Roche
Innovation: Reinventing Healthcare

Exane BNP Paribas 14th Healthcare Conference
May 10, 2012

Dr. Stefan Frings, Global Head Medical Affairs Oncology
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2. legislative and regulatory developments and economic conditions;
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Performance update and strategy

Update on oncology portfolio

Summary and short term news flow
Q1 2012: Group sales
On track to meet full-year guidance

<table>
<thead>
<tr>
<th></th>
<th>2012 CHF m</th>
<th>2011 CHF m</th>
<th>change in % CHF</th>
<th>CER</th>
</tr>
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<tr>
<td>Pharmaceuticals Division</td>
<td>8,624</td>
<td>8,712</td>
<td>-1</td>
<td>2</td>
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<tr>
<td>Diagnostics Division</td>
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<td>2,408</td>
<td>0</td>
<td>4</td>
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<td>Roche Group</td>
<td>11,027</td>
<td>11,120</td>
<td>-1</td>
<td>2</td>
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</tbody>
</table>

1 CER=Constant Exchange Rates
Q1 2012: Highlights

**Sales**

- Group and Pharma: +2%\(^1\) (+3%\(^1\) excluding Tamiflu)
- Diagnostics: +4%\(^1\)
- Negative currency impact (-3%p)

**2 Approvals of New Molecular Entities**

- Erivedge in advanced basal cell carcinoma – approved in US
- Zelboraf in metastatic melanoma – approved in EU

**5 positive late-stage trials and regulatory filings**

- Avastin in metastatic colorectal cancer: treatment through multiple lines (TML)
- T-DM1 in HER2+ metastatic breast cancer (EMILIA)
- Herceptin subcutaneous in HER2+ breast cancer (HANNAH)-filed in EU
- Actemra in polyarticular-course juvenile idiopathic arthritis (CHERISH)
- Actemra in rheumatoid arthritis (ADACTA)

\(^1\) at Constant Exchange Rates
R&D productivity of Pharma industry
Output relatively flat, while R&D costs have increased

Notes: R&D spend figures may not include overhead components as reported in company annual reports
R&D productivity
Excellence in science key lever to reduce attrition

- Understanding of **disease biology**
- Leveraging **Personalized Healthcare** - stratify patient population early on
- **Rigorous decision making** – transition only most promising projects

### Industry success rate 2005-2009

<table>
<thead>
<tr>
<th>Probability of success</th>
<th>Research</th>
<th>Phase 0</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3 Registration</th>
<th>Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>64%</td>
<td>48%</td>
<td>25%</td>
<td>67%</td>
<td>83%</td>
<td>0%</td>
<td>4%</td>
</tr>
</tbody>
</table>

| Industry: | 4% |
| Roche:    | 9% |

Source: Industry success rates - Linda Martin, KMR, Bernstein R&D conference 2011
Roche – publically available data, BCG analysis
Medical breakthroughs have always driven our business

- **Vitamin synthesis** e.g. Vitamin C
- **Benzodiazepines** e.g. Valium
- **Anti-bacterials** e.g. Rocephin
- **Monoclonal antibodies** e.g. MabThera, Herceptin, Avastin
- **PCR**

Sales:
- 1896
- 1930
- 1960
- 1980
- 2000
- 2011
Unique diversity of approaches

“Federation” of >150 partners

Autonomous centers

- Genentech R&ED*
- Roche R&ED*
- Roche Dx
- Chugai

Worldwide execution

- Global Product Development
- Manufacturing
- Commercialisation

Diversity

Scale, Reach, Speed

* R&ED = Research & Early Development
A leading late stage pipeline

Number of New Molecular Entities

- **Virology**
- **CNS**
- **Metabolic**
- **Inflammation**
- **Oncology**

<table>
<thead>
<tr>
<th>Year</th>
<th>Actemra</th>
<th>ocrelizumab</th>
<th>dalcetrapib</th>
<th>taspoglutide</th>
<th>pertuzumab</th>
<th>GA101</th>
<th>T-DM1</th>
<th>Zelboraf</th>
<th>Erivedge</th>
<th>mericitabine</th>
<th>ocrelizumab</th>
<th>lebrikizumab</th>
<th>danoprevir</th>
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<td>2009</td>
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<tr>
<td>2010</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>2011</td>
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</tbody>
</table>

