme tumors
- CD79b ADC- heme tumors
- HER3/EGFR- m. epithelial tumors
- Glypican-3 MAb- liver cancer
- Etorolizumab- ulcerative colitis
- Rontalizumab- SLE
- Pateclizumab (LT alpha Mab)- RA
- Quilizumab (M1 prime Mab)- asthma
- Mercitabine- HCV
- Danoprevir- HCV
- Sotrobuvir- HCV
- Inclonumab (P selectin Mab)- ACS/CVD
- OxLDL MAb- sec prev CV events
- PCSK9 MAb- metabolic diseases
- Gantenerumab- Alzheimer’s
- MAO-B inh- Alzheimer’s
- MgLUr2 antag- depression
- MgLUr5 antag- TRD
- Crenezumab- Alzheimer’s
- Anti-factor D Fab- geographic atrophy

## Phase III (8 NMEs)
- Onartuzumab (MetMab)- solid tumors
- Obinutuzumab (GA101)- hem. tumors
- Lebrizumab- severe asthma
- Aleglitazar- CV risk reduction in T2D
- Tofogliflozin (SGLT2)- type 2 diabetes
- Ocrolizumab- MS
- Bitopertin- schizophrenia
- Arbaclofen- fragile X syndrome (FXS)
- Perjeta (pertuzumab)*- HER2+ mBC 1L
- Erivedge*- advanced BCC
- T-DM1- HER2+ mBC

## Registration (3 NMEs)
- CIM331RA- atopic dermatitis
- ACE910- hemophilia A

As of September 30 2012; * Approved in US, filed in EU
Focus on innovation and growth

1. Strategic focus on innovation and driving Personalised Healthcare

2. Strong growth in Emerging Markets facilitated by innovative access models

3. Leading product pipeline providing value for the future
Roche

We Innovate Healthcare
Innovation in treatment of HER2-positive tumors

5th Annual Biosimilars Conference

Liz Homans, Global Head of HER2 franchise
Roche strategy for post-patent biologics marketplace

**Actively pursuing multiple strategies**

| Innovate       | Re-define the standard of care  
|                | Mode of administration, combination therapies and new drugs |
| Protect        | Protect high standards  
|                | Enforce efficacy and safety standards, defend intellectual property |
| Expand         | Act to expand patient access in emerging markets  
|                | Change from global pricing to tiered pricing, including 2nd brand |
Herceptin

More than 27,000 women in WE did not develop metastatic disease

HER2 Franchise
Securing future growth by improving the standard of care

**2nd line mBC**
- Xeloda + Iapatinib
- T-DM1 (EMILIA)

**1st line mBC**
- Herceptin + chemo
- Herceptin & Perjeta + chemo (CLEOPATRA)
- T-DM1 & Perjeta (MARIANNE)

**Adjuvant BC**
- Herceptin + chemo
- Herceptin subcutaneous + chemo (HannaH)
- Herceptin & Perjeta + chemo (APHINITY)
- T-DM1 & Perjeta + chemo

**Biosimilars launch (EU)**

**Filing timelines**

- Established standard of care
- Potential new standard of care
- Potential future standard of care
2nd line mBC: EMILIA study
T-DM1 in metastatic breast cancer

Overall survival: confirmatory analysis

Quality of life: Patient reported outcomes
Time to symptom progression

<table>
<thead>
<tr>
<th></th>
<th>Median (mos)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cap + Lap</td>
<td>4.6</td>
<td>445</td>
</tr>
<tr>
<td>T-DM1</td>
<td>7.1</td>
<td>450</td>
</tr>
<tr>
<td>HR=0.80 (95% CI, 0.67, 0.95)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>( P=0.0121 )</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Median (mos)</th>
<th>No. events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cap + Lap</td>
<td>25.1</td>
<td>182</td>
</tr>
<tr>
<td>T-DM1</td>
<td>30.9</td>
<td>149</td>
</tr>
<tr>
<td>Stratified HR=0.682 (95% CI, 0.55, 0.85)</td>
<td></td>
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<tr>
<td>( P=0.0006 )</td>
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</tbody>
</table>

In collaboration with Immunogen

Filed in US and EU, priority review granted by FDA
HER2 Franchise
Securing future growth by improving the standard of care

Established standard of care
Potential new standard of care
Potential future standard of care

Filing timelines


2nd line mBC
Xeloda + lapatinib T-DM1 (EMILIA)

1st line mBC
Herceptin + chemo Herceptin & Perjeta + chemo (CLEOPATRA) T-DM1 & Perjeta (MARIANNE)

Adjuvant BC
Herceptin + chemo Herceptin subcutaneous + chemo (HannaH) Herceptin & Perjeta + chemo (APHINITY) T-DM1 & Perjeta + chemo

