Roche Pharma Day 2015

Life cycle management & new market opportunities

Bill Anderson  Chief Marketing Officer
Pharmaceuticals Division
Maximising existing franchises

New growth opportunities

Access in a changing healthcare environment
Multiple major pivotal trials reading out near term
Significant filing and launch activities ahead

<table>
<thead>
<tr>
<th>Year</th>
<th>Molecule</th>
<th>Indication</th>
<th>Market opportunity</th>
<th>Incremental infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>Alectinib</td>
<td>ALK+ NSCLC</td>
<td>⬤</td>
<td>Low to medium</td>
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<tr>
<td></td>
<td>Cotellic/Zelboraf</td>
<td>Melanoma</td>
<td>⬤</td>
<td>Low</td>
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<tr>
<td></td>
<td>Venetoclax</td>
<td>Hematology (CLL 17p del)*</td>
<td>⬤</td>
<td>Low</td>
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<tr>
<td></td>
<td>Ocrelizumab</td>
<td>Multiple Scelerosis</td>
<td>⬤</td>
<td>Medium</td>
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<tr>
<td></td>
<td>Atezolizumab</td>
<td>NSCLC, bladder (2/3L)</td>
<td>⬤</td>
<td>Medium</td>
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<tr>
<td>2016</td>
<td>Lebrikizumab</td>
<td>Asthma, AD, IPF, COPD</td>
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<td>Large</td>
</tr>
<tr>
<td></td>
<td>APHINITY</td>
<td>Adj HER2+ breast cancer</td>
<td>⬤</td>
<td>Low</td>
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<tr>
<td></td>
<td>GOYA</td>
<td>NHL (aggressive)</td>
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<td>Low</td>
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<td>Lampalizumab</td>
<td>Geographic atrophy</td>
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<td>2017</td>
<td>GALLIUM</td>
<td>NHL (indolent)</td>
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<td>Low</td>
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<tr>
<td></td>
<td>Atezolizumab+chemo</td>
<td>NSCLC (1L)</td>
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<td></td>
<td>Taselisib (PI3KI)</td>
<td>HER2-/HR+ breast cancer</td>
<td>⬤</td>
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<tr>
<td></td>
<td>Idasanutlin (MDM2)</td>
<td>Acute myeloid leukemia</td>
<td>⬤</td>
<td>Low to medium</td>
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- **Oncology**
- **Neuroscience**
- **Ophthalmology**
- **Immunology**

°°°° Small: up to CHF 0.5 bn 
°°°°°° medium = CHF 0.5 to CHF 1bn 
°°°°°°°° large > CHF1bn

NSCLC=non-small cell lung cancer; CLL=chronic lymphocytic leukemia; AD=atopic dermatitis; IPF=idiopathic pulmonary fibrosis; COPD=chronic obstructive pulmonary disease; NHL=non-hodgkin's lymphoma; * first indication
Roche’s approach in oncology: First- and best-in-class necessary for success

Data sources: Evaluate Pharma, Decision Resources, Roche/Genentech PMR launch trackers

Note: *Market shares represent either % sales of target product relative to sales competing products in similar indications or patient shares from Roche PMR trackers; sales data are actuals (≤ 2013) + consensus broker forecasts (2013-2020) where applicable
Anti-CD20: Multiple approaches across the franchise

1L CLL Typical
5%
1L CLL Fit
6%
CLL 17p-del
1%
R/R CLL
5%
iNHL
49%
1L aNHL
27%
R/R aNHL
6%

Gazyva (GREEN) - Extend chemo backbone
Venetoclax – Extend efficacy

Rapidly and sustainably convert market to SC
Gazyva (GALLIUM) (improve > SoC)

GAZYVA (GOYA) in aNHL (improve > SoC)

Rapidly and sustainably convert market to SC

SoC=standard of care; SC=subcutaneous; CLL=chronic lymphocytic leukemia; iNHL=indolent non-hodgkin’s lymphoma; aNHL=aggressive NHL
Anti-CD20 franchise
Strategies for long term growth

Protect. Replace. Extend..

Venetoclax
Polatuzumab
Atezolizumab

Medical value

Protect
MabThera
MabThera SC
Await GOYA and GALLIUM
Extend Gazyva with GREEN
Rapidly and sustainably convert the market to SC

Replace
Gazyva

Extend
Gazyva
Increase medical benefit with Venetoclax in NHL, CLL and expand into new diseases e.g. Multiple Myeloma

Venetoclax in collaboration with AbbVie; SC=subcutaneous; CLL=chronic lymphocytic leukemia; NHL=non-hodgkin’s lymphoma
HER2+ breast cancer adjuvant: Still high medical need despite major advances

**Adjuvant - HERA trial**

- HR = 0.76 (95% CI: 0.67-0.86)
- P < 0.0001
- Disease-Free Survival

**Neoadjuvant - NOAH trial**

- HR = 0.64 (95% CI: 0.44-0.93)
- P = 0.016
- Event-Free Survival

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1 Roche data on file; 2 L. Gianni et al, ASCO Annual Meeting 2013
HER2 franchise: Strengthening standard of care

Franchise expected to grow further

**Established SoC**

**Potentially new SoC**

**New trials**

atezolizumab (aPD-L1 MAb); SoC=standard of care
HER2 franchise: Significant growth opportunities in current indications

Patient shares

- **Herceptin Adjuvant**
  - US: 96%
  - EU5: 93%
  - EM: 25%
- **Perjeta Neoadjuvant**
  - US: <5%
  - EU5: <5%
  - EM: <5%
- **1L Perjeta mBC**
  - US: 63%
  - EU5: 51%
  - EM: <5%
- **2L Kadcyla**
  - US: 58%
  - EU5: 58%
  - EM: <5%

**Growth**

- Increased patient share
- Longer treatment duration
- Emerging markets

Sources: Market research tracking studies; Latest quarter Q315 in EU5 and US
### Franchise strategies for long term growth

**New indications and longer duration**

<table>
<thead>
<tr>
<th>Growth opportunity</th>
<th>Indication</th>
<th>Global peak sales potential</th>
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<tbody>
<tr>
<td><strong>HER2</strong></td>
<td>Perjeta adjuvant (APHINITY)</td>
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<td><strong>Potential and new indications</strong></td>
<td>Herceptin SC*</td>
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<td>Gazyva aNHL (GOYA)</td>
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<td>Gazyva iNHL (GALLIUM)</td>
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<td>MabThera SC*</td>
<td><img src="image" alt="Small: up to CHF 0.5 bn" /> <img src="image" alt="Medium: CHF 0.5 to CHF 1bn" /> <img src="image" alt="Large: &gt; CHF1bn" /></td>
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<td>Venetoclax</td>
<td><img src="image" alt="Small: up to CHF 0.5 bn" /> <img src="image" alt="Medium: CHF 0.5 to CHF 1bn" /> <img src="image" alt="Large: &gt; CHF1bn" /></td>
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*Sales replacing current IV products; SC=subcutaneous; iNHL=indolent non-hodgkin’s lymphoma; aNHL=aggressive NHL*
Avastin: Further growth opportunities

**Existing markets**
- Continued growth in emerging markets
- Continued uptake in lung, ovarian and cervical cancer

**New indications**
- Avastin + Tarceva (filed in EU)
- Mesothelioma (filing ongoing)

**Market extension**
- Avastin + Atezolizumab in lung, renal, colorectal

Avastin global sales (incl. Chugai) at 2014 average exchange rates; NSCLC=non-small cell lung cancer; mCRC=metastatic colorectal cancer; RCC=renal cell carcinoma; BC=breast cancer; OC=ovarian cancer; GBM=glioblastoma; CC=cervical cancer
What does it take to succeed in chronic diseases?
Importance of incremental differentiation

**Humira in TNF-α Inhibitors**

*All indications*

- SC vs Remicade’s IV
- Less frequent dosing than Enbrel

**Tecfidera in MS**

- Better efficacy than 1st gen
- Better safety than 2nd gen

**Victoza in T2D**

- Better device
- QD vs. BID

MS=multiple sclerosis; T2D=type 2 diabetes; SC=subcutaneous; IV=intravenous; QD=once a day dosing; BID=twice a day dosing
Actemra: Success in a competitive space  
Focus on differentiation

Clear positioning: Focus on monotherapy

“ADACTA Study Shows Actemra Superior in Monotherapy”

“Monotherapy: for patients who cannot tolerate Methotrexate”

