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# Roche Pharma Day 2019

## *Pharma Strategy*

**Bill Anderson** | CEO Roche Pharmaceuticals

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## **Roche has a strong track record of innovation and growth**

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**Our environment is changing and so have we**

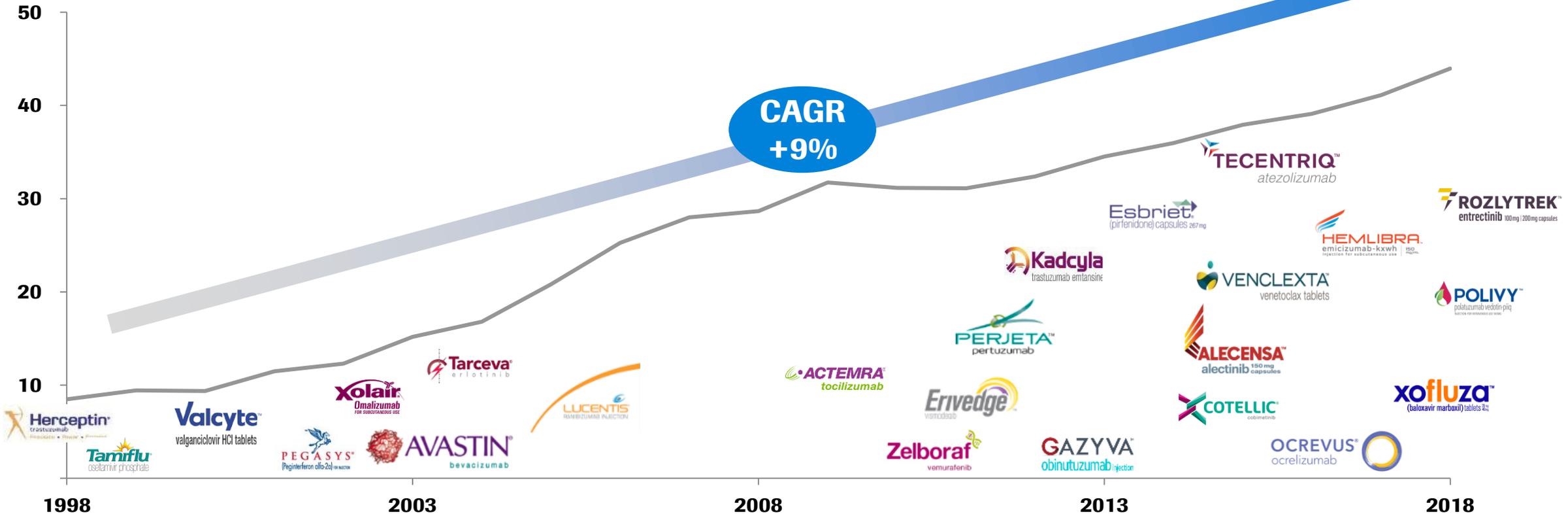
**Making a difference for patients**

**Summary**

# Roche has a strong track record of innovation

## *Industry leading medicines as basis for our continuous growth*

Pharma Division  
Sales CHFbn



Sales excluding OTC at 2018 average exchange rates; Approved medicines shown do not represent the entire portfolio rather a selection, timeline reflects year of approval

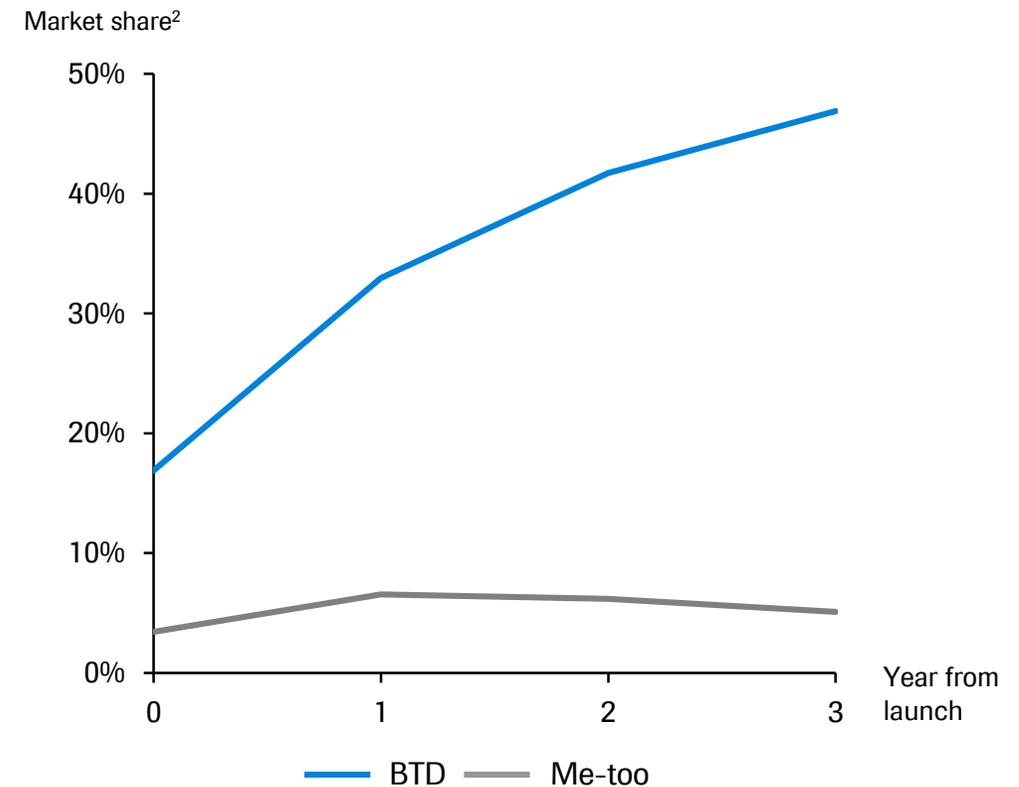
# 26 Breakthrough Therapy Designations

## Reflecting the quality of our research

### Breakthrough Therapy Designations (BTD)

Year	Molecule	Indication
2019	Venclexta + Gazyva	1L unfit CLL
	Kadcyla	Adjuvant HER2+ BC
	satralizumab	NMOSD
2018	Xolair	Food allergies
	Tecentriq + Avastin	HCC
	Hemlibra	Hemophilia A non-inhibitors
	entrectinib	NTRK+ solid tumors
	balovaptan	Autism spectrum disorders
	polatuzumab vedotin + BR	R/R DLBCL
2017	Venclexta + LDAC	1L unfit AML
	Zelboraf	BRAF-mutated ECD
	Rituxan	Pemphigus vulgaris
	Actemra	Giant cell arteritis
2016	Alecensa	1L ALK+ NSCLC
	Ocrevus	PPMS
	Venclexta + HMA	1L unfit AML
	Venclexta + Rituxan	R/R CLL
	Actemra	Systemic sclerosis
2015	Tecentriq	NSCLC
	Venclexta	R/R CLL 17p del
	Hemlibra	Hemophilia A inhibitors
	Esbriet	IPF
2014	Lucentis	Diabetic retinopathy
	Tecentriq	Bladder
2013	Alecensa	2L ALK+ NSCLC
	Gazyva	1L CLL

