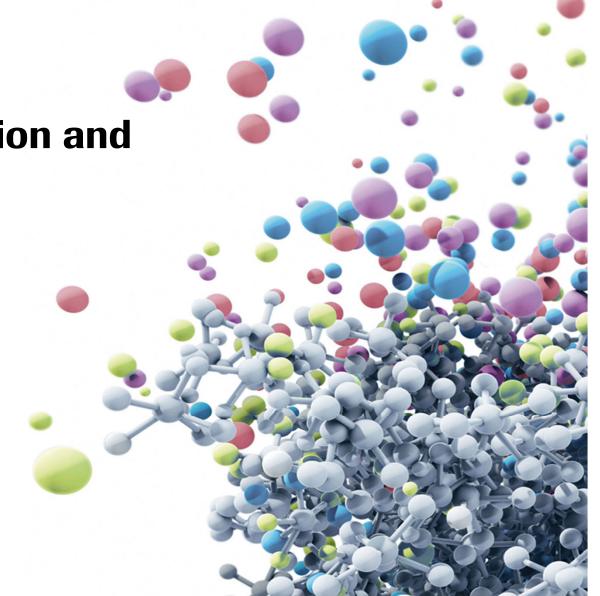


Committed to innovation and growth

Dr. Karl Mahler Head of Investor Relations

5th Annual Biosimilars Conference Sanford Bernstein December, 2012





This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

- 1 pricing and product initiatives of competitors;
- 2 legislative and regulatory developments and economic conditions;
- 3 delay or inability in obtaining regulatory approvals or bringing products to market;
- 4 fluctuations in currency exchange rates and general financial market conditions;
- 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
- 11 adverse publicity and news coverage.

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Our strategy

R&D and market dynamics

Changing the standard of care

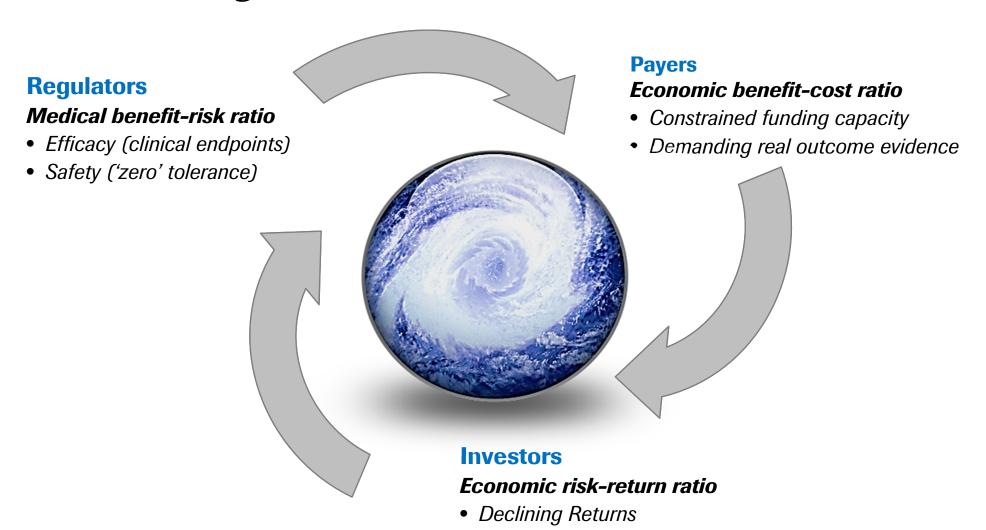
Expanding in Emerging markets

Summary





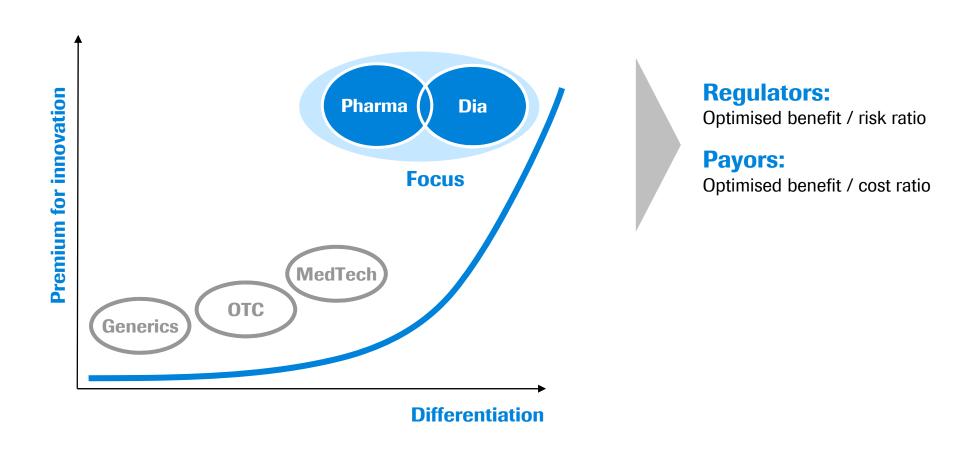
An increasingly challenging environment Where do we go from here?