1 LIP or phase III decision pending; 2Approved in US, filed in EU; 3Filed in US and EU
Performance update and strategy

Update on oncology portfolio

Summary and short term news flow
Oncology: Roche’s largest therapeutic area

Roche 2011 sales

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
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<tr>
<td>Oncology</td>
<td>45%</td>
</tr>
<tr>
<td>Other Pharma</td>
<td>32%</td>
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<tr>
<td>Diagnostics</td>
<td>23%</td>
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</table>

Major Oncology products

<table>
<thead>
<tr>
<th>Product</th>
<th>2011 Sales (CHF m)</th>
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<tbody>
<tr>
<td>Avastin</td>
<td>5’292</td>
</tr>
<tr>
<td>Herceptin</td>
<td>5’253</td>
</tr>
<tr>
<td>MabThera/Rituxan¹</td>
<td>5’027</td>
</tr>
<tr>
<td>Xeloda</td>
<td>1’354</td>
</tr>
<tr>
<td>Tarceva</td>
<td>1’251</td>
</tr>
<tr>
<td>Other oncology</td>
<td>1’033</td>
</tr>
</tbody>
</table>

¹ Sales in Oncology only; total MabThera/Rituxan sales CHF 6’005 m
Roche Oncology Development Pipeline
40 New Molecular Entities

### phase I
(29 NMEs + 1 AIs)

- **RG7112** MDM2 ant solid & hem tumors
- **RG7116** HER3 MAb solid tumors
- **RG7155** CSF-1R MAb solid tumors
- **RG7167** CIf/MEK inh solid tumors
- **RG7204** Zelboraf + ipilimumab met. melanoma
- **RG7212** Tweak MAb oncology
- **RG7256** BRAF inh (2) BRAF mut melanoma
- **RG7304** Raf & MEK dual inh solid tumors
- **RG7334** PIgF MAb solid tumors
- **RG7356** CD44 MAb solid tumors
- **RG7420** MEK inh solid tumors
- **RG7421** MEK inh solid tumors
- **RG7388** MDM2 ant solid & hem tumors
- **RG7440** AKT inhibitor solid tumors
- **RG7446** PD-L1 MAb solid tumors
- **RG7450** ADC prostate ca.
- **RG7458** ADC ovarian ca.
- **RG7593** CD22 ADC hem malignancies
- **RG7594** anti-angiogenic solid tumors
- **RG7596** ADC heme tumors
- **RG7598** ADC multiple myeloma
- **RG7599** ADC oncology
- **RG7600** ADC oncology
- **RG7601** Bcl-2 inh CLL and NHL
- **RG7602** ChK-1 inh solid tum & lymphoma
- **RG7604** PI3K inh solid tumors
- **RG7636** ADC metastatic melanoma
- **CHU** ALK inhibitor NSCLC
- **CHU** PI3K inh solid tumors
- **CHU** WT-1 peptide cancer vaccine

### phase II
(6 NMEs + 8 AIs)

- **RG1273** pertuzumab HER2+ mBC 2nd line
- **RG1273** pertuzumab HER2+ gastric cancer
- **RG3502** T-DM1 HER2+ EBC
- **RG3616** Ervedge operable BCC
- **RG3638** onartuzumab mBC
- **RG3638** onartuzumab mCRC 1L
- **RG3638** onartuzumab NSCLC non squamous
- **RG7160** EGFR MAb solid tumors
- **RG7204** Zelboraf papillary thyroid cancer
- **RG7222** PI3K/mTOR inh solid & hem tumors
- **RG7414** EGFL7 MAb solid tumors
- **RG7597** HER3/EGFR m. epithelial tumors
- **RG7686** glypicanc-3 MAb liver cancer