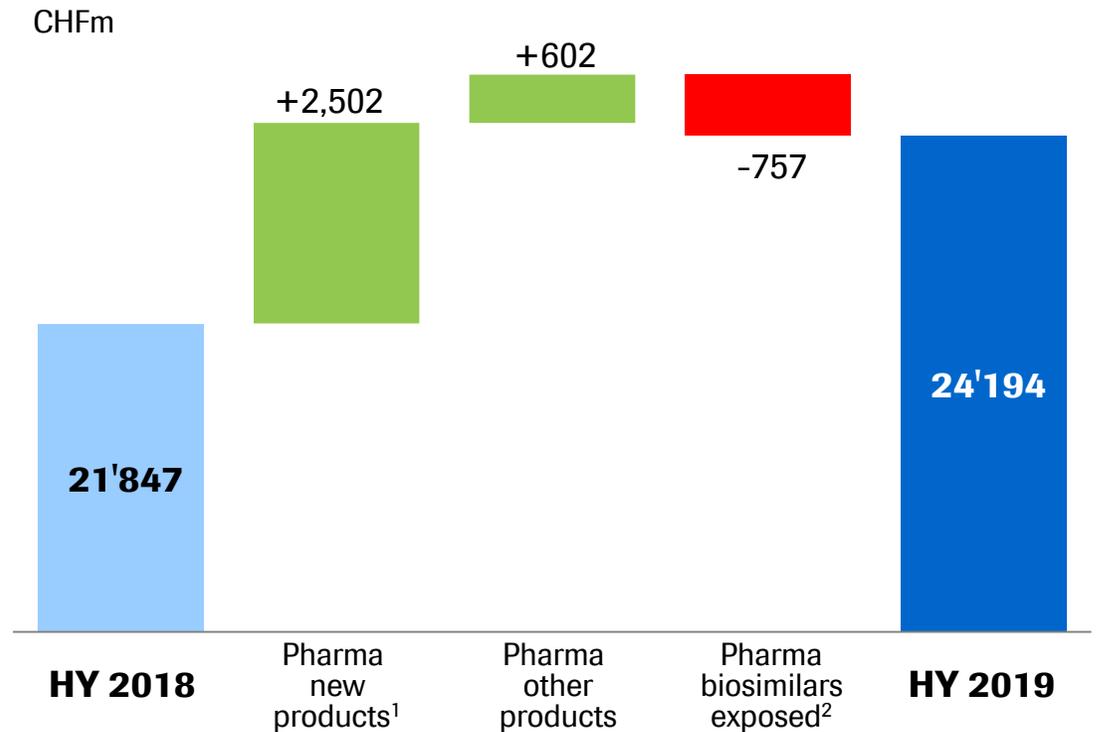
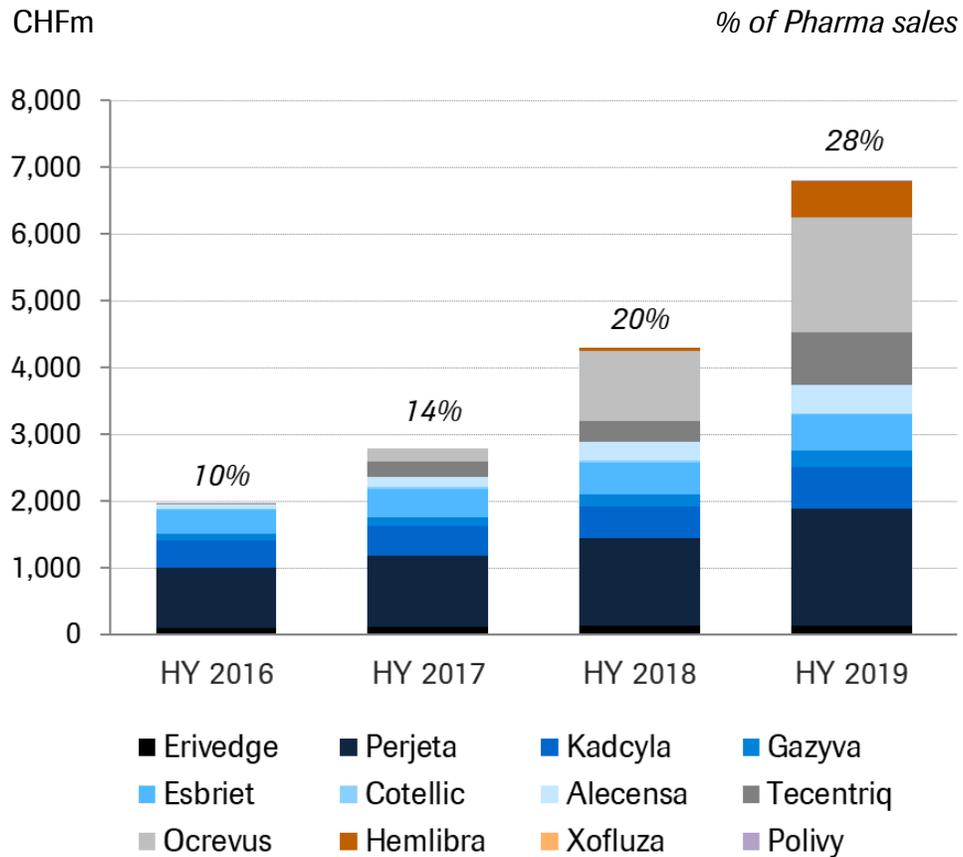
### Product launch up-take in oncology<sup>1</sup>



<sup>1</sup> Selected oncology products launched over 2013-2016; <sup>2</sup> Market shares represent sales of target product relative to sales competing products in similar indications; Data source: Evaluate Pharma, Decision Resources, Prismaccess

# Innovation driving portfolio rejuvenation

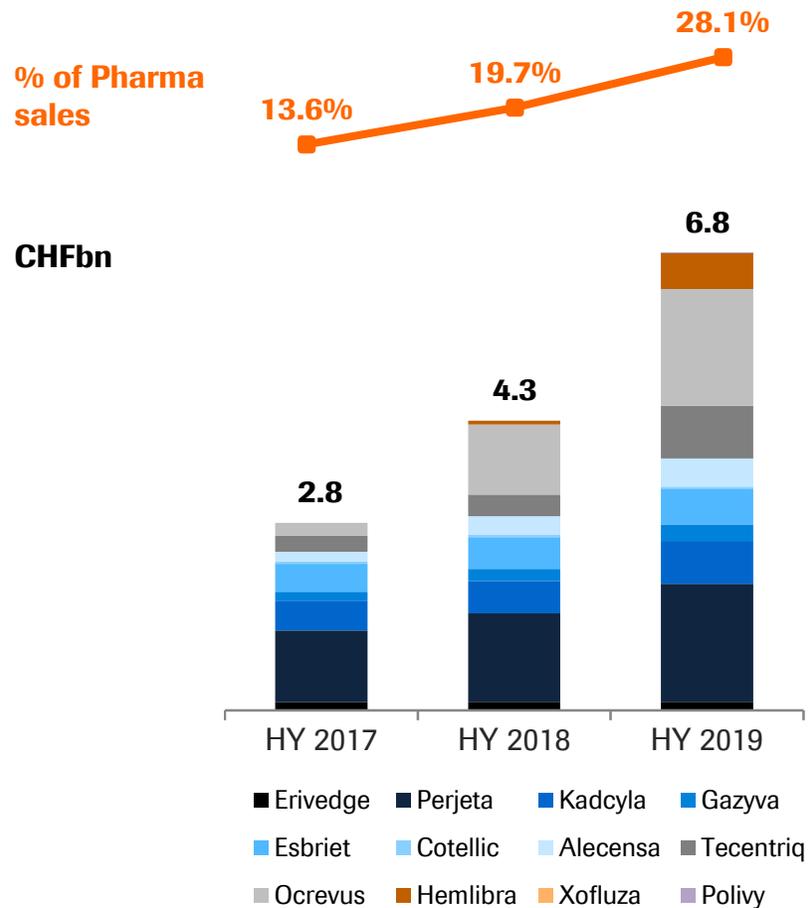
## *Increasing share of sales coming from recent launches*