• Declining Growth



Roche strategy: Focused on medically differentiated therapies





Our strategy

R&D and market dynamics

Changing the standard of care

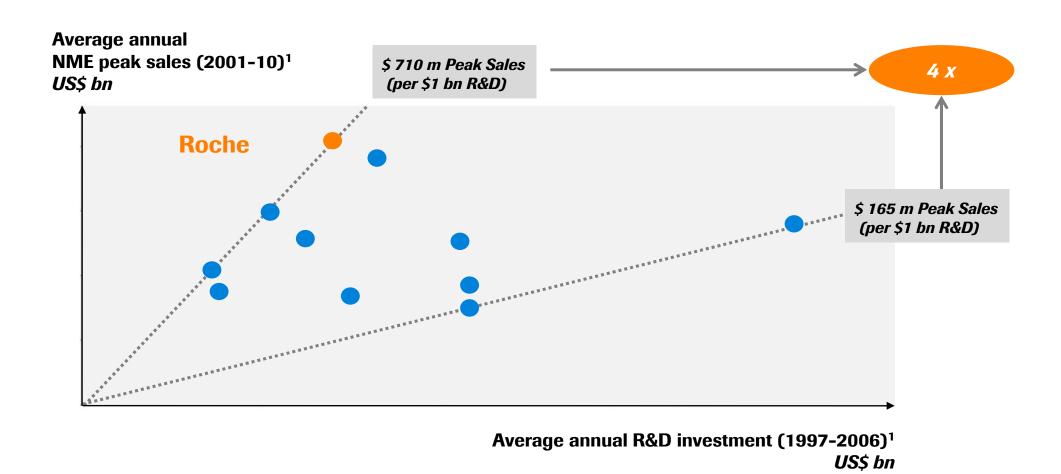
Expanding in Emerging markets

Summary

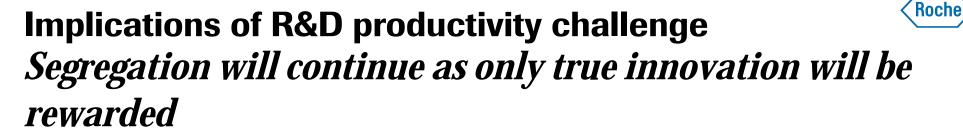


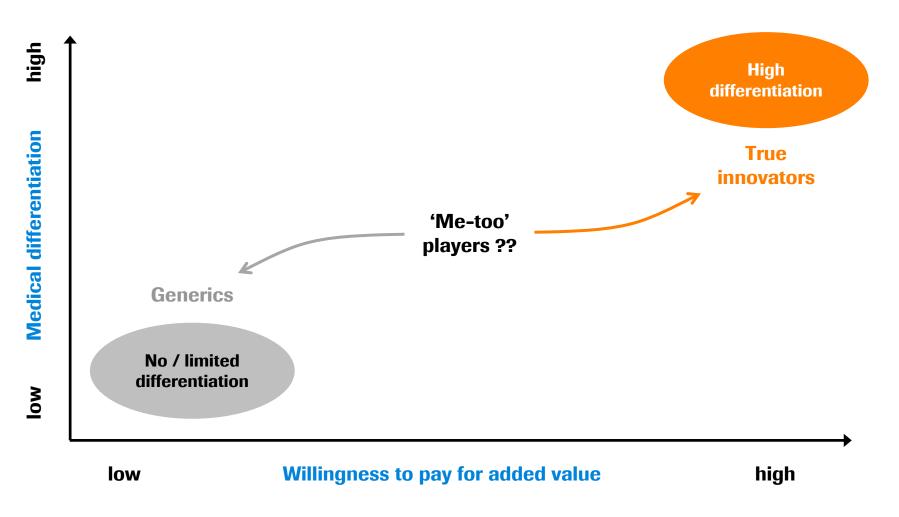
Roche

R&D productivity differs substantially among players



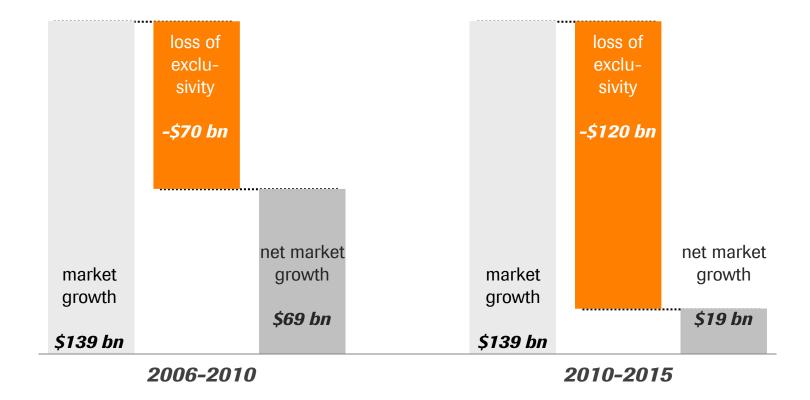
¹ Peak sales and R&D calculated pro forma to account for major M&A *Source:* EvaluatePharma; BCG analysis; Roche analysis







Upcoming patent expiries in developed markets improve affordability of innovative drugs





Our strategy

R&D and market dynamics

Changing the standard of care

Expanding in Emerging markets

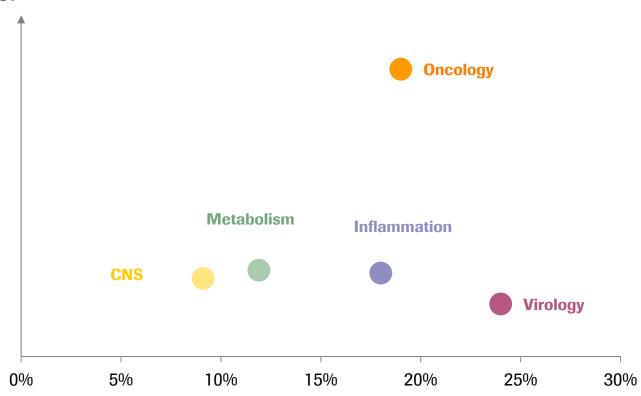
Summary





Roche: R&D well balanced from a risk & disease point of view

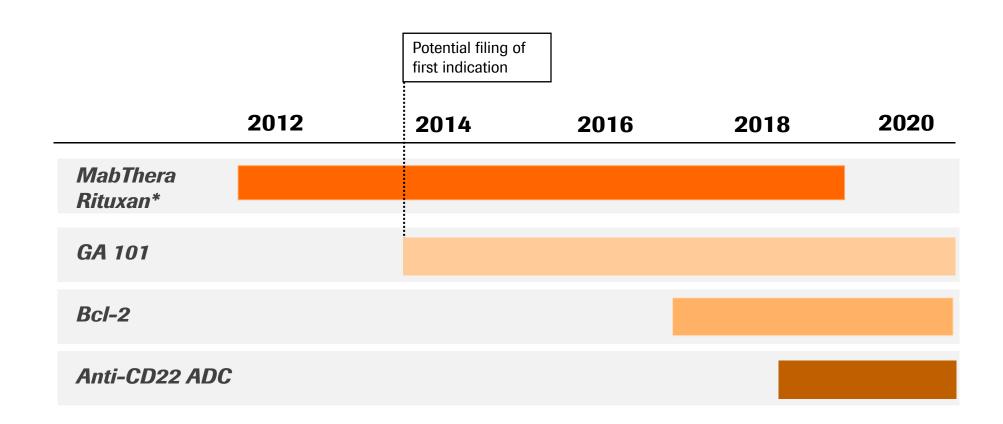




Industry average probability of success - Phase 0 to Registration



Hematological cancers Different mechanisms of action





Our strategy

R&D and market dynamics

Changing the standard of care

Expanding in Emerging markets

Summary





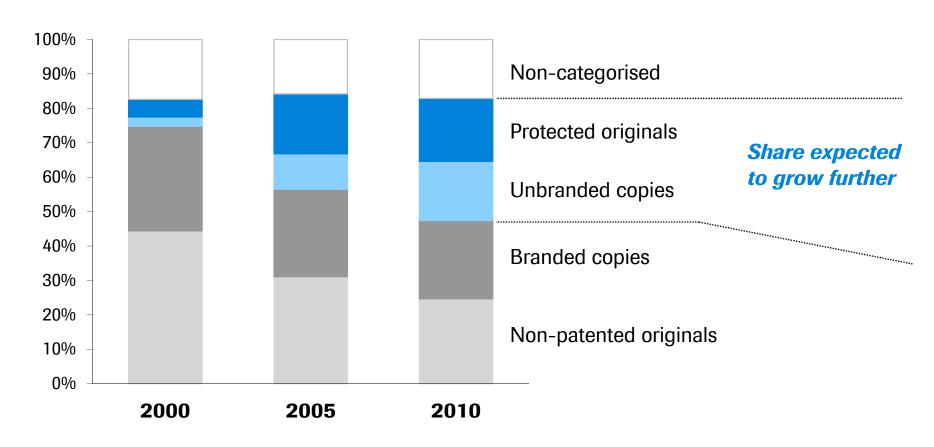
Roche growth in E7 countries is largely exceeding the market

| | | Current | 2011 <i>growth</i> | |
|----------|------------|-------------|---------------------------|------------|
| | | market rank | Roche | Market |
| Brazil | | 2 | 10 % | 5% |
| China | *} | 3 | 34 % | 16% |
| Russia | | 3 | 11% | 3% |
| Mexico | | 5 | 3 % | <i>5</i> % |
| Turkey | C× | 11 | -1% | 3% |
| S. Korea | | 16 | 17 % | 6% |
| India | (a) | 28 | 17 % | <i>12%</i> |



Increasing polarisation in emerging markets Growth in patented medicines and unbranded generics

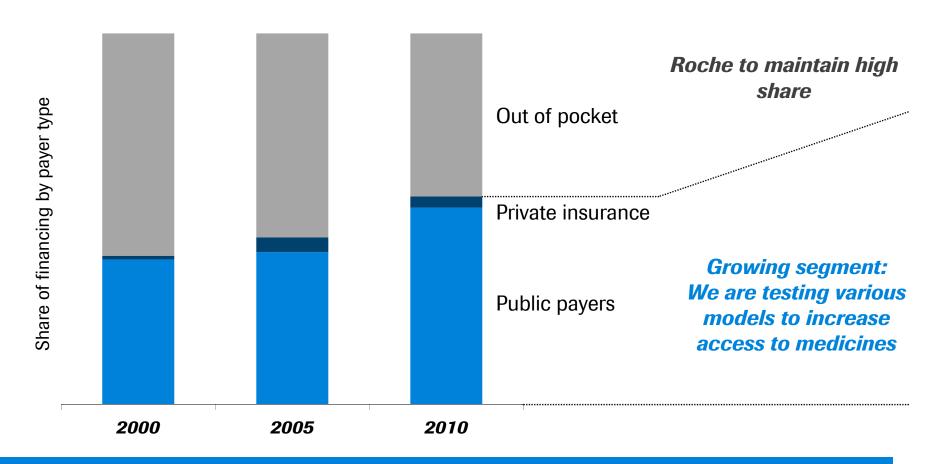
Example: Brazil market showing evidence of polarisation



Source: IMS

Growing segments in Emerging markets





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



Our strategy

R&D and market dynamics

Changing the standard of care

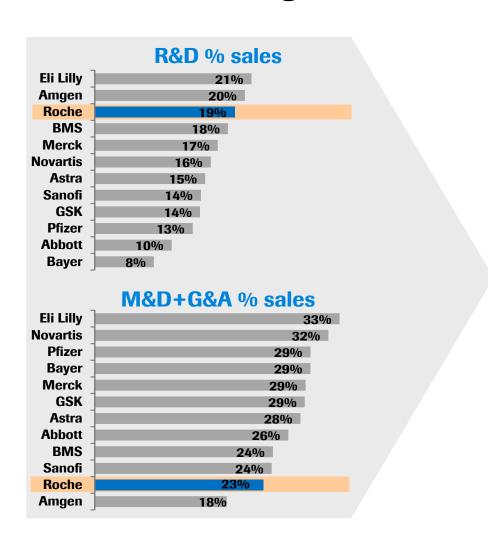
Expanding in Emerging markets

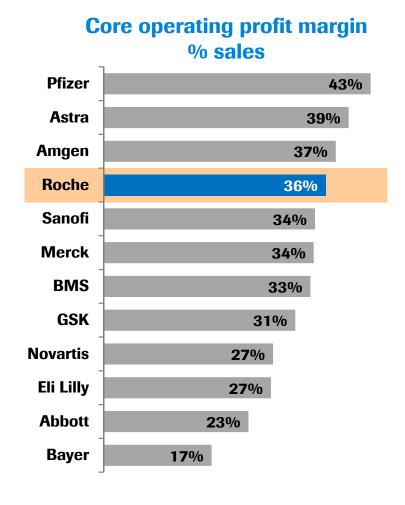
Summary





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





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 |
| CIF/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 |
| - | infectious diseases |
| GIP/GLP-1 dual a | ago type 2 diabetes |
| GABRA5 NAM | cogn. disorders |
| V1 receptor anta | g autism |
| BACE inh | Alzheimer's |
| ACE910 | hemophilia A |
| | |

Phase II (24 NMEs)

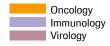
| EGFR MAb | solid tumors |
|--------------------|----------------------|
| PI3K inh | solid tumors |
| PI3K/mTOR inh | solid & hem tumors |
| EGFL7 MAb | solid tumors |
| CD22 ADC | heme tumors |
| CD79b ADC | heme tumors |
| HER3/EGFR | m. epithelial tumors |
| glypican-3 MAb | liver cancer |
| etrolizumab | ulcerative colitis |
| rontalizumab | SLE |
| pateclizumab (LT a | lpha Mab) RA |
| quilizumab (M1 pri | me Mab) asthma |
| mericitabine | HCV |
| danoprevir | HCV |
| setrobuvir | HCV |
| inclaumab (P selec | tin 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 | geograph. atrophy |
| | |

Phase III (8 NMEs)

| onartuzumab | (MetMAb) | solid tumors |
|------------------|-----------|-----------------|
| obinutuzumah | (GA101) | hem. tumors |
| lebrikizumab | | severe asthma |
| aleglitazar | CV risk r | eduction in T2D |
| tofogliflozin (S | GLT2) | type 2 diabetes |
| ocrelizumab | | MS |
| bitopertin | | schizophrenia |
| arbaclofen | fragile X | syndrome (FXS) |

Registration (3 NMEs)

| Perjeta (pertuzumab)* | HER2+ mBC 1L |
|-----------------------|--------------|
| Erivedge* | advanced BCC |
| T-DM1 | HER2+ mBC |







3



- Strategic focus on innovation and driving Personalised Healthcare
- Strong growth in Emerging Markets facilitated by innovative access models

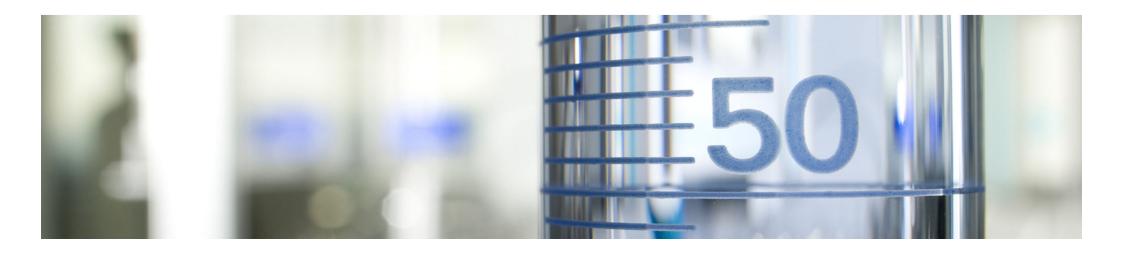
Leading product pipeline providing value for the future



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

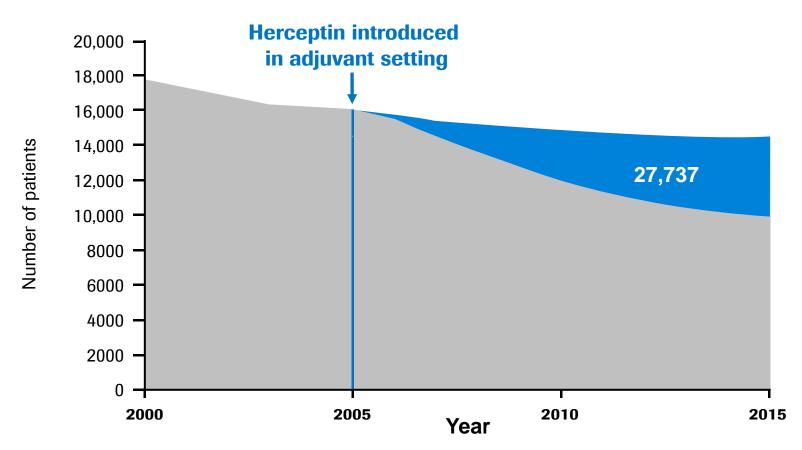
Act to expand patient access in emerging markets

Change from global pricing to tiered pricing, including 2nd brand

Herceptin



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



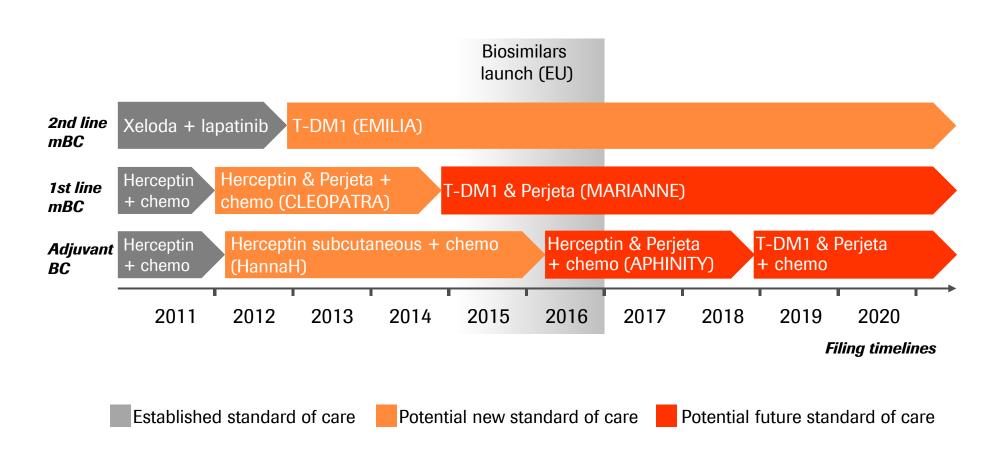
Number of women prevented from developing metastases

■ Incidence of HER2-positive MBC without Herceptin



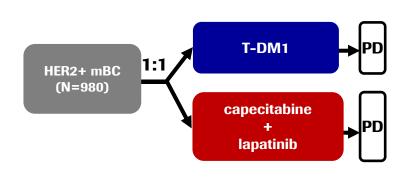
HER2 Franchise

Securing future growth by improving the standard of care

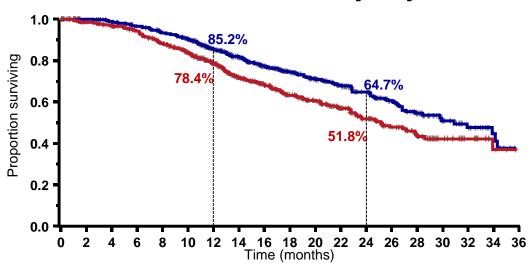




2nd line mBC: EMILIA study *T-DM1 in metastatic breast cancer*



Overall survival: confirmatory analysis



Quality of life: Patient reported outcomes Time to symptom progression

| | Median (mos) | N | |
|------------------------------|--------------|-----|--|
| Cap + Lap | 4.6 | 445 | |
| T-DM1 | 7.1 | 450 | |
| HR=0.80 (95% CI, 0.67, 0.95) | | | |
| <i>P</i> =0.0121 | | | |

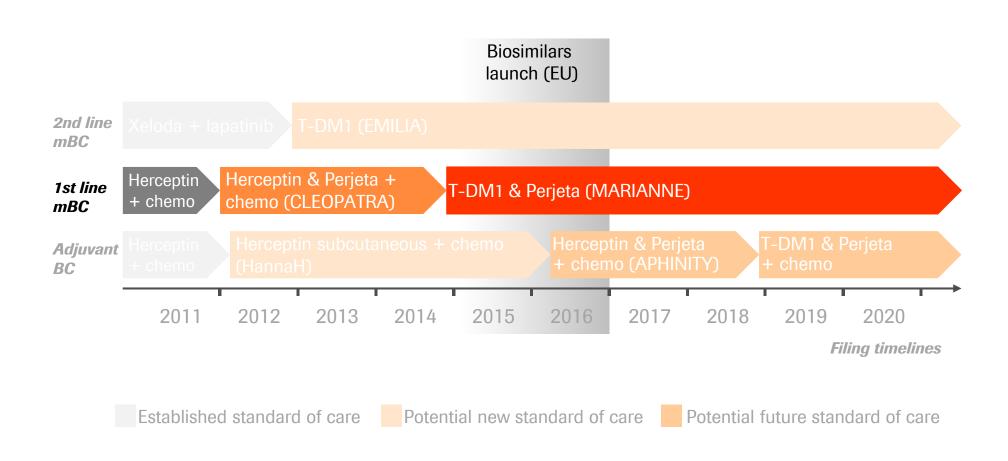
| | Median (mos) | No. events | |
|------------------------------------------|--------------|------------|--|
| Cap + Lap | 25.1 | 182 | |
| T-DM1 | 30.9 | 149 | |
| Stratified HR=0.682 (95% CI, 0.55, 0.85) | | | |
| <i>P</i> =0.0006 | | | |

Filed in US and EU, priority review granted by FDA



HER2 Franchise

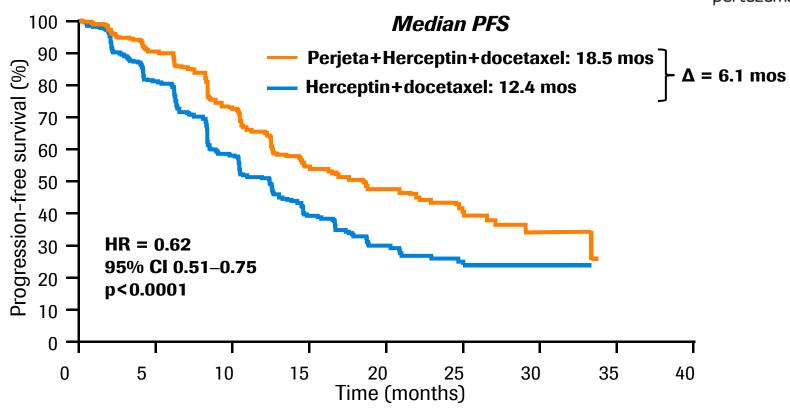
Securing future growth by improving the standard of care



1st line mBC: Herceptin & Perjeta *CLEOPATRA study*







Perjeta initial US market feedback





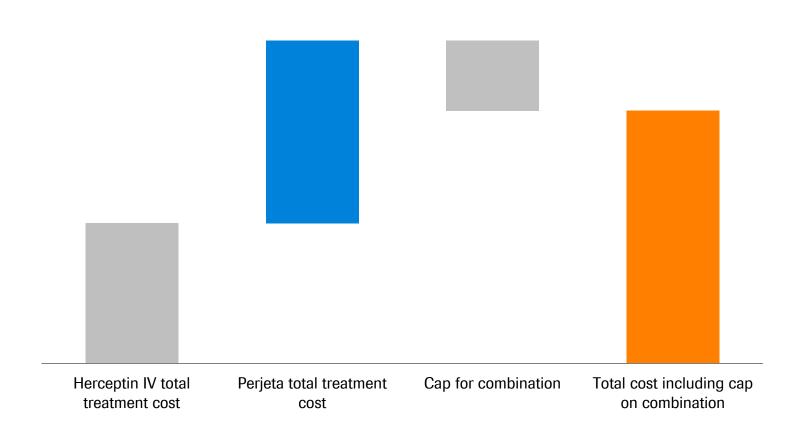
Market update

- 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



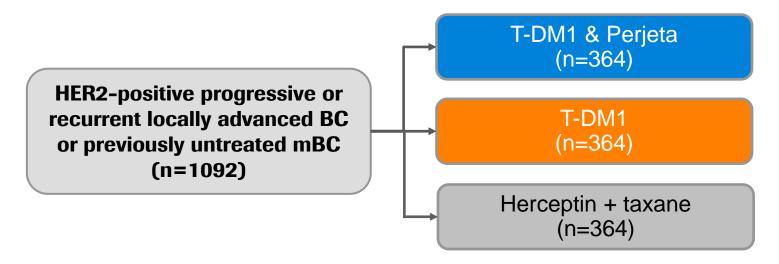
Innovation remains rewarded: Example of Perjeta

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*

year 1

docetaxel

6.1 months PFS

Herceptindocetaxel

12.4 months PFS



year 2

Herceptin & Perjeta

+ docetaxel

18.5 months PFS

T-DM1 & Perjeta

22 months PFS*

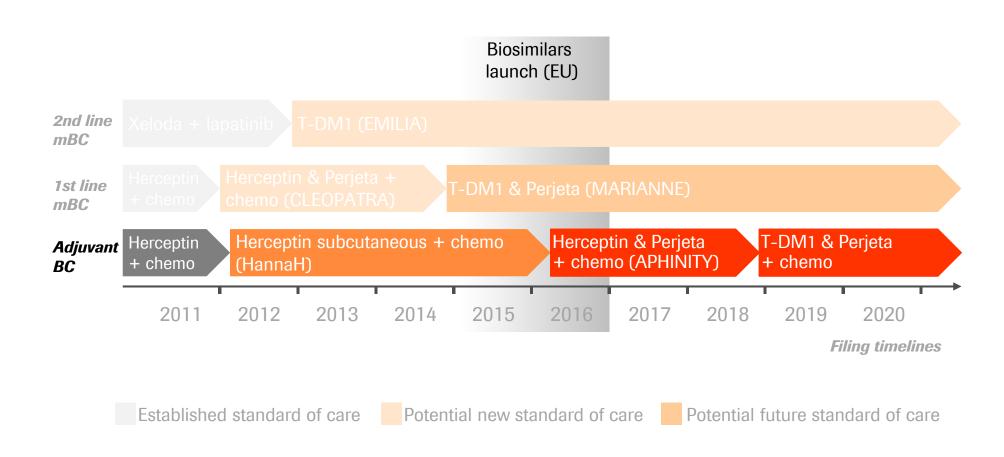


^{*} target profile



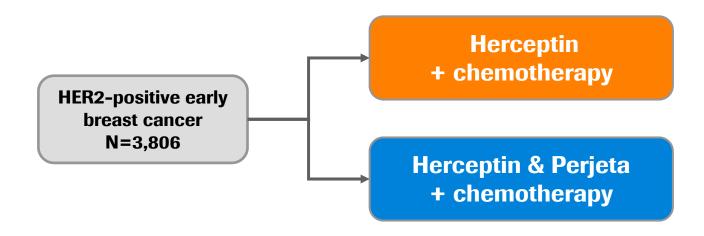
HER2 Franchise

Securing future growth by improving the standard of care





Herceptin & Perjeta in the adjuvant setting *APHINITY trial*



Primary end-point

3 year Disease Free Survival

- 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

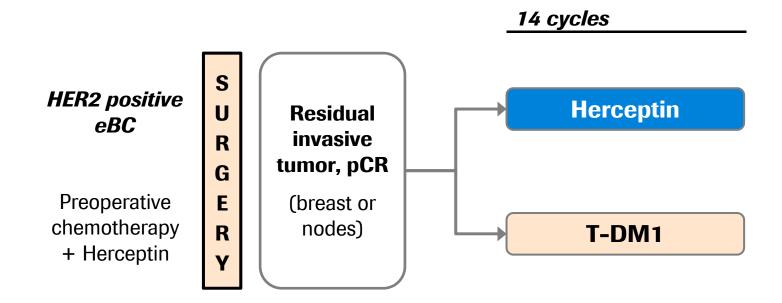
Utilizing pCR as surrogate end-point

Neoadjuvant study

T-DM1-based chemotherapy in neoadjuvant setting



Adjuvant treatment in patients with residual invasive tumor (non-pCR responders)



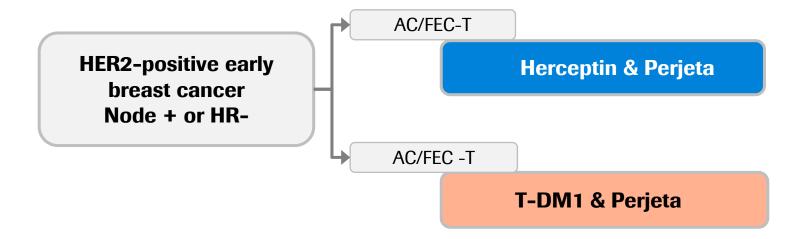
Primary Endpoint

• 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



Primary Endpoint

Disease Free Survival (DFS)

• FPI expected 2013

• Expect data: 2018



T-DM1 neo-adjuvant study Pathological Complete Response (pCR) as surrogate end-point

Primary 6 cycles **Endpoint** Up to 1 year Herceptin +docetaxel+carboplatin S Herceptin & Perjeta U +docetaxel+carboplatin R T-DM1 *pCR* Herceptin G +docetaxel E T-DM1 & Perjeta R +docetaxel T-DM1 & Perjeta

HER2 positive eBC

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



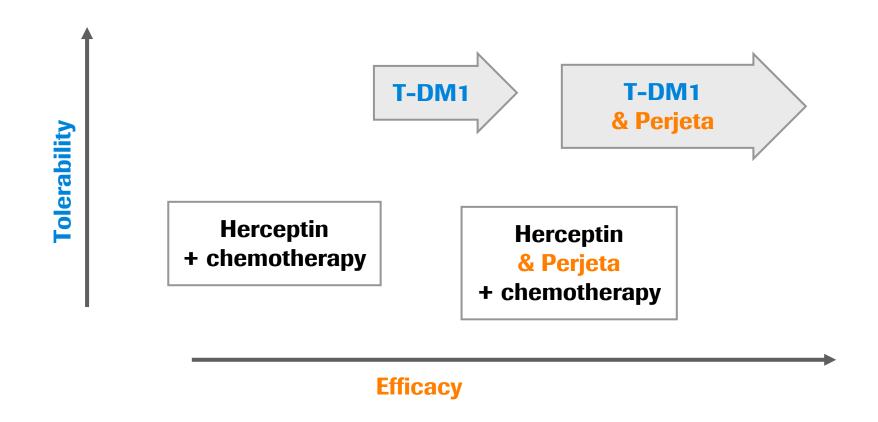
- EBC programme to be discussed with FDA early 2013
- CHMP Scientific Advice to be initiated shortly



- NOAH study approved in EU (Neoadjuvant/adjuvant indication)
- HannaH SC application ongoing (pCR co-primary endpoint)

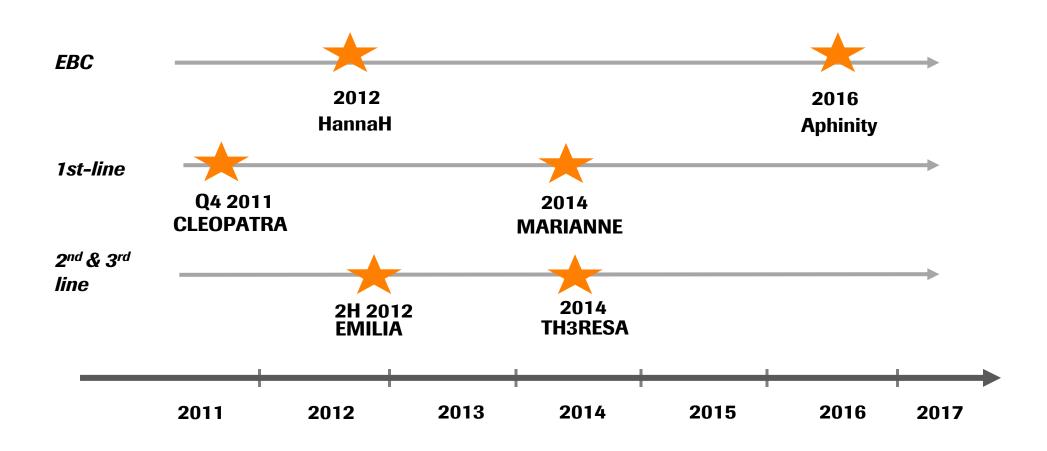


Redefining HER2 blockade Increasing the efficacy and tolerability





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





We Innovate Healthcare



Biosimilar Challenges 5th Annual Biosimilars Conference Fermin Ruiz de Erenchun M.D., Ph.D.





Market Overview

EMA biosimilars guideline

Our Strategy

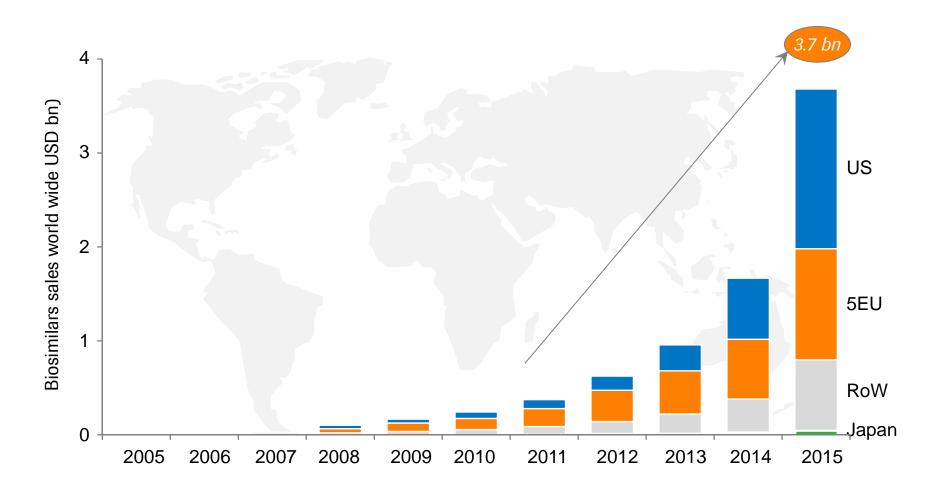
Innovate

Protect

Expand

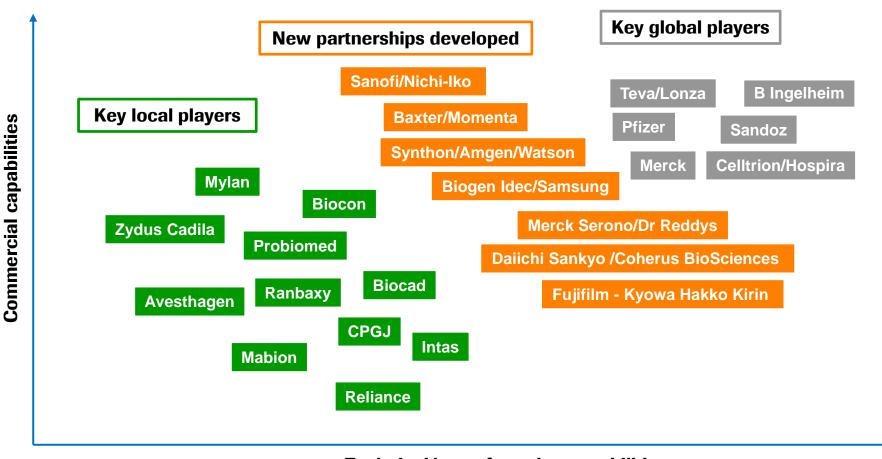


Biosimilars were expected to be a large market by 2015



Source: Datamonitor 45

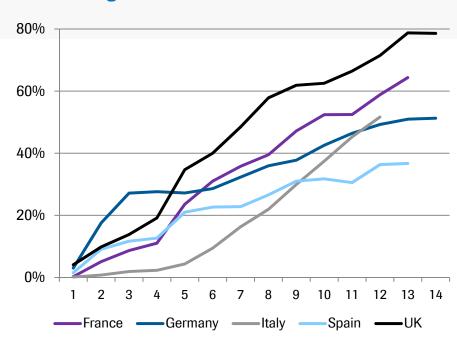
Wide and diverse range of biosimilar competitors Commercial opportunities for generics, CMOs & originators





Biosimilars uptake varies across countries and therapy areas

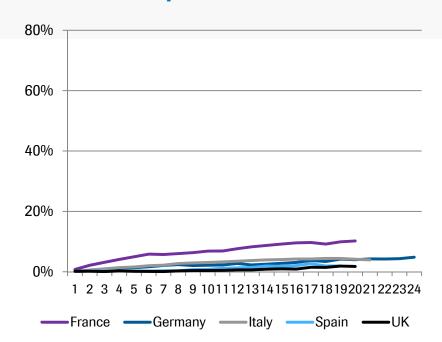
Filgrastim volume market share



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



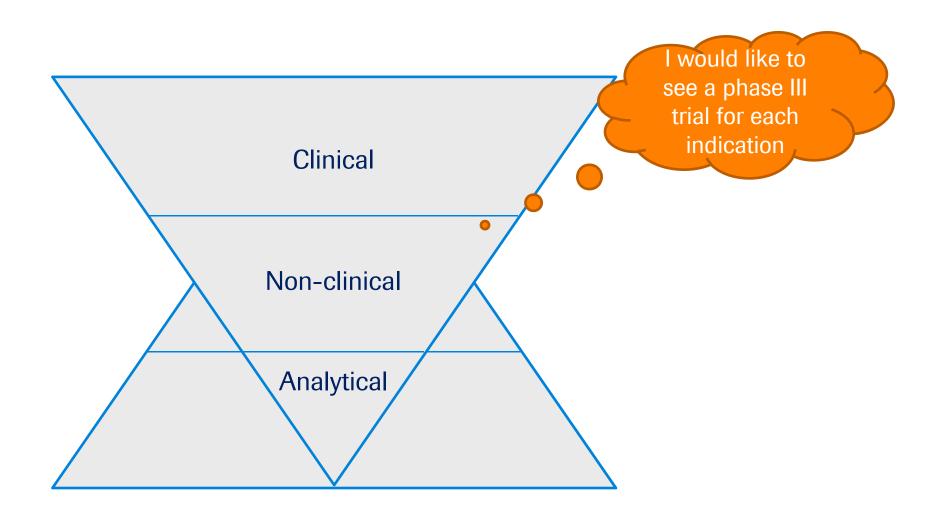
Requirements and study designs are different for the biosimilar vs. innovator

| Aspects of development | Biosimilar | Innovator | |
|------------------------|---------------------------------------------------------|----------------------------------------------------------------------------------------|--|
| Patient population | Sensitive and homogeneous (patients are <i>models</i>) | 3 | |
| Clinical design | Comparative versus innovator, normally equivalence | Superiority vs standard of care (SoC*) | |
| Study endpoints | Sensitive Clinically validated PD markers | Clinical outcomes data or accepted/established PD markers surrogates (e.g. OS and PFS) | |
| Safety | Similar safety profile to innovator; no new findings | Acceptable benefit/risk profile versus SoC* | |
| Immunogenicity | Similar immunogenicity profile to innovator | Acceptable risk/benefit profile versus SoC* | |
| Extrapolation | Possible if justified | Not allowed | |

^{*} In some cases SoC may not exist

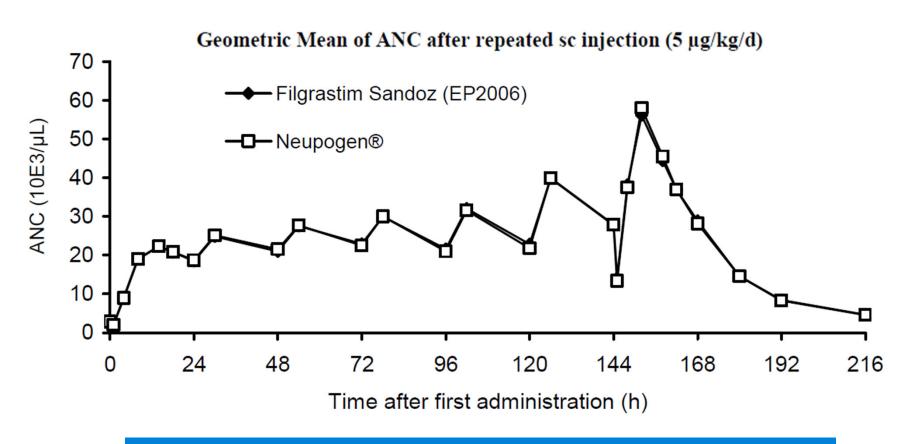


How should residual extrapolation risk be managed?





Phase III clinical trials will be required for biosimilar antibodies



PD markers only suitable for some products



What is the right patient population to establish clinical Roche similarity to Herceptin®?

| Topic | Metastatic population | Neoadjuvant/Adjuvant population | | | | |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|--|--|--|--|
| PK | Affected by patients status & tumour burden | ✓ Homogeneous population can be selected | | | | |
| PD | Clinically validated PD marker not available | | | | | |
| Clinical efficacy/safety | 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. | Populations less likely to be confounded by baseline characteristics and external factors | | | | |
| Immunogenicity | Immune system affected by performance status and concomitant chemotherapies received | ✓ Immune system impaired during chemotherapy cycles, but likely to recover to <i>normal</i> status thereafter | | | | |



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

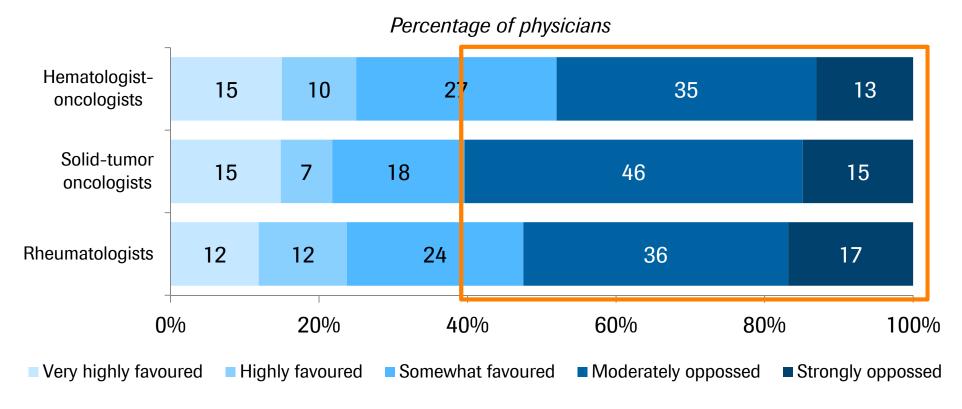
Automatic substitution not standard practice in the EU

- In the EU determined at country level
- Landscape unlikely to change:
 - New EU pharmacovigillance law addresses traceability of biologics
 - Draft EMA quality guideline acknowledge future product drifts between originator and biosimilar



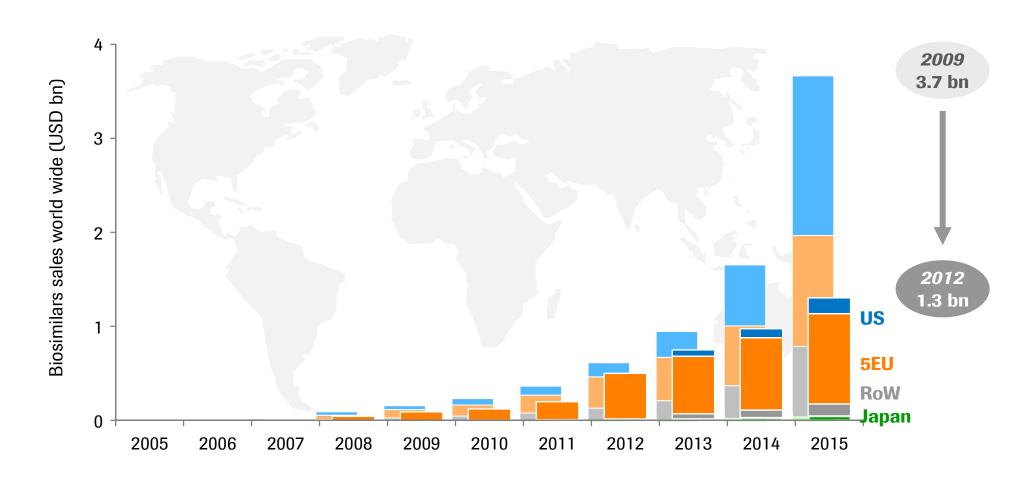
Physicians are wary of indication extrapolation

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?



Roche

Market uptake barriers are likely to limit biosimilars sales potential



54



Developing a biosimilar globally today seems to be a challenge: the rituximab example

| Company | Initiation of clinical trials | Current status | EMA requirements | US FDA requirements | Recent amendments/ future steps |
|-------------------------|-------------------------------|----------------|------------------|---------------------|---------------------------------------------------|
| Teva | Q1/2 2010 | Suspended | √ | X | Redesigning clinical trial/s |
| Sandoz | Q1 2011 | Ongoing | √ | ? | No changes in the current clinical trial strategy |
| Samsung | Q1 2012 | Suspended | √ | X | Redesigning clinical trial/s |
| Merck | Q1/2 2012 | Ongoing | √ | √ | Recently added US-sourced comparator arm |
| Pfizer | Q1/2 2012 | Ongoing | √ | √ | No changes in the current clinical trial strategy |
| Celltrion | Q3 2012 | Ongoing | √ | Х | No changes in the current clinical trial strategy |
| Boehringer Ingelheim | Q4 2012 | Ongoing | √ | √ | No changes in the current clinical trial strategy |



Market Overview

EMA biosimilars guideline

Our Strategy

Innovate

Protect

Expand

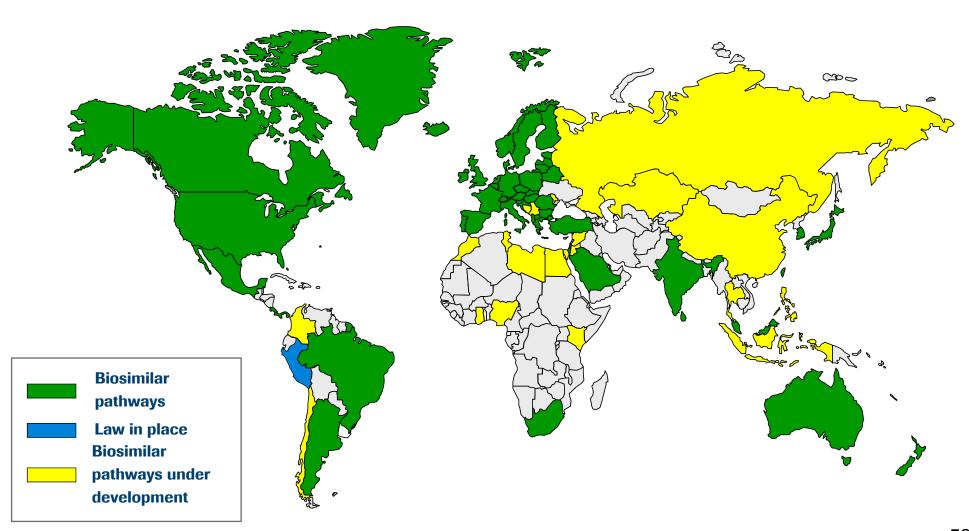


How advanced were biosimilar regulatory pathways before 2010?



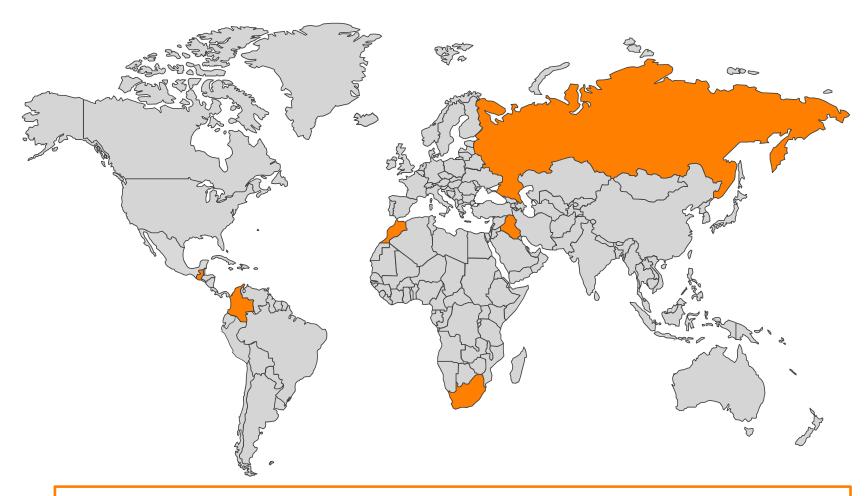
...and where are we today?







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 biosimilars guideline

Our Strategy

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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