Share of Voice

US Share of Voice

In 2010

10%

In 2011

4%

Continued evidence generation

<table>
<thead>
<tr>
<th>Key Ph IV Studies</th>
<th>Patients</th>
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<tbody>
<tr>
<td>Monotherapy Efficacy</td>
<td>&gt;8,500</td>
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<tr>
<td>Monotherapy H2H vs Humira</td>
<td>~320</td>
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<tr>
<td>Early RA monotherapy</td>
<td>~1,500</td>
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</tbody>
</table>

• EULAR Guidelines: Recommended for monotherapy

Source for share of voice: IMS SPD, Q1 2015 & US PMR 2010-11
Actemra: Increasing patient shares through smart clinical development and focused marketing

Patient shares in EU5 in rheumatoid arthritis monotherapy

- **Strategy: Focus on monotherapy**
- **H2H superiority in 1L monotherapy**
- **Leveraging sub-cutaneous formulation**

Source: GFK quarterly tracker Q1’15, based on survey of Roche targeted accounts
Maximising existing franchises

New growth opportunities

Access in a changing healthcare environment
New growth opportunities outside oncology

- alectinib
- Cotellic
- venetoclax
- ocrelizumab
- ACE910
- lampalizumab
- lebrikizumab
- olesoxime
- etrolizumab
- gantenerumab
- crenezumab
- taselisib

- Herceptin + Perjeta
- Gazyva
- atezolizumab + chemo
- Gazyva

- Oncology/hematology
- Neuroscience
- Ophthalmology
- Immunology
Multiple sclerosis (MS): Level of differentiation important for new entrants

Global market shares Q2 2015¹

- Multiple treatment options in Relapsing and Remitting MS
- Continued high unmet medical need
- Primary Progressive MS (PPMS) – no approved treatments for this indication

¹ Source: Evaluate Pharma Multiples Sclerosis report, October 2015. Note: Market shares based on value (sales)

² ABCR's refers to Avonex®, Betaferon® / Betaseron®, Copaxone®, Rebir®, Extavia®, Plegridy®
Multiple Sclerosis: Improvements over SoC driving market growth

Source: Evaluate Pharma Multiple Sclerosis report, October 2015; * Includes Imusera sales; SoC = standard of care
Range of treatment options in RMS
Varying efficacy and safety profiles

RMS=relapsing forms of multiple sclerosis; ABCR=Avonex®; Betaseron®; Copaxon®; Rebif®;
Ocrelizumab: Effective, safe, convenient

**Efficacy**

- **RMS**
  - Superior to standard of care DMT

- **PPMS**
  - First investigational treatment to show efficacy

**Safety**

- Incidence of adverse events & serious adverse events (incl. serious infections) similar to interferon beta-1a in both RMS studies and similar to placebo in PPMS

**Convenience**

- IV – Twice yearly

*Based on ARR, CDP, T1/T2 lesions; DMT=disease modifying treatment; AE=adverse event; CDP=confirmed disability progression; PPMS=primary progressive multiple sclerosis; SAE=serious adverse event; IV=intravenous
New growth opportunities outside oncology

<table>
<thead>
<tr>
<th>Year</th>
<th>NMEs</th>
<th>Extensions</th>
</tr>
</thead>
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<tr>
<td>2015</td>
<td>alectinib, venetoclax</td>
<td>Herceptin + Perjeta, Gazyva</td>
</tr>
<tr>
<td>2016</td>
<td>ocrelizumab, lebrikizumab</td>
<td>Gazyva</td>
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<td>2017</td>
<td>ACE910, atezolizumab, lampalizumab</td>
<td>atezolizumab + chemo, Gazyva</td>
</tr>
<tr>
<td>Post 2017</td>
<td>crenezumab, taselisib, olesoxime, etrolizumab</td>
<td>gantenerumab</td>
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</table>
Severe asthma: High unmet need in growing market

Global asthma market 2014 vs 2020

- Approx. 300m patients worldwide and growing strongly
- 5-10% asthma patients have severe disease, and ~30% of severe disease is uncontrolled despite maximal therapy
- Over 4.5m severe asthmatics with uncontrolled disease

Note: Market shares based on value (sales); Source: Evaluate; defined by daily use of ≥500ug ICS + LABA
Asthma: >CHF 15bn market

Small molecules majority of SoC

<table>
<thead>
<tr>
<th>GINA</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
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<tbody>
<tr>
<td>NHBLI</td>
<td>Step 1</td>
<td>Step 2</td>
<td>Step 3</td>
<td>Step 4</td>
<td>Step 5</td>
</tr>
</tbody>
</table>

SABA (Rapid acting β2 agonist) as needed

- Low-dose
- medium dose
- high dose
- ICS

Long acting β2 agonist

OCS

Xolair®

Key brands / oral

Flixotide®

Seretide® / Advair® / Symbicort®

Small molecule

Biologic

Source: GINA guidelines in Global initiative for asthma 2012, NHLBI guidelines from Asthma Care September 2012 and International ERS/ATS guidelines published in ERJ on Dec. 12, 2013, *Evaluate Pharma 2013; SoC=standard of care; OCS=oral corticosteroid; ICS=inhalable corticosteroid
Asthma: Biologic market expected to grow strongly to CHF 5bn by 2020

New guidelines

New biologics with different MoAs within 5yrs

Biomarkers: Emergence of phenotyping

Source: 1. Decision resources, Asthma (Moderate to Severe), April 2014. Timeframe considered = when mepolizumab, reslizumab and lebrikizumab will be available; 2. Evaluate pharma, analysis on January 28th 2015; OCS=oral corticosteroid; MoA=mechanism of action
Lebrikizumab: Differentiated mode of action with solid dual biomarker profile

- **Efficacy**
  - Efficacy beyond clinical asthma exacerbations (CAE) reduction
  - Broad development beyond asthma in related diseases

- **Safety**
  - Improve on significant side effects associated with oral corticosteroid (OCS) use

- **Biomarker**
  - Biomarkers to show clinically meaningful effect in distinct populations
Lebrikizumab in atopic dermatitis
Chron*ic disease with high unmet medical need

**Disease**
- Inflamed skin, chronic, relapsing
- Severe itching, poor sleep, psycho-social dysfunction
- Th2 driven disease, with high expression of IL-13

**Prevalence**
- Most common dermatologic disease (~2x psoriasis)
- 20-30% moderate to severe

**Unmet need**
- Current treatment options: Burdersome, non-targeted, significant toxicity
- Up to 60% with moderate-severe disease do not adequately respond
New growth opportunities outside oncology

- alectinib
- ocrelizumab
- venetoclax
- Cotellic
- lebrikizumab
- HERCEPTIN + Perjeta
- Gazyva
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Hemophilia A: Current treatment strategies

**Episodic (on demand) treatment**
- Patients treated only when they bleed
- Can be up to 30-60 times per year

**Prophylaxis**
- Goal is to prevent bleeds
- IV infusion 2-3 times per week
- Can reduce bleed rate to 0-2 per year for non-inhibitor patients
- Should be the standard, but is still not used in ~35% of patients (treatment burden, adherence, IV access issues)
Hemophilia A: There are significant limitations of current treatment options

**FVIII market (USD 6.1bn in 2012)**

- **Current FVIII treatments**
  - Limited half-life of only 8-12 hrs
  - Frequent IV injections
  - Induce neutralizing antibodies, which inhibit their function

**By-passing agent market (USD 2.1bn)**

- **Current by-passing treatments**
  - Much shorter half-life of ~4-6 hrs
  - Multiple frequent IV infusions
  - Long infusion times (30+mins) for FEIBA
  - Unstable efficacy compared to FVIII

*Company reported sales; ^1EvaluatePharma consensus analyst estimates
ACE910 can address the major medical needs for both inhibitor and non-inhibitor patients

Inhibiting Factor VIII antibodies in 20–30% of the patients

- **INHIBITOR**
  - **On-demand treatment with by-passing agents**
    - 2-3h intervals, IV
  - **Prophylaxis with by-passing agents**
    - Every other day, IV
  - Immune Tolerance Induction
    - 70-80% success rate
    - limitation due to very high cost and heavy burden for patients

- **NON-INHIBITOR**
  - **On-demand treatment**
    - 1-3 times/bleeding event, IV
  - **Prophylaxis treatment**
    - 3 times/week, IV

ACE 910

- Less frequent & SC injection
- No potential to induce FVIII inhibitor
- Potentially more effective prophylaxis

**Roche**
ACE 910: Differentiated mode of action with less frequent dosing

**MoA**
- Bi-specific fully humanized antibody designed to promote clot formation at site of injury
- Novel approach that promotes FX activation, a key step in acceleration of coagulation and stable clot formation

**Efficacy**
- More effective prophylaxis for inhibitor patients
- Substantial improvement in bleed rates

**Safety / Convenience**
- No potential to induce FVIII inhibitors
- Subcutaneous administration
- Less frequent dosing (potentially Q4W) due to long half life
- Allow more non-inhibitor patients to be on prophylaxis

Q4w=monthly dosing
New growth opportunities outside oncology

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Line extensions:

- Oncology/hematology
- Neuroscience
- Ophthalmology
- Immunology
Geographic Atrophy (GA): Significant unmet need with no approved treatments

- Progressive and irreversible disease, responsible for 20% of legal blindness
- Currently no effective therapies approved
- Lampalizumab: Selective inhibitor of the alternative complement pathway

### AMD Market overview

- **Geographic Atrophy**: 5m+ pts
  - GA is a progressive, irreversible disorder severely impacting visual function and patient quality of life
- **Neovascular AMD**
  - Neovascularization
- **Lampalizumab**
  - CFI biomarker profile +ve
  - CFI biomarker profile -ve
  - Other

### Phase III study population

GA prevalence is estimated to be similar to the prevalence of neovascular AMD

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AMD=age-related macular degeneration; CFI=Complement Factor I
Lampalizumab: First-in-class disease modifying therapy

**Efficacy**
- Phase II showed promising efficacy in all comers; higher efficacy in exploratory biomarker group

**Safety / Convenience**
- No unexpected or unmanageable SAEs

**Biomarker**
- CFI profile biomarker included in pivotal trials
Maximising existing franchises

New growth opportunities

Access in a changing healthcare environment
The key challenge to access: Differentiated solutions across geographic clusters

- **United States (US)**
  - (35% of world market, 5% of population)
  - Free, stable pricing

- **Developed countries ex-US**
  - (37% of world market, 10% of population)
  - Payers negotiate price

- **Emerging Markets**
  - (28% of world market, 85% of population)
  - Spend limited by GDP per capita

---

**Access**

**Pricing flexibility**

- **Emerging markets**
  - High
  - India, Brazil, Mexico, Turkey, Russia, China

- **United States**
  - Low
  - Free, stable pricing

- **Developed countries**
  - Low
  - Germany, France, Italy, UK

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**Pricing strategy**

1. **High access, High pricing flexibility**
   - Developed countries

2. **High access, Low pricing flexibility**
   - United States

3. **Low access, High pricing flexibility**
   - Emerging markets

4. **Low access, Low pricing flexibility**
   - Developing countries ex-US
Roche’s solution: 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”

AIFA - Payment by Results procedure

- Start of the new treatment in all eligible patients

NON-RESPONDERS
- 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

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

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

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

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

<table>
<thead>
<tr>
<th>Indication A</th>
<th>Price X</th>
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<tbody>
<tr>
<td>Indication B</td>
<td>Price Y</td>
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<tr>
<td>Indication C</td>
<td>Price Z</td>
</tr>
<tr>
<td>Other</td>
<td>Price X</td>
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(+) - Best reflects reality of current treatment paradigms, particularly in oncology

(-) - Requires drug-utilisation tracking substantial at patient level
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)

- Price X
- Price Y
- Price Z
- Potential Price

(+)
- 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
Positive outlook

**Strong pipeline mitigates biosimilar impact**

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<td>2023</td>
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**NME launches**

Venetoclax, Alectinib, Cotellic, Ocrelizumab, Atezolizumab, Lebrikizumab, ACE910, Lampalizumab

**Biosimilars**

MabThera, Herceptin, Avastin

**Conceptual**

**Pipeline**

**Marketed products**

**Sales**

Late-stage development program

Market opportunities through to 2017

NMEs

2015
- Herceptin + Perjeta
- Gazyva

2016
- alectinib
- atezolizumab
- lebrikizumab

2017
- ocrelizumab
- ACE910
- olesoxime
- Gazyva

Post 2017
- alectinib
- atezolizumab
- lebrikizumab
- Gazyva

line extensions

small (up to CHF 0.5bn)
medium (CHF 0.5 to CHF 1.0bn)
large (> CHF 1bn)