Turning science into patient benefits

Alan Hippe, CFO Roche Group

June 2016
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2. legislative and regulatory developments and economic conditions;
3. delay or inability in obtaining regulatory approvals or bringing products to market;
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Performance update

Innovation and differentiation

Improving the standard of care

Outlook
Q1 2016: Sales growth for fifth consecutive year

All growth rates at Constant Exchange Rates (CER)
2015: Strong underlying Group Core operating profit & margin

CER=Constant Exchange Rates; * Excluding sale of filgrastim rights in 2014
2015: Dividend and payout ratio further increased

Payout ratio calculated as dividend per share divided by Core earnings per share (diluted); 2015 dividend as proposed by the Board of Directors;
Note: For 1995, a special dividend was paid out to mark F. Hoffmann-La Roche’s 100th anniversary in 1996
Performance update

Innovation and differentiation

Improving the standard of care

Outlook
Roche significantly advancing patient care
Recognition for innovation 2013-present

12 Breakthrough Therapy Designations

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<th>Rank</th>
<th>Company</th>
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<td><strong>Ocrelizumab</strong> <em>(PPMS)</em></td>
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<td><strong>Venclexta</strong> <em>(AML)</em></td>
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<td></td>
<td><strong>Venclexta + Rituxan</strong> <em>(R/R CLL)</em></td>
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<td>2015</td>
<td><strong>Actemra</strong> <em>(Systemic sclerosis)</em></td>
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<td><strong>Tecentriq</strong> <em>(NSCLC)</em></td>
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<td><strong>Venclexta</strong> <em>(R/R CLL 17p del)</em></td>
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<td><strong>Emicizumab</strong>/ACE 910 <em>(Hemophilia A)</em></td>
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<td>2014</td>
<td><strong>Esbriet</strong> <em>(IPF)</em></td>
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<td></td>
<td><strong>Lucentis</strong> <em>(Diabetic retinopathy)</em></td>
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<td></td>
<td><strong>Tecentriq</strong> <em>(Bladder)</em></td>
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<tr>
<td>2013</td>
<td><strong>Alecensa</strong> <em>(2L ALK+ NSCLC)</em></td>
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<tr>
<td></td>
<td><strong>Gazyva</strong> <em>(1L CLL)</em></td>
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Source: [http://www.focr.org/breakthrough-therapies](http://www.focr.org/breakthrough-therapies) as at June 2016; PPMS=Primary Progressive Multiple Sclerosis; CLL=Chronic Lymphocytic Leukemia; NSCLC=Non-Small Cell Lung Cancer; IPF=Idiopathic Pulmonary Hypertension
Roche strategy: Focused on medically differentiated therapies

Regulators: Optimised benefit / risk ratio

Payors: Optimised benefit / cost ratio
Approach towards innovation

Exploring broad …

We invest more early stage

% of budget

R & Early D  54%
Late D  46%
Industry avg  46%
Roche  60%

…to increase options to choose from

# of NME’s entering Pre-clinical

2012  11
2013  18
2014  19

Industry avg.

External sources: Investment split based on the CMR Pharmaceutical R&D Factbook (data from 10 companies, 2014); Number of entries into Pre-clinical for Industry based on data from KMR, data for 2011-2013.
Approach towards innovation
…but prioritizing rigorously

We select at late stage entry

Illustrative

Medical need

low

high

Clinical differentiation

low

high

Threshold

Greater differentiation

Continued

Disqualified

...to increase sales potential

Sales

Time
Achievements: Innovation

Above-average R&D success rate

Likelihood of launch from phase 0

Note: Success rates calculated at the project/indication level for overlapping 5-year periods based on KMR data (13 peers and Roche)
Data management

Collaborations are key

Clinical Trials

Controlled, clinical trial data on *expected* benefit and side effects

Clinical Practice

Real outcome data on *actual* benefit and side effects

Analysis

Decisions on treatment
Insight for R&D
Performance update

Innovation and differentiation

Improving the standard of care

Outlook
New growth opportunities

NMEs

- Alecensa
- Cotellic
- Venclexta

2015

- ocrelizumab
- Tecentriq
- lebrikizumab

2016

- ACE910
- lampalizumab
- olesoxime

2017

- crenezumab
- taselisib
- etrolizumab

Post 2017

- gantenerumab

line extensions

- Herceptin + Perjeta
- Gazyva (GOYA)
- Gazyva (GALLIUM)
- Tecentriq + chemo

Oncology/hematology
- Neuroscience
- Ophthalmology
- Immunology
New growth opportunities

NMEs

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line extensions

Oncology/hematology
Neuroscience
Ophthalmology
Immunology
Anti-CD20 franchise
Strategies for long term growth

Protect.. Replace.. Extend..

Venetoclax in collaboration with AbbVie; SC=subcutaneous; CLL=chronic lymphocytic leukemia; NHL=non-hodgkin’s lymphoma
Third positive readout for Gazyva

**GALLIUM in 1L iNHL**

**Primary end-point:**

**CLL11: Ph III Chronic Lymphocytic Leukemia (CLL)**

- 1L CLL  
  - n=781
- Gazyva + chlorambucil
- Rituxan + chlorambucil
- chlorambucil

**GADOLIN: Ph III Recurrent Indolent NHL (iNHL)**

- Gazyva + bendamustine
- bendamustine

- Maintenance
  - Gazyva q2mo x 2 years

**GALLIUM: Ph III 1L Indolent NHL (iNHL)**

- 1L iNHL  
  - n=1401
- Gazyva + CHOP or
  - Gazyva + CVP or
  - Gazyva + bendamustine
- Rituxan + CHOP or
  - Rituxan + CVP or
  - Rituxan + bendamustine

- Maintenance
  - Gazyva q2mo x 2 years

**GOYA: Ph III 1L Diffuse Large B-cell Lymphoma (DLBCL)**

- Front-line DLBCL (aggressive NHL)  
  - n=1418
- Gazyva + CHOP
- Rituxan + CHOP

**Gazyva in collaboration with Biogen Idec; CHOP=Cyclophosphamide, Doxorubicin, Vincristine and Prednisone; CVP=Cyclophosphamide, Vincristine and Prednisolone**

- PFS
  - Approved in Q4 2013
  - Approved in Q1 2016
  - Stopped at interim analysis
  - Data expected in H2 2016
Establishing Gazyva as new CD20 backbone

Pie chart shows 2014 Rituxan sales split according to indications; CLL=chronic lymphocytic leukemia; iNHL (FL)=indolent non-hodgkin's lymphoma; aNHL (DLBCL)=aggressive NHL; R/R=relapsed/refractory; Gazyva in collaboration with Biogen Idec
New growth opportunities

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Oncology/hematology
Neuroscience
Ophthalmology
Immunology
CIT portfolio: 10 in-house assets in the clinic

**Priming & activation**
- anti-CEA-IL2v FP (cergutuzumab amunaleukin)
- anti-FAP-IL2v FP
- anti-OX40

**Antigen presentation**
- anti-CD40

**Antigen release**
- EGFRi (Tarceva)
- ALKi (Alecensa)
- BRAFi (Zelboraf)
- MEKi (Cotellic)
- anti-CD20 (Gazyva)
- anti-HER2 (Herceptin; Kadryla; Perjeta)
- various chemotherapies
- lenalidomide* (Celgene)
- rociletinib* (Clovis)
- daratumumab* (Janssen)

**T cell Trafficking**

**T cell infiltration**
- anti-VEGF (Avastin)

**Cancer T cell recognition**
- anti-CEA/CD3 TCB
- anti-CD20/CD3 TCB

**T cell killing**
- Tecentriq (atezolizumab)
- anti-CSF-1R (emactuzumab)
- IDOi (NewLink)
- anti-TIGIT

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Chen and Mellman. Immunity 2013
NME=new molecular entity; CIT=cancer immunotherapy; FP=fusion protein; TCB=T-cell bispecific
# Atezolizumab: Pivotal programs by disease

<table>
<thead>
<tr>
<th>Lung</th>
<th>Bladder</th>
<th>Kidney</th>
<th>Breast</th>
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</table>
| FIR and BIRCH
  Dx+ mono  | IMpower 130&150
  1L non-sq. combo | IMvigor 210
  1L cis-inel. & 2L | IMmotion 150
  1L combo |
| POPLAR
  2L+ mono   | IMpower 111
  1L sq. Dx+ mono | IMvigor 211
  2L mono     | IMmotion 151
  1L combo   |
| OAK
  2L mono    | IMpower 131
  1L sq. combo | IMvigor 010
  Adj.        | IMpassion 131
  1L combo   |
| IMpower 110
  1L non-sq. Dx+ mono | IMpower 010
  Adj. Dx+ mono |                                      |                        |

- **Rolling filing initiated**
- **Data in 2016**
- **Data in 2017**
- **approved**

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Going *deep* in diseases where we have strong scientific rationale

cis-inel. = cisplatin ineligible patients
May 2015: Combinations in clinical development

emactuzumab (aCSF-1R); cergutuzumab amunaleukin (aCEA-IL2v FP); vanucizumab (aAng2/VEGF); polatuzumab vediotin (aCD79b ADC); taselisib (PI3Ki); ipatasertib (AKTı); SERD (selective estrogen receptor degrader); idasanutlin (MDM2 antagonist)

Status: May 2015
May 2016: Combinations in clinical development

Status: May 2016

- **emactuzumab** (aCSF-1R)
- **cergutuzumab amunaleukin** (aCEA-IL2v FP)
- **vanucizumab** (aAng2/VEGF)
- **polatuzumab vediotin** (aCD79b ADC)
- **taselisib** (PI3Ki)
- **ipatasertib** (AKTi)
- **SERD** (selective estrogen receptor degrader)
- **idasanutlin** (MDM2 antagonist)

**Launched portfolio**

- **azacitidine**
- **polatuzumab vediotin**
- **idarubicin**
- **lenalidomide**
- **daratumumab**

**Immunotherapy portfolio**

- **emactuzumab**
- **cergutuzumab amunaleukin**
- **aFAP-IL2v FP**
- **aCD40**
- **aOx40**
- **IDOi**
- **aCEA/CD3 TCB**
- **aCD20/CD3 TCB**
- **aTIGIT**
- **vanucizumab**

**Combination approved**

**Combination in development**

- **Roche NME late stage**
- **Roche NME early stage**
- **Non-Roche approved drugs**
New growth opportunities

<table>
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- **Oncology/hematology**
- **Neuroscience**
- **Ophthalmology**
- **Immunology**
Ocrelizumab: Active in both RMS & PPMS

- Selective depletion of a B cell subset leaving the ability to generate new B cells intact
- Administered IV twice yearly

RMS = relapsing forms of multiple sclerosis (MS) which includes patients with RRMS and SPMS with superimposed relapses; RRMS = relapsing-remitting MS; SPMS = secondary progressive MS; PPMS = primary progressive MS.
Multiple Sclerosis: Improvements over SoC driving market growth

Global sales (lc) USDm

<table>
<thead>
<tr>
<th>Year</th>
<th>ABCRs</th>
<th>New biologics</th>
<th>Orals</th>
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<td>2014</td>
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<td>Q2 2015</td>
<td>19,420</td>
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Source: Evaluate Pharma Multiple Sclerosis report, October 2015; * Includes Imusera sales; SoC=standard of care
New growth opportunities

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- Neuroscience
- Ophthalmology
- Immunology
Emicizumab (ACE 910) development plan
Non-interventional study expanded to all patients

- Inhibitor study: Enrollment progressing well
- Inhibitor non-interventional study fully recruited (>90 patients) and expanded to non-inhibitors
- Non-inhibitor, pediatric and Q4W dosing studies expected to start in 2016

QW=weekly dosing; Q2W=dosing every 2 weeks; Q4W=dosing every 4 weeks; OLE=open label extension
Performance update

Innovation and differentiation

Improving the standard of care

Outlook
Positive outlook

*Strong pipeline mitigates biosimilar impact*

**NME launches**
Venetoclax, Alectinib, Cotelllic, Ocrelizumab, Atezolizumab, Lebrikizumab, ACE910, Lampalizumab

**Biosimilars**
MabThera, Herceptin, Avastin

**Conceptual**

**Pipeline**

**Marketed products**

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### 2016 outlook

<table>
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<th>Outlook</th>
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<td>Group sales growth&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Mid-single digit</td>
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<tr>
<td>Core EPS growth&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Ahead of sales growth</td>
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<tr>
<td>Dividend outlook</td>
<td>Further increase dividend in Swiss francs</td>
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<sup>1</sup> At constant exchange rates (CER)
Appendix
Roche vision: Personalised reimbursement models

Personalised reimbursement models

1. Pay for performance

2. Multiple-indication pricing

3. Combinations

- Pricing according to benefits delivered to patients in different indications and combinations

- Personalised reimbursement models include:
  - Pay for performance
  - Multiple-indication pricing
  - Combination pricing
Pay for performance

“Level of reimbursement based on a patient’s response to a medicine over a specified time period”

(+)
- Fair reimbursement for patients on an individual level

(-)
- Only a few healthcare systems technically support reimbursement at patient level
- Which outcome is important?

AIFA - Payment by Results procedure

Start of the new treatment in all eligible patients

NON-RESPONDERS
- Evaluation after x days/cycles
- Treatment is stopped
- The overall patient’s cost of treatment is not reimbursed
- Pay-back by Market Authorization Holder to public hospital

RESPONDERS
- Treatment is continued
- Treatment is reimbursed by NHS

Non responders defined as disease progression or progression-related death, unacceptable toxicity not allowing continuation of treatment or toxicity-related death

Source: Managed Entry agreements for pharmaceuticals. The European experience - LSE April 2013
The obligation and rules to report adverse events (AE) applies equally for treatments registered in the AIFA registry according to the national pharmacological requirements.
Multiple-indication pricing

“Allows a medicine approved in different indications and combinations to be priced according to benefits delivered in each indication and combination”

**Now** – unit of drug has same price across all indications

All indications

List price (invoice price)

**Future** – single or combination drug price varies by indication based on benefit

Indication A

Indication B

Indication C

Other

Indication A

- Best reflects reality of current treatment paradigms, particularly in oncology

Indication B

- Requires drug-utilisation tracking substantial at patient level

Indication C

Other

Price X

Price Y

Price Z

Price X

Price X

Price X

Price X
Combination pricing

“Ensures benefits of combination therapies are reflected while considering the limits of healthcare budgets”

Now – unit of drug has same price, whether used as single agent or in combination

- Single use or combination
- List price product A (invoice price)
- List price product B (invoice price)

Future – price varies by single or combination use based on benefit

- Product A
- Product B
- Product A + B (without PRM)
- Product A + B (with PRM)

(+) - Addresses the reality of combination treatments, particularly oncology
- Takes healthcare budget into consideration

(-) - Not all drug combos are from the same company
- High complexity with many possible combinations
Doing now what patients need next