### phase III
(3 NMEs + 19 AIs)

- **RG105** MabThera NHL sc formulation
- **RG435** Avastin HER2+ BC adj
- **RG435** Avastin HER2-neg. BC adj
- **RG435** Avastin triple-neg. BC adj
- **RG435** Avastin mBC 2nd line
- **RG435** Avastin NSCLC adj
- **RG435** Avastin high risk carcinoid
- **RG435** Avastin gatroblastoma 1st line
- **RG435** Avastin mCRC TML
- **RG435** Avastin ovarian cancer 1st line
- **RG597** Herceptin HER2+ adj BC (2yrs)
- **RG1273** pertuzumab HER2+ EBC
- **RG1415** Tarceva NSCLC EGFR mut 1st line
- **RG1415** Tarceva NSCLC adj
- **RG3502** T-DM1 HER2+ pretreated mBC
- **RG3502** T-DM1 HER2+ mBC 3rd l
- **RG3502** T-DM1 HER2+ mBC 1st l
- **RG3638** onartuzumab mNSCLC
- **RG7159** GA101 CLL
- **RG7159** GA101 iNHL relapsed
- **RG7159** GA101 DLBCL
- **RG7159** GA101 iNHL front-line

### Registration
(2 NMEs + 3 AIs)

- **RG105** RituXan NHL fast infusion
- **RG435** Avastin relapsed ovarian cancer
- **RG1273** pertuzumab HER2+ mBC 1st line
- **RG3616** Ervedge advanced BCC
- **RG597** Herceptin HER2+ BC sc form

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Status as of March 31, 2012
**Personalised Healthcare is a reality today**

**Significant progress in 2011**

<table>
<thead>
<tr>
<th>APPROVED</th>
<th>FILED</th>
<th>TO FILE IN 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zelboraf</td>
<td>Pertuzumab</td>
<td>T-DM1</td>
</tr>
<tr>
<td>Metastatic Melanoma</td>
<td>Metastatic Breast Cancer</td>
<td>Metastatic Breast Cancer</td>
</tr>
<tr>
<td>BRAF V600E Mutation</td>
<td>HER2 expression level</td>
<td>HER2 expression level</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ph III</th>
<th>Ph III</th>
<th>Ph III decision in 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>MetMAb</td>
<td>Lebrikizumab</td>
<td>Mericitabine and</td>
</tr>
<tr>
<td>NSCLC</td>
<td>Severe uncontrolled asthma</td>
<td>danoprevir Hepatitis C</td>
</tr>
<tr>
<td>Met Status</td>
<td>Periostin level</td>
<td>HCV viral load, genotype</td>
</tr>
</tbody>
</table>
**HER2 franchise**

**Building on the strength of Herceptin**

**Pertuzumab**
- Disrupts HER2:HER3 receptor dimers and downstream signaling
- In combination with Herceptin: potential to create new standard of care for women with HER2-positive metastatic BC

**T-DM1**
- Retains Herceptin’s biologic activity
- Targeted intracellular delivery of a potent cell-killing agent, DM1
- No need for conventional chemotherapy
Securing growth for HER2 franchise
Pertuzumab and T-DM1 advancing the standard of care

Timelines refer to the expected dates of first filing
Pertuzumab in HER2+ 1st line mBC
CLEOPATRA study

D, docetaxel; PFS, progression-free survival; T, trastuzumab

File in US and EU Dec 2011, PDUFA date June 8th 2012
Herceptin & pertuzumab in adjuvant setting
Potentially increasing the cure rate: APHINITY study

Herceptin & pertuzumab + chemotherapy

Primary end-point:
- 3 year Disease Free Survival
- FPI: H2 2011
- Follow-up: 3 years (median)
- Expect data 2016

Chemotherapy: FEC x 3 → TH x 3 or AC x 4 → TH x 4 or TCH x 6; Total duration of Herceptin treatment=1 year
FEC = 5-fluorouracil, Epirubicin, Cyclophosphamide; TH=Taxotere, Herceptin; AC=cyclophosphamide, doxorubicin; TCH=Taxotere, Carboplatin, Herceptin
Redefining HER2 blockade
Increasing the efficacy and tolerability

- Herceptin + chemotherapy
- T-DM1
- Herceptin & pertuzumab + chemotherapy
- T-DM1 & pertuzumab

Tolerability

Efficacy
MEK inhibitor (GDC-0973) in combination with Zelboraf

Before initiation of Zelboraf  15 weeks on Zelboraf  after relapse

MEK inh. (GDC-0973) in combination with Zelboraf

Nature 468, 902–903; 16 December 2010
Erivedge in metastatic and locally advanced Basal Cell Carcinoma