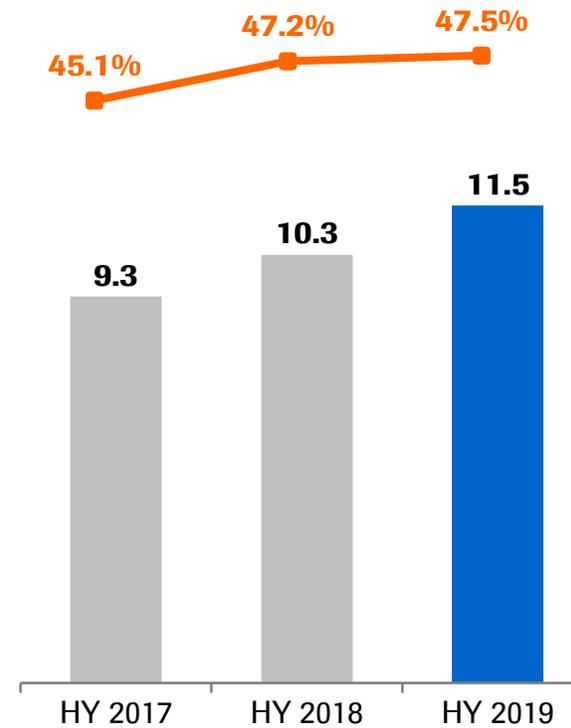
All absolute values are presented in CHFm reported; <sup>1</sup> Erivedge, Perjeta, Kadcylla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, and Polivy; <sup>2</sup> MabThera and Herceptin in Europe and Japan

# Successfully managing the transition

## New products contribution



## Core operating profit Pharma

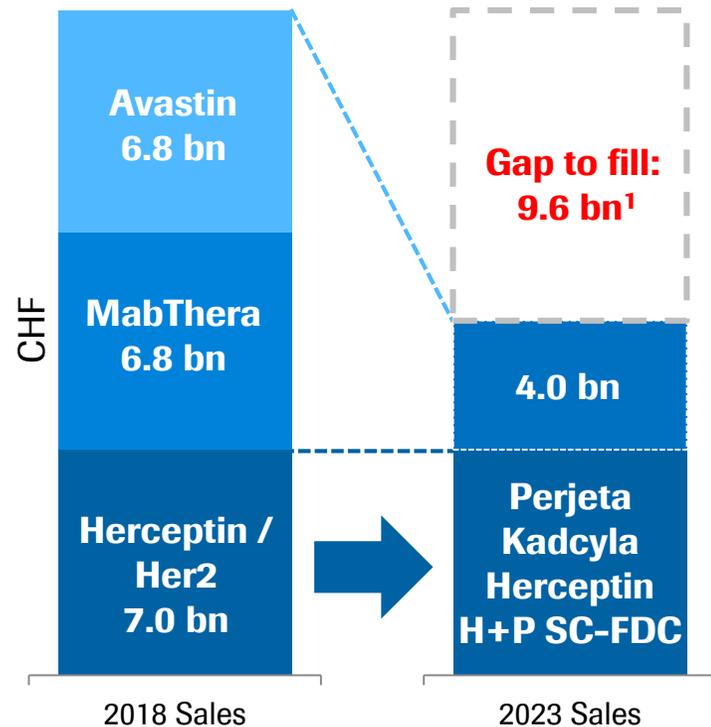


# New product growth with strong momentum

## Considerable optionality

### Biosimilar gap (18-23)

**Sensitivity analysis:** Assuming *conservative* planning assumptions of 60-70% erosion from biosimilars



### Consensus sales growth (18-23)

Post-HY 2019 consensus survey

Ocrevus	3.8 bn
Tecentriq	3.5 bn
Hemlibra	3.5 bn
Gazyva	0.8 bn
Alecensa	0.9 bn
Xofluza	0.5 bn
Polivy	0.9 bn
Rozlytrek	0.4 bn
In-market & mature <sup>2</sup>	(0.9) bn
Pipeline value <sup>3</sup>	2.9 bn

**Total 16.3 bn**

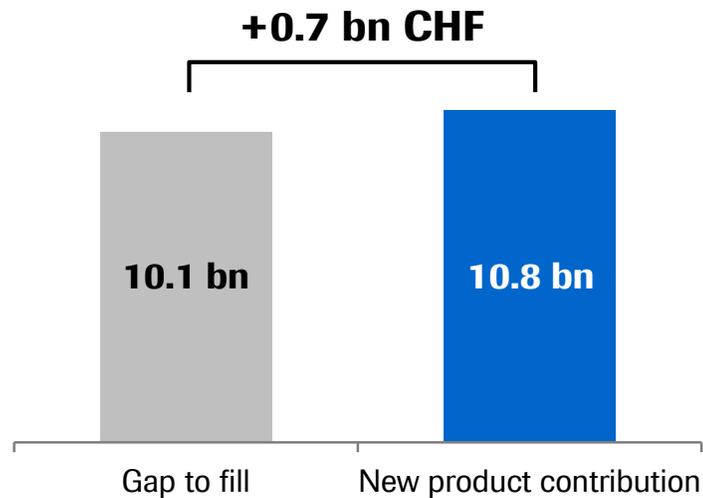
**Up-side potential to consensus above are:**  
**Oncology** (Venclexta, mosunetuzumab/ CD20xCD3, PI3Kα, SERD) **Autism** (balovaptan), **Alzheimer's** (gantenerumab),  
**Ophthalmology** (port delivery system), **Immunology** (Gazyva in lupus), **Infectious diseases** (chronic hepatitis B)

<sup>1</sup> Gap value including the total HER2 franchise change from 2017 to 2023, assuming Lucentis will be replaced by faricimab; <sup>2</sup> Esbriet, Tarceva, Xolair, Pulmozyme, Rocephin, CellCept, Mircera, NeoRecormon/Epogin, Activase/TNKase, Xeloda, Valcyte/Cymevene, Actemra/RoActemra, Tamiflu, Madopar, Pegasys; <sup>3</sup> satralizumab, etrolizumab, idasanutlin, ipatasertib, risdiplam, HTT-ASO

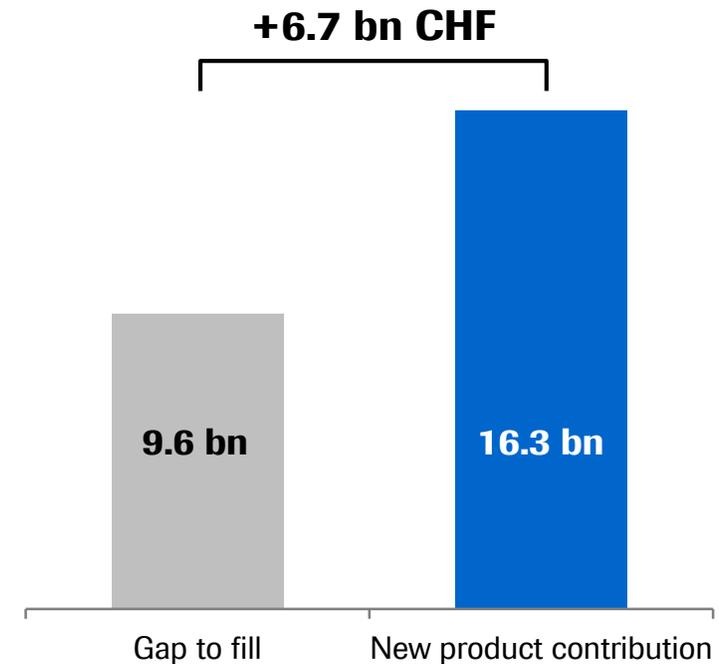
# What has changed since our Pharma day a year ago?