Biosimilars launch (EU)


Established standard of care
Potential new standard of care
Potential future standard of care
1st line mBC: Herceptin & Perjeta
CLEOPATRA study

**Median PFS**

- Perjeta+Herceptin+docetaxel: 18.5 mos
- Herceptin+docetaxel: 12.4 mos

$\Delta = 6.1$ mos

HR = 0.62
95% CI 0.51–0.75
p<0.0001

Launched in US, filed in EU; OS to be presented at SABCS
Perjeta initial US market feedback

**Market update**

- US price reflects **high medical benefit** and is well received
- NCCN guidelines endorsed Perjeta:
  - as the **preferred first-line treatment** in mBC in combination with Herceptin
  - also for those patients who have **already received Herceptin** in metastatic setting
- Reimbursement facilitated by granting of the **C code in October** (hospitals use a C code to bill Medicare); Perjeta also has a miscellaneous J code
- 67% of oncologists have already used Perjeta
Innovation remains rewarded: Example of Perjeta

**Illustrative pricing for metastatic breast cancer, ex-US**
1st line HER2-positive mBC: MARIANNE trial
T-DM1 and Perjeta vs. standard of care

Primary end-point
- Progression-free survival
- Recruitment completed Q2 2012
- Expect filing 2014

Plan to file T-DM1 and T-DM1+Perjeta in 1L HER2+ MBC with PFS superiority over Herceptin + taxane
1st line HER2-positive metastatic breast cancer

Giving patients time and quality of life

** docetaxel  
6.1 months PFS

Herceptin 
+ docetaxel  
12.4 months PFS

Herceptin & Perjeta  
+ docetaxel  
18.5 months PFS

T-DM1 & Perjeta  
22 months PFS*

* target profile
HER2 Franchise

Securing future growth by improving the standard of care

**Adjuvant BC**
- Herceptin + chemo (HannaH)
- Herceptin subcutaneous + chemo
- Herceptin & Perjeta + chemo (APHINITY)

**1st line mBC**
- Herceptin + chemo
- Herceptin & Perjeta + chemo (CLEOPATRA)
- T-DM1 & Perjeta (MARIANNE)

**2nd line mBC**
- Xeloda + lapatinib
- T-DM1 (EMILIA)

Biosimilars launch (EU)

Established standard of care
Potential new standard of care
Potential future standard of care

Filing timelines

Herceptin & Perjeta in the adjuvant setting
APHINITY trial

**HER2-positive early breast cancer**
- N=3,806

**Primary end-point**
- 3 year Disease Free Survival

**Results**
- FPI: Q4 2011
- Follow-up: 3 years (median)
- Expect filing 2016
T-DM1 in early breast cancer strategy
A three-pronged approach

**Targeting indication with high unmet medical need**

**Non-pCR adjuvant study**
- T-DM1 single agent in patients with residual disease

**Setting high bar for clinically meaningful benefit**

**Adjuvant study**
- T-DM1 & Perjeta vs. Herceptin & Perjeta in adjuvant setting

**Utilizing pCR as surrogate end-point**

**Neoadjuvant study**
- T-DM1-based chemotherapy in neoadjuvant setting
Adjuvant treatment in patients with residual invasive tumor (non-pCR responders)

**Primary Endpoint**
- 3 year Disease Free Survival (DFS)
- FPI expected Q1 2013
- Expect data: 2018
T-DM1 & Perjeta in adjuvant setting
High bar for clinically meaningful benefit

HER2-positive early breast cancer
Node + or HR-

AC/FEC-T
Herceptin & Perjeta

AC/FEC-T
T-DM1 & Perjeta

Primary Endpoint

• Disease Free Survival (DFS)

• FPI expected 2013
• Expect data: 2018

AC=doxorubicin/cyclophosphamide; FEC=5FU/epirubicin/cyclophosphamide; T=docetaxelQ3W or paclitaxelQW
T-DM1 neo-adjuvant study
Pathological Complete Response (pCR) as surrogate end-point

Primary endpoint
- Pathological complete response, pCR (ypT0N0)

SPA granted by FDA

- FPI expected Q1 2013
- Expect pCR data: 2015
pCR as a surrogate endpoint in neoadjuvant breast cancer

FDA commissioned meta-analysis to be presented at SABCS Dec 5, 2012

• “Meta-analysis Results from the Collaborative Trials in Neoadjuvant Breast Cancer”
• To confirm relevant population for correlation between pCR and DFS/OS, definition of pCR, etc

Final FDA pCR guideline expected mid-2013

• Neosphere and Tryphena studies to be discussed with FDA early 2013

• EBC programme to be discussed with FDA early 2013
• CHMP Scientific Advice to be initiated shortly

• NOAH study approved in EU (Neoadjuvant/adjuvant indication)
• HannaH SC application ongoing (pCR co-primary endpoint)
Redefining HER2 blockade
Increasing the efficacy and tolerability

Efficacy

T-DM1

Herceptin + chemotherapy

Herceptin & Perjeta + chemotherapy

T-DM1 & Perjeta

Tolerability
Our near term focus: Making history in Pharma
3 EU launches within a year

EBC
- 2012: HannaH
- 2016: Aphinity

1st-line
- Q4 2011: CLEOPATRA
- 2014: MARIANNE

2nd & 3rd line
- 2H 2012: EMILIA
- 2014: TH3RESA
We Innovate Healthcare
Biosimilar Challenges
5th Annual Biosimilars Conference
Fermin Ruiz de Erenchun M.D., Ph.D.
Market Overview

EMA biosimilars guideline

Our Strategy

Innovate

Protect

Expand
Biosimilars were expected to be a large market by 2015
Wide and diverse range of biosimilar competitors

Commercial opportunities for generics, CMOs & originators

Key global players
- Teva/Lonza
- B Ingelheim
- Pfizer
- Sandoz
- Merck
- Celltrion/Hospira
- Merck Serono/Dr Reddys
- Daiichi Sankyo /Coherus BioSciences
- Fujifilm - Kyowa Hakko Kirin

New partnerships developed
- Sanofi/Nichi-Iko
- Baxter/Momenta
- Synthon/Amgen/Watson
- Biogen Idec/Samsung

Key local players
- Mylan
- Biocon
- Probiomed
- Ranbaxy
- Biocad
- CPGJ
- Intas
- Reliance

Technical/manufacturing capabilities
Biosimilars uptake varies across countries and therapy areas

- Market driven by payers
- Price-driven competition
- Efficacy visible immediately

Somatropin volume market share

- Complex market landscape
- Market driven by price and patient offering
- Efficacy visible only long term

Source: IMS Biosimilar Dashboard Q1 2012
Requirements and study designs are different for the biosimilar vs. innovator

<table>
<thead>
<tr>
<th>Aspects of development</th>
<th>Biosimilar</th>
<th>Innovator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient population</strong></td>
<td>Sensitive and homogeneous (patients are <em>models</em>)</td>
<td>Any</td>
</tr>
<tr>
<td><strong>Clinical design</strong></td>
<td>Comparative versus innovator, normally equivalence</td>
<td>Superiority vs standard of care (SoC*)</td>
</tr>
<tr>
<td><strong>Study endpoints</strong></td>
<td>Sensitive</td>
<td>Clinical outcomes data or accepted/established surrogates (e.g. OS and PFS)</td>
</tr>
<tr>
<td></td>
<td>Clinically validated PD markers</td>
<td></td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>Similar safety profile to innovator; no new findings</td>
<td>Acceptable benefit/risk profile versus SoC*</td>
</tr>
<tr>
<td><strong>Immunogenicity</strong></td>
<td>Similar immunogenicity profile to innovator</td>
<td>Acceptable risk/benefit profile versus SoC*</td>
</tr>
<tr>
<td><strong>Extrapolation</strong></td>
<td>Possible if justified</td>
<td>Not allowed</td>
</tr>
</tbody>
</table>

* In some cases SoC may not exist
How should residual extrapolation risk be managed?

I would like to see a phase III trial for each indication.
Phase III clinical trials will be required for biosimilar antibodies

PD markers only suitable for some products

Source: CHMP Assessment report for Zarzio, page 20; EMA/CHMP/651339/2008
## What is the right patient population to establish clinical similarity to Herceptin®?

<table>
<thead>
<tr>
<th>Topic</th>
<th>Metastatic population</th>
<th>Neoadjuvant/Adjuvant population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PK</strong></td>
<td>✗ Affected by patients status &amp; tumour burden</td>
<td>✗ Homogeneous population can be selected</td>
</tr>
<tr>
<td><strong>PD</strong></td>
<td>✗ Clinically validated PD marker not available</td>
<td>✗ Populations less likely to be confounded by baseline characteristics and external factors</td>
</tr>
<tr>
<td><strong>Clinical efficacy/safety</strong></td>
<td>✗ Difficult to select homogeneous group. Need to control and stratify for multiple factors (e.g. prior use of chemotherapy, performance status…). Population with heterogeneous characteristics affecting final clinical outcome.</td>
<td>✗ Immune system impaired during chemotherapy cycles, but likely to recover to normal status thereafter</td>
</tr>
<tr>
<td><strong>Immunogenicity</strong></td>
<td>✗ Immune system affected by performance status and concomitant chemotherapies received</td>
<td>✗ Immune system impaired during chemotherapy cycles, but likely to recover to normal status thereafter</td>
</tr>
</tbody>
</table>

*Table adapted from Roche.*
Extrapolation and automatic substitution will be key drivers for the uptake

**Extrapolation in oncology will be challenging**

- Contribution of **multiple Modes-of-Actions** vary from indication to indication
- **Validated PD markers of efficacy** for mAbs in oncology currently do not exist
- **Sensitive populations** to establish similar efficacy, safety and immunogenicity **might be different**

**Automatic substitution not standard practice in the EU**

- **In the EU** determined at country level
- Landscape unlikely to change:
  - New EU pharmacovigilance law addresses **traceability** of biologics
  - Draft EMA quality guideline acknowledge future **product drifts between originator and biosimilar**
Physicians are wary of indication extrapolation

Biosimilar needs only to show similarity in a Phase III study for one indication, and it will be granted approval for other indications for which the branded product is used?

Percentage of physicians

Hematologist-oncologists

- Very highly favoured: 15%
- Highly favoured: 10%
- Somewhat favoured: 27%
- Moderately opposed: 35%
- Strongly opposed: 13%

Solid-tumor oncologists

- Very highly favoured: 15%
- Highly favoured: 7%
- Somewhat favoured: 18%
- Moderately opposed: 46%
- Strongly opposed: 15%

Rheumatologists

- Very highly favoured: 12%
- Highly favoured: 12%
- Somewhat favoured: 24%
- Moderately opposed: 36%
- Strongly opposed: 17%

Decision Ressource Biosimilar Advisory Service: Physician Perception Study in Oncology October 2011 (EU)
Market uptake barriers are likely to limit biosimilars sales potential

Source: Data Monitor for 2009 estimate
Developing a biosimilar globally today seems to be a challenge: the rituximab example

<table>
<thead>
<tr>
<th>Company</th>
<th>Initiative of clinical trials</th>
<th>Current status</th>
<th>EMA requirements</th>
<th>US FDA requirements</th>
<th>Recent amendments/future steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teva</td>
<td>Q1/2 2010</td>
<td>Suspended</td>
<td>√</td>
<td>X</td>
<td>Redesigning clinical trial/s</td>
</tr>
<tr>
<td>Sandoz</td>
<td>Q1 2011</td>
<td>Ongoing</td>
<td>√</td>
<td>?</td>
<td>No changes in the current clinical trial strategy</td>
</tr>
<tr>
<td>Samsung</td>
<td>Q1 2012</td>
<td>Suspended</td>
<td>√</td>
<td>X</td>
<td>Redesigning clinical trial/s</td>
</tr>
<tr>
<td>Merck</td>
<td>Q1/2 2012</td>
<td>Ongoing</td>
<td>√</td>
<td>√</td>
<td>Recently added US-sourced comparator arm</td>
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<td>Pfizer</td>
<td>Q1/2 2012</td>
<td>Ongoing</td>
<td>√</td>
<td>√</td>
<td>No changes in the current clinical trial strategy</td>
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<tr>
<td>Celltrion</td>
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<td>√</td>
<td>X</td>
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<td>Boehringer Ingelheim</td>
<td>Q4 2012</td>
<td>Ongoing</td>
<td>√</td>
<td>√</td>
<td>No changes in the current clinical trial strategy</td>
</tr>
</tbody>
</table>
Market Overview

EMA biosimilars guideline

Our Strategy

Innovate

Protect

Expand
How advanced were biosimilar regulatory pathways before 2010?
…and where are we today?
Roche supports biosimilar regulatory pathways

“Reditux“ example

Columbia, Guatemala, Iraq, Panama, Morocco, Russia and S. Africa

Reditux registration rejected or delayed, additional data on clinical trial results requested
Market Overview

EMA biosimilar guideline

Our Strategy

Innovate

Protect

Expand
Innovative approaches to improve market access

Established markets
Environment increasingly complex
Payers more active/influential

Emerging markets
Build-up of healthcare systems,
but applying stricter cost regulations already
Conclusions: Biosimilar challenges

**Global biosimilar uptake will be limited in the short and mid term**
- Is the competitive landscape resulting from the M&A activity sustainable in the long term?

**National regulatory authorities are setting a high bar**
- Development programs suggest not fully aligned position across agencies
- In emerging markets, the *old* generic model is not applicable for biosimilars

*Extrapolation of indications in oncology will be challenging*

**Roche strategy is coherent with our core business model**

1. **Innovate** - Redefine the standard of care
2. **Protect** – Ensure high standards for patients
3. **Expand** – Improve patient access
We Innovate Healthcare