In collaboration with Curis; A. Sekulic et al., EADO 2011

*Basal cell carcinoma is not tracked in most cancer registries, including SEER. Prevalence is difficult to estimate and there is high uncertainty in our projections. Shown are estimates from incidence rates reported in literature and primary market research.
MetMAb: a new compound that inhibits HGF-mediated activation

**MetMAb**
- Monovalent format designed to prevent HGF-mediated stimulation of pathway
- Preclinical activity across multiple tumor models

<table>
<thead>
<tr>
<th>Cancers in which Met potentially plays role</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indication</strong></td>
</tr>
<tr>
<td>Non-small cell lung carcinoma (NSCLC)</td>
</tr>
<tr>
<td>Renal cell carcinoma (RCC)</td>
</tr>
<tr>
<td>Colorectal cancer (CRC)</td>
</tr>
<tr>
<td>Glioblastoma multiforme (brain cancer)</td>
</tr>
<tr>
<td>Hepatocellular carcinoma (HCC)</td>
</tr>
</tbody>
</table>

**Rationale for targeting Met**
- Met is amplified, mutated, overexpressed or uniquely activated in various cancers
- Met overexpression associated with worse prognosis in many cancers

HGF=Hepatocyte Growth Factor
Diagnostic companion test
Understanding the biology of Met signalling

**NSCLC: Intensity of Met staining on tumor cells scored on 0–3 scale**

1+  
2+  
3+  

‘Met high’ definition: ≥50% tumor cells with a staining intensity of 2+ or 3+

- Phase III in NSCLC with prospective testing of Met receptor over-expression
- Estimated that about one-half of NSCLC patients have Met high tumours
- Met IHC assay will be a companion test for the approval for MetMAb in NSCLC

Spigel et al, ESMO 2010
MetMAb + Tarceva in lung cancer
Efficacy analysis in overall population

Early analysis of all patients
2nd/3rd line mNSCLC

PFS HR=1.09

OS HR=1.09

23 patients from the erlotinib+placebo arm crossed over to MetMAb.

Median PFS and OS are consistent with previously reported findings in similar disease setting.

Spigel et al, ESMO 2010
MetMAb + Tarceva in lung cancer
New example of Personalised Healthcare approach

Early analysis of Met High Patients
2nd/3rd line mNSCLC

- 54% patients had ‘Met High’ NSCLC
- 12/23 patients from the Tarceva+placebo arm who crossed over to MetMAb were Met High

Spigel et al, ESMO 2010
MetMAb development plan
NSCLC, triple-negative mBC and mCRC

<table>
<thead>
<tr>
<th>Patient population</th>
<th>2nd- and 3rd-line Met-positive metastatic NSCLC</th>
<th>1st and 2nd-line triple negative metastatic breast cancer</th>
<th>1st-line metastatic colorectal cancer</th>
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<tbody>
<tr>
<td>Phase</td>
<td>Phase III</td>
<td>Phase II</td>
<td>Phase II</td>
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<tr>
<td># of patients</td>
<td>N=480</td>
<td>N=180</td>
<td>N=188</td>
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<tr>
<td>Design</td>
<td>• ARM A: Tarceva plus onartuzumab</td>
<td>• ARM A: Avastin and paclitaxel plus onartuzumab</td>
<td>• ARM A: FOLFOX plus Avastin plus onartuzumab</td>
</tr>
<tr>
<td></td>
<td>• ARM B: Tarceva plus placebo</td>
<td>• ARM B: Avastin and paclitaxel plus placebo</td>
<td>• ARM B: FOLFOX plus Avastin plus placebo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ARM C: Paclitaxel plus onartuzumab</td>
<td></td>
</tr>
<tr>
<td>Primary endpoint</td>
<td>• Overall survival</td>
<td>• Progression–free survival</td>
<td>• Progression–free survival in ITT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Progression-free survival in pre-specified Met+ patients</td>
</tr>
<tr>
<td>Status</td>
<td>• FPI Q1 2012</td>
<td>• FPI Q1 2011</td>
<td>• FPI Q3 2011</td>
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</table>
Performance update and strategy

Update on oncology portfolio

Summary and short term news flow
Key clinical data to be presented at upcoming meetings

<table>
<thead>
<tr>
<th>Event</th>
<th>Location</th>
<th>Presentation</th>
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<tr>
<td><strong>ASCO</strong></td>
<td>Chicago, June 1-5</td>
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<tr>
<td><strong>T-DM1</strong></td>
<td></td>
<td>- EMILIA pretreated HER2+ mBC</td>
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<tr>
<td></td>
<td></td>
<td>- PhII safety study in HER2+ eBC</td>
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<td><strong>Avastin</strong></td>
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<td>- TML treatment through multiple lines in mCRC</td>
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<td></td>
<td></td>
<td>- AURELIA platinum resistant ovarian cancer</td>
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<td><strong>EULAR</strong></td>
<td>Berlin, June 6-9</td>
<td></td>
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<tr>
<td><strong>Actemra</strong></td>
<td></td>
<td>- ADACTA (submitted) Head-to-Head vs. Humira</td>
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### Major clinical and regulatory news flow

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Compound</th>
<th>Indication</th>
<th>Milestone</th>
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<tr>
<td></td>
<td><strong>Avastin</strong></td>
<td>mCRC</td>
<td>Ph III TML</td>
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<tr>
<td></td>
<td><strong>pertuzumab</strong></td>
<td>1&lt;sup&gt;st&lt;/sup&gt; line HER2+ mBC</td>
<td>US, EU approval</td>
</tr>
<tr>
<td><strong>2012</strong></td>
<td><strong>Erivedge</strong></td>
<td>advanced BCC</td>
<td>US approval, EU approval (2012/13)</td>
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<tr>
<td></td>
<td><strong>Zelboraf</strong></td>
<td>metastatic melanoma</td>
<td>EU approval</td>
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<td></td>
<td><strong>Lucentis</strong></td>
<td>DME</td>
<td>US approval</td>
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<td><strong>T-DM1</strong></td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; line HER2+ mBC</td>
<td>Ph III EMILIA</td>
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<td></td>
<td><strong>Herceptin subcutaneous</strong></td>
<td>early HER2+ BC</td>
<td>Ph III HANNAH (data presentation)</td>
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<td></td>
<td><strong>Herceptin</strong></td>
<td>adjuvant HER2+ BC</td>
<td>Ph III HERA 2 years vs. 1 year</td>
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<td><strong>MabThera subcutaneous</strong></td>
<td>front-line follicular NHL</td>
<td>Ph III</td>
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<td><strong>Actemra</strong></td>
<td>RA DMARD IR</td>
<td>Ph III ADACTA H2H vs. Humira</td>
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<tr>
<td></td>
<td><strong>Actemra subcutaneous</strong></td>
<td>RA, moderate to severe</td>
<td>Ph III SUMMACTA BREVACTA</td>
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<tr>
<td></td>
<td><strong>Avastin subcutaneous</strong></td>
<td>newly diagnosed glioblastoma</td>
<td>Ph III AVAglio</td>
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<td></td>
<td><strong>dalcetrapib</strong></td>
<td>Atherosclerosis CV risk red.</td>
<td>Ph III dal-OUTCOMES final analysis; 2&lt;sup&gt;nd&lt;/sup&gt; interim analysis in H1 2012</td>
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<tr>
<td><strong>2013</strong></td>
<td><strong>GA101</strong></td>
<td>Front line CLL</td>
<td>Ph III vs. chemotherapy</td>
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<tr>
<td></td>
<td><strong>bitopertin (GlyT-1)</strong></td>
<td>Schizophrenia</td>
<td>Ph III (several studies)</td>
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</table>

Oncology and CV outcome studies are event driven, timelines may change.
Outlook for 2012 confirmed

| **Sales growth (CER)** | Group & Pharma: low to mid-single digit  
Diagnostics: above market |
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<tbody>
<tr>
<td><strong>Operational Excellence savings</strong></td>
<td>2012+: CHF 2.4 bn*</td>
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<tr>
<td><strong>Core EPS growth target (CER)</strong></td>
<td>High single-digit</td>
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<tr>
<td><strong>Dividend outlook</strong></td>
<td>Continue attractive dividend policy</td>
</tr>
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Barring unforeseen events; CER=Constant Exchange Rates; * vs. 2011: CHF 1.8 bn
We Innovate Healthcare