## *Further increased confidence in delivering growth*

2017-2022 consensus view<sup>1</sup>



2018-2023 consensus view<sup>2</sup>



**Strong new product contribution & ongoing launches driving growth**

<sup>1</sup> Roche Post-HY 2018 consensus survey; <sup>2</sup> Roche Post-HY 2019 consensus survey

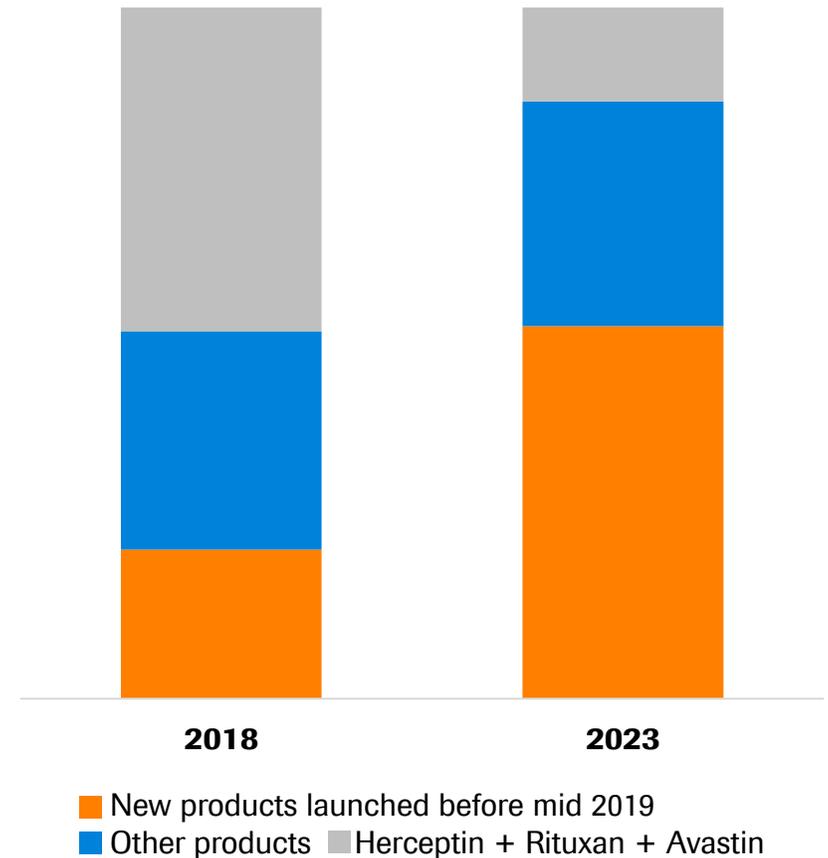
# Roche transitioning: Replace and extend the business

## Replace/extend existing businesses

## Entering new franchises

MabThera/Rituxan	Gazyva, Venclexta, Polivy, mosunetuzumab, CD20 x CD3, idasanutlin	<b>MS:</b> Ocrevus
Herceptin	Perjeta, Kadcyta, Herceptin + Perjeta FDC-SC	<b>Hemophilia A:</b> Hemlibra
Avastin	Tecentriq, Alecensa, Rozlytrek, ipatasertib	<b>CNS:</b> NMOSD, SMA, Huntington's, Autism, Alzheimer's
Lucentis	faricimab Port delivery system (PDS)	
Tamiflu	Xofluza	

## Sales mix (100%) (Conceptual)



# Strong commercial potential throughout late stage portfolio

**+17** late-stage assets  
with large sales potential

Polivy	✓
Rozlytrek	✓
Venclexta*	✓
Xofluza	✓
risdiplam	filing 2019
satralizumab	filing 2019

balovaptan
HTT-ASO
gantenerumab
idasanutlin
PI3K $\alpha$ (RG6114)
ipatasertib
bi-specifics
Gazyva
etrolizumab
PDS w/ ranibizumab
faricimab

**14** blockbusters

Hemlibra
Tecentriq
Alecensa
Kadcyla

**10** blockbusters

Ocrevus	Esbriet
MabThera	Actemra
Herceptin	Lucentis
Avastin	Xolair
Perjeta	Activase

**2018**

Ocrevus	Esbriet
MabThera	Actemra
Herceptin	Lucentis
Avastin	Xolair
Perjeta	Activase

**2020 consensus**

Neuroscience
  Immunology
  Ophthalmology  
 Oncology
  Infectious Disease
 ✓ launched

\* Venclexta sales are booked by partner AbbVie

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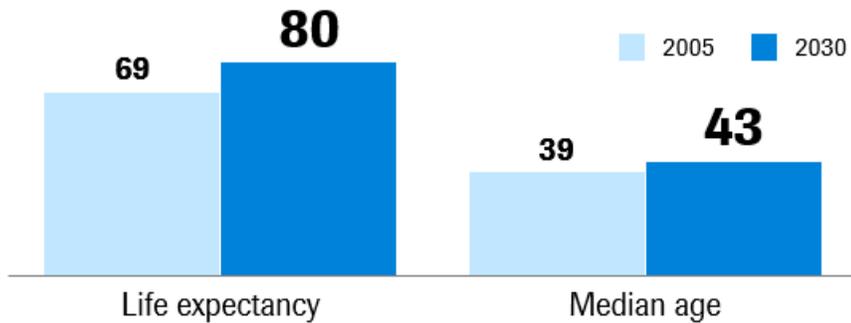
**Making a difference for patients**

**Summary**

# Macro disruptions - trends impacting our business environment

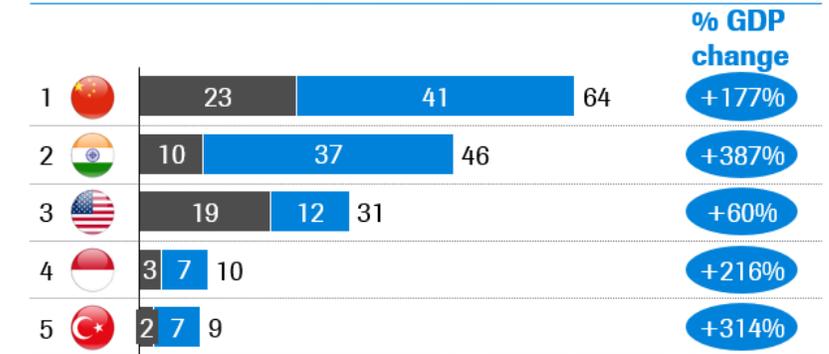
## Society: Aging population<sup>1</sup>

Life Expectancy and Median age over time, years, in 2005 and 2030



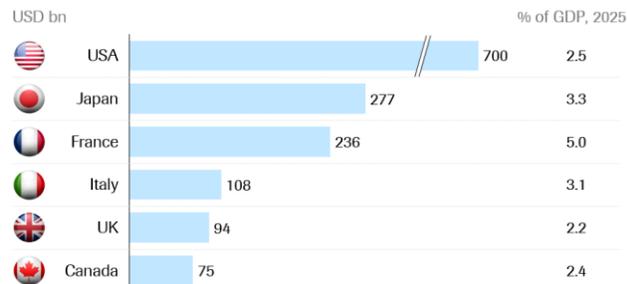
## Economy: Center moving East<sup>2</sup>

Projected GDP of top world economies in 2030 (PPP) vs. their GDP in 2017 (PPP), USD tn



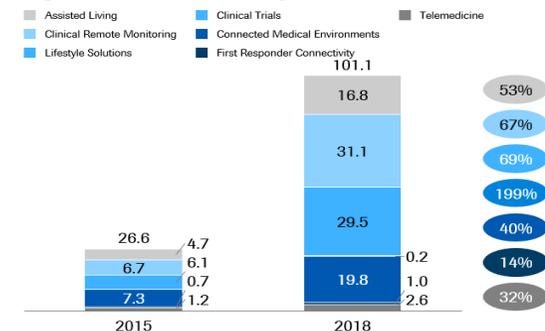
## Affordability: Gap of funding in healthcare increasing<sup>3</sup>

Projected gap between public health expenditure and government budgets<sup>1</sup>



## Digital Health: Increasingly visible and driving innovation<sup>4</sup>

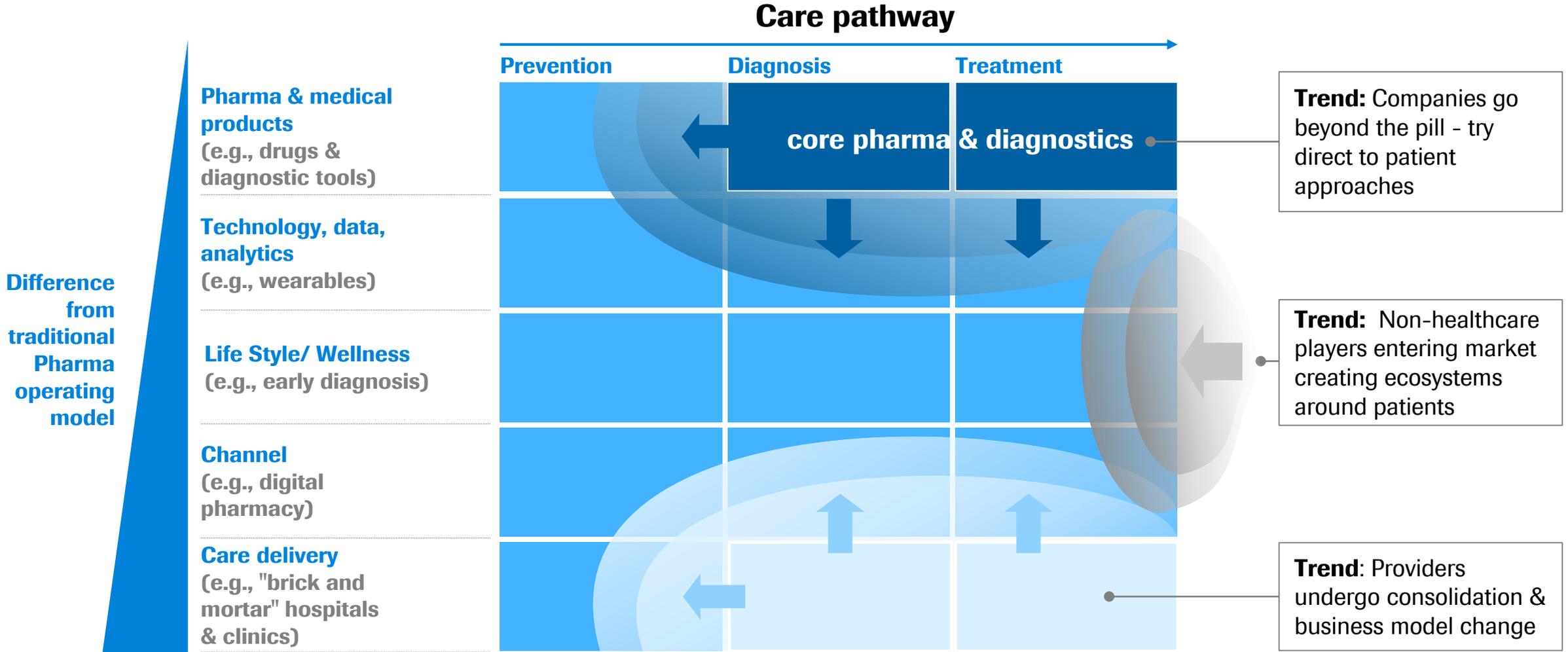
Digital Health Internet of Things Market, USD bn



<sup>1</sup> Global Institute, World Bank; <sup>2</sup> World Bank, 2017, IMF (2017 data), Standard Chartered (2030 projected data), Oxford Economics, Brookings; <sup>3</sup> If expenditure continues at current pace - McKinsey; <sup>4</sup> Machina analysis

# Industry disruptions – trends impacting our Core business dynamics

## Care pathway and delivery



# Digitalisation transforming Roche's entire Pharma value chain



**Breakout session**



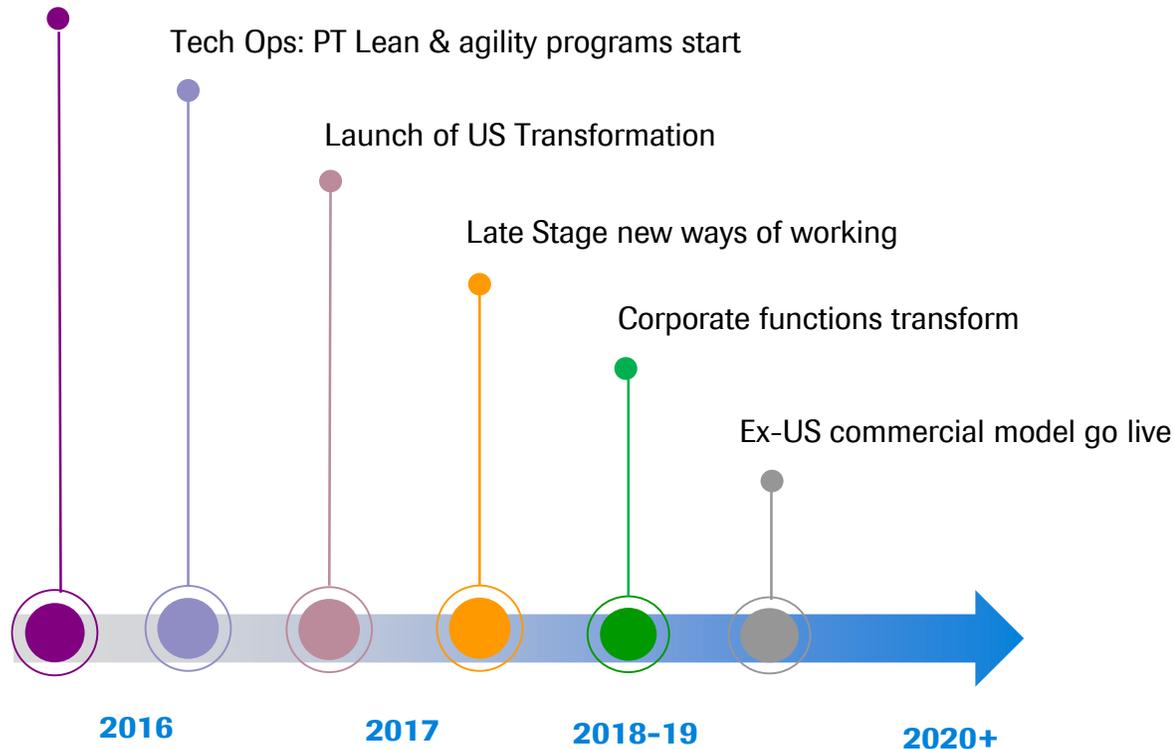
	Pre-clinic	Clinical development	Registration	Access	Production & Supply	Diagnosis	Treatment
Meaningful data at scale (MDAS)	🗄️	🗄️	🗄️	🗄️	🗄️	🗄️	🗄️
Genomics		🗄️				🗄️	
Real world data (RWD)		🗄️	🗄️	🗄️		🗄️	🗄️
Digital biomarkers		🗄️				🗄️	🗄️
Artificial Intelligence (AI)	🗄️	🗄️			🗄️	🗄️	🗄️



 **Data with impact on current business**

# Our cultural transformation: Simplify processes and empower our people to enhance productivity in service of patients

Executive Committee focus on agile: start of major changes to increase flexibility and dynamism



## Some of our guiding principles:

- From silos, functional and top down focus to small empowered teams with accountability for results
- From internal / org chart orientation to patient and external focus
- From leadership as command & control to setting a vision, architecting the system, coaching and catalysing change

# Adjusting to the new environment: Cross-organizational transformation to improve productivity and patient experience

## Product development

## Commercial

### Structure

Upgraded **Life Cycle Leader** role – smaller, fit for purpose teams

**Radical simplification of structures by eliminating the middlemen:** implement “communities of practise” working virtually across the organisation

### Processes

**80% of portfolio decisions delegated** to life cycle teams, all bureaucratic hurdles (external to teams) eliminated\*

**Eliminated budgets** and replaced them with defined actions & accountability

### Behaviours

#### Recognising our people for:

- Achieving medical progress
- Improving patient access
- Thinking entrepreneurial: Act, think and feel like a business owner

\* Formerly with Life Cycle Portfolio Committee

# Adjusting to the new environment

*Making a greater impact - increasing financial flexibility*

## Pharma Development (HY19 vs. HY16)

**NMEs at pivotal stage  
+50%**

**PD spend +12% and  
headcount +4%**

## Pharma Technical (HY19 vs. HY16)

**Volume growth  
+38%**

**Direct spend -3% and  
headcount -18%**

## Pharma US (HY19 vs. HY16)

**Sales growth  
+40%**

**OPEX +6% and  
headcount -6%**

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**Making a difference for patients**

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**Summary**

# Oncology: We focus on leadership across established core areas, while still investing in differentiated growth opportunities



## Lead in Hematology

**NHL:** Rituxan, Gazyva, Venclexta, Polivy, mosunetuzumab, CD20xCD3

**CLL:** Venclexta, Gazyva

**AML:** Venclexta, idasanutlin

**MM:** Venclexta

**Hemophilia A:** Hemlibra

High medical need in later lines, aNHL and AML



## Lead in Breast Cancer

**HER2+ BC:** Herceptin, Perjeta, Kadcyra, H+P FDC SC

**TNBC:** Tecentriq, ipatasertib

**HR+ BC:** ipatasertib, PI3Ka inhibitor (RG6114); SERD (RG6171)

> 80% patients in adjuvant



## Growth in Lung

**ALK+/ROS1+/NTRK+:** Alectinib, Rozlytrek

**SCLC:** Tecentriq

**NSCLC:** Tecentriq, Avastin

>70% still metastatic

## Establish presence (with Tecentriq and combos)

**mUC:** Expand in 1L; Move into adjuvant

**HCC:** Potential new SOC

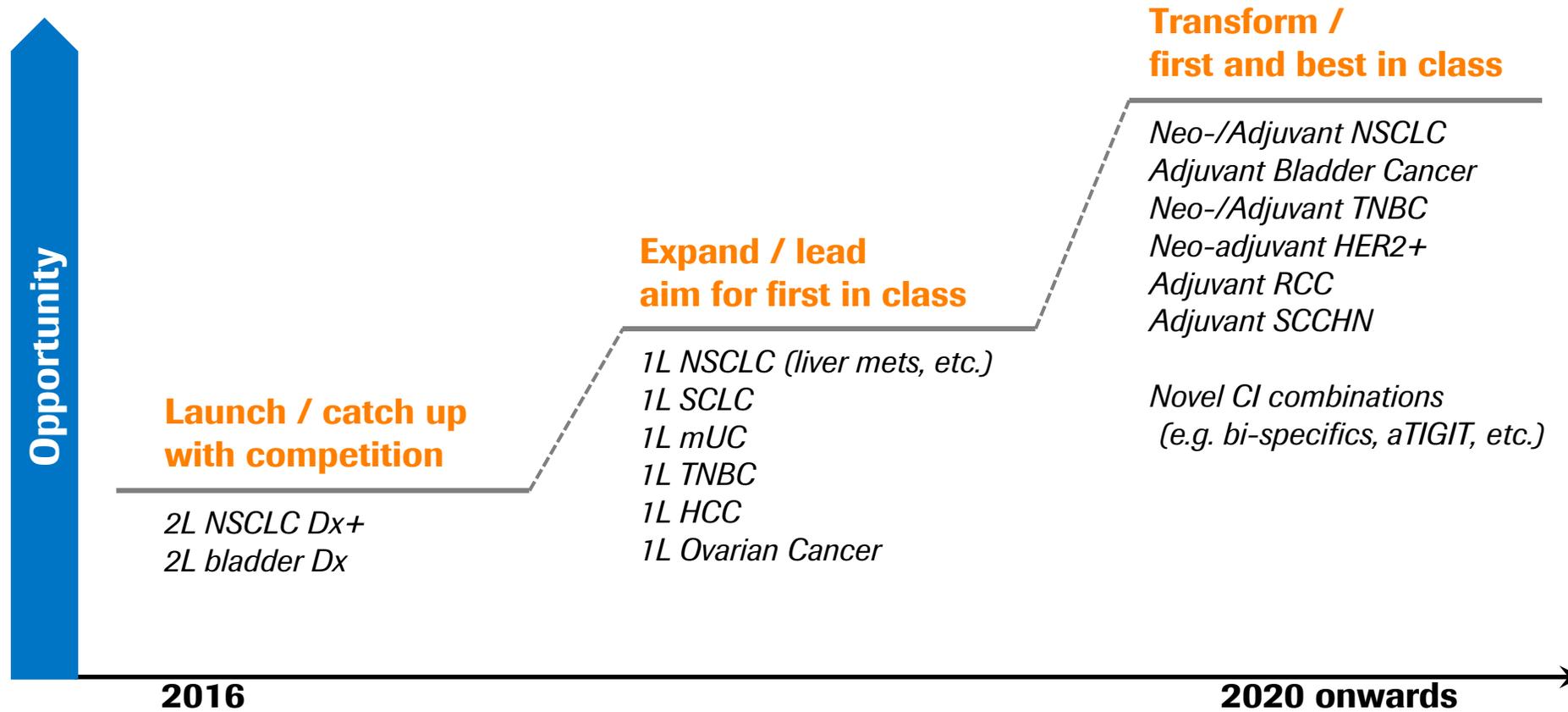
**CRPC:** Potential new SOC

**OC:** Potential new SOC

**RCC and CRC:** Explore opportunities

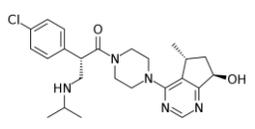
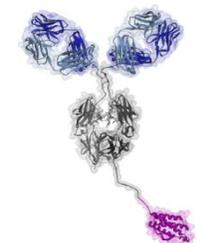
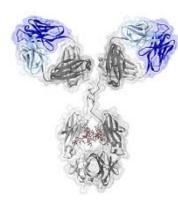
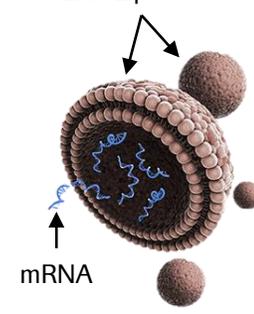
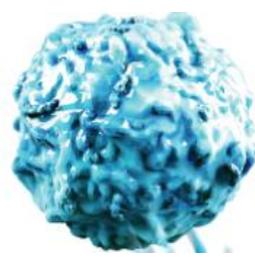
# Transforming standard of care in immuno-oncology

## *Earlier lines, new indications, combinations*



# Our technology platforms in cancer

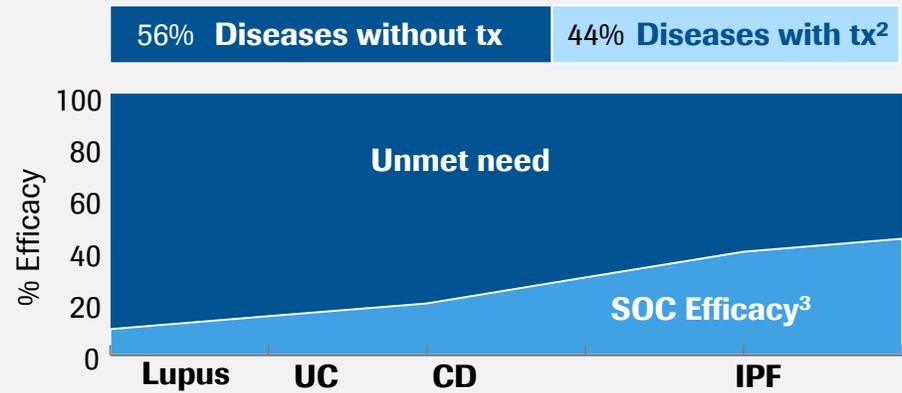
## *Roche pipeline includes differentiated therapeutic platforms*

Small molecules	Bi-specifics		Fusion protein	mAb	ADC	Personalized mRNA vaccine	Personalized T cells
	 <p>2:1 format</p> <p>1:1 format</p>					<p>iNeST platform: mRNA-LPX Liposome</p>  <p>mRNA</p>	<p>Activated T cell with neoantigen specificity</p> 
<p><b>ipatasertib</b> <b>idasanutlin</b> <b>PI3Ka inhibitor</b> <b>SERD</b></p>	<p><b>mosunetuzumab</b> <b>CD20 x CD3</b> <b>CEA x CD3</b> <b>HER2 x CD3</b> <b>glypican-3 x CD3</b></p>		<p><b>FAP x IL2v</b></p>	<p><b>aTIGIT</b> <b>(tiragolumab)</b></p>	<p><b>Polivy</b> <b>Kadcyla</b></p>	<p><b>iNeST</b></p>	<p><b>programmed T cells</b></p>
<p>Target oncogenes, induce apoptosis, suppress tumor growth</p>	<p>Engage and activate T cells to kill tumour cells</p>		<p>Amplify immune response</p>		<p>Targeted toxic payload</p>	<p>Patient's neo-antigens for anti-tumour immune response</p>	

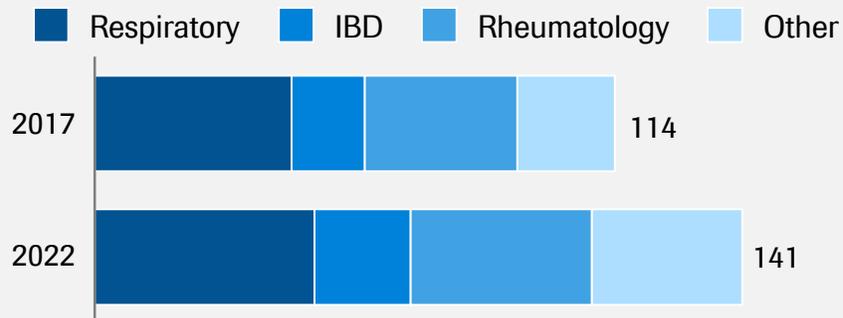
# Immunology and Ophthalmology

## *Addressing high medical need*

**Breakout Session**



Global Immunology Market Sales<sup>1</sup> (\$bn)



**Retina Portfolio:**  
faricimab, PDS

- Develop industry leading portfolio
- Build ex US infrastructure
- Gene-based therapies (4DMT)

**IBD:**  
etrolizumab

- Establish etrolizumab as SOC in UC and Crohn's

**Lupus:**  
Gazyva

- First in class

<sup>1</sup> Decision Resources, Evaluate Pharma 2017; <sup>2</sup> Disease modifying treatment, based on UpToDate; <sup>3</sup> Lupus – Benlysta SRI-4; UC & CD – TNF Sustained Remission; Asthma – Dupixent exacerbations; IPF – Esbriet FVC; RA – TNF ACR50, McKinsey analysis based on data from Evaluate

**Neuroscience  
Presentation**

# Pushing towards new frontiers in Neuroscience

## *Creating new opportunities across modalities*

### Neuroimmunology disorders

### Neuromuscular disorders

### Neurodegenerative disorders

### Neurodevelopmental disorders

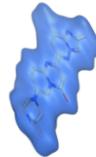
#### Ocrevus

*First B-cell targeted therapy in MS*



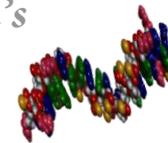
#### Risdiplam

*First oral therapy for spinal muscular atrophy*



#### HTT-ASO

*First disease modifying therapy for Huntington's disease*

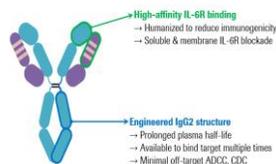


#### Balovaptan

*First treatment for core social and communication deficits*

#### Satralizumab

*BTB in NMOSD*



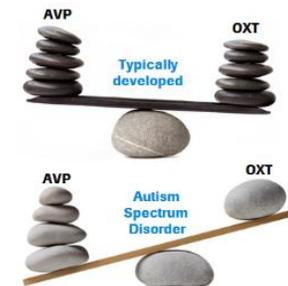
#### Duchenne Muscular Dystrophy (DMD)

*Anti-myostatin with the potential to treat core symptoms*

#### Parkinson's

*First disease modifying agent*

##### Smartphone digital biomarkers



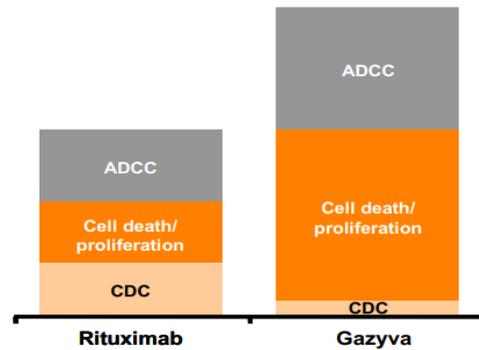
Haga, D., Neumann, D., and Nelson-Le Gall, D. (2017). Behavioral and neurophysiological indicators for anxiety, depression, and social behaviors. *Frontiers in Neuroinformatics* 11:1-11. doi:10.3389/fninf.2017.00011

# Addressing real medical needs already early in development

## *First and best in class to succeed in competitive markets*

### Gazyva

**Lupus: First in disease product**



**Ph III program in preparation based on proof of concept**

### risdiplam

**SMA: Targeting broad access**

**FIREFISH**

Type 1  
1–7 months

**SUNFISH**

Type 2 or 3  
2 – 25 years

**JEWELFISH**

Type 1, 2 or 3  
6 mo. – 60 years

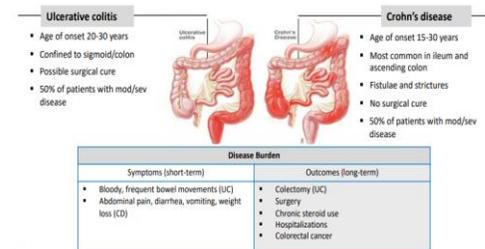
**RAINBOWFISH**

Birth – 6 weeks  
All gene copy

**Addressing types 1/2/3 right at launch**

### etrolizumab

**UC & Crohn's: Entering a new therapeutic area**



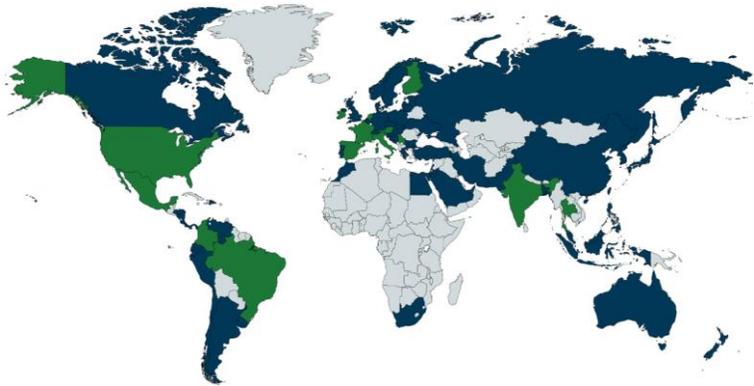
**8 large Ph III trials in UC and Crohn's - head to head vs. SoC in UC**

Immunology Neuroscience

# Our principles for pricing and access

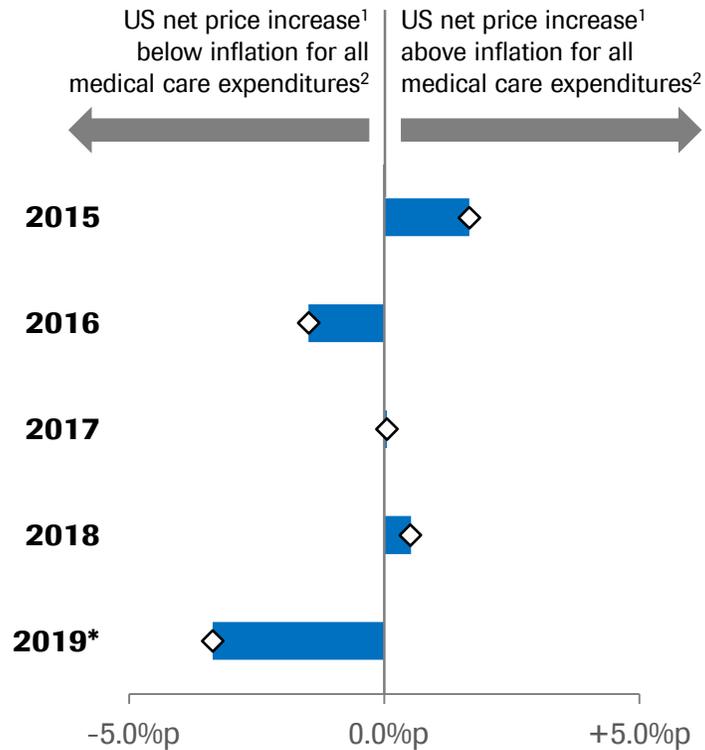
*Committed to patient access and investment in future breakthroughs*

## Flexible pricing solutions (FPS)



- Financial based arrangements
- Performance & financial based arrangements
- Broader capacity building initiatives

## Net price increases in line with medical inflation in the US



## Recent examples of responsible pricing

 ocrelizumab	~25%	discount <sup>3</sup> to Rebif list price in the US
 emicizumab-kxwh	~50%	discount <sup>3</sup> to BPA prophylaxis in the US
 entrectinib	~50%	discount <sup>3</sup> to Vitrakvi list price in the US

<sup>1</sup> Genentech's annual average net price increase in the U.S., weighted by sales; <sup>2</sup> for inflation CPI-U Medical Care is used for all medical care expenditures (incl. prescription and non-prescription drugs, medical supplies, physicians' services, hospital services, and health insurance) – source: U.S. Bureau of Labor Statistics (US BLS); <sup>3</sup> discount at launch; \* TTM for CPI-U Medical Care in 2019

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**Our environment is changing and so have we**

**Making a difference for patients**

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**Summary**

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# Strong short term news flow

## *Diversifying the late stage pipeline and setting new standards of care*

Product	Filing date	Population
<b>risdiplam in SMA</b>	2019 in type 1/2/3	~ <b>18k</b> (rare disease)
<b>satralizumab in NMOSD</b>	2019	~ <b>21k</b> (rare disease)
<b>HTT-ASO in Huntington's</b>	Ph II & III ongoing; filing latest 2022	~ <b>83k</b> (rare disease)
<b>Gazyva in lupus nephritis</b>	initiating Ph III	~ <b>190k</b>
<b>etrolizumab in UC and Crohn's Disease</b>	filing in UC in 2020	<b>UC ~700k</b> <b>CD ~600k</b> (moderate to severe)
<b>PDS in nAMD</b>	fully recruited; filing in 2020	<b>nAMD ~4,100k</b> <b>DME ~4,400k</b>
<b>faricimab in DME/nAMD</b>	recruitment ahead of plan; filing in 2021/22	

<span style="display:inline-block; width:15px; height:15px; background-color:#ffff00; border:1px solid black;"></span> Neuroscience	<span style="display:inline-block; width:15px; height:15px; background-color:#4682b4; border:1px solid black;"></span> Ophthalmology
<span style="display:inline-block; width:15px; height:15px; background-color:#6a5acd; border:1px solid black;"></span> Immunology	<span style="display:inline-block; width:15px; height:15px; background-color:#ffa500; border:1px solid black;"></span> Oncology

Product	Filing date	Population
<b>Tecentriq in 1L HCC</b>	2019/20	~ <b>300k</b> <sup>1</sup>
<b>Tecentriq in neoadj TNBC</b>	2020	~ <b>22k</b>
<b>Tecentriq in 1L mUC</b>	2019	~ <b>45k</b>
<b>Tecentriq in adj bladder cancer</b>	2020	~ <b>50k</b>
<b>Tecentriq in 1L melanoma</b>	2020	~ <b>11k</b> (Dx+)
<b>Tecentriq in FL ovarian cancer</b>	2020	~ <b>41k</b>
<b>idasanutlin in R/R AML</b>	2020	~ <b>22k</b>
<b>Herceptin + Perjeta FDC-SC</b>	2019/20	~ <b>77k</b>
<b>ipatasertib 1/2L TNBC</b>	2020	~ <b>11k</b> (Dx+)
<b>ipatasertib 1L+ HR+ BC (chemo treated only)</b>	2020	~ <b>83k</b> (Dx+) ~ <b>15k</b> (Dx+/chemo only)
<b>ipatasertib in 1L mCRPC</b>	2020	~ <b>200k</b> (AC) <b>100k</b> (Dx+)
<b>Polivy in 1L DLBCL</b>	2020/21	~ <b>52k</b>
<b>Tecentriq in (neo)adj NSCLC</b>	2021	~ <b>75k</b>

# Late stage pipeline update

## Topics covered in presentations and break-out sessions

<p><b>1. Hematology franchise</b></p> <ul style="list-style-type: none"> <li>• CLL: Venclexta, Gazyva</li> <li>• DLBCL: <b>Polivy</b>, Venclexta</li> <li>• NHL, DLBCL: mosunetuzumab, CD20xCD3</li> <li>• AML: Venclexta, idasanutlin</li> <li>• MM: Venclexta</li> </ul> <p><b>2. Breast Cancer franchise</b></p> <ul style="list-style-type: none"> <li>• HER2+: Kadcyla, Perjeta, FDC SC, Tecentriq</li> <li>• TNBC: Tecentriq, ipatasertib</li> <li>• HR+: <b>ipatasertib; PI3Ka inhibitor; SERD</b></li> </ul> <p><b>3. Lung Cancer franchise</b></p> <ul style="list-style-type: none"> <li>• <b>NSCLC: Tecentriq</b></li> <li>• <b>ALK+: Alecensa</b></li> <li>• <b>ROS1+/NTRK+: Rozlytrek</b></li> </ul> <p><b>4. GU franchise</b></p> <ul style="list-style-type: none"> <li>• <b>mUC: Tecentriq</b></li> <li>• <b>CRPC: ipatasertib</b></li> </ul>	<p><b>5. Pan tumor</b></p> <ul style="list-style-type: none"> <li>• NTRK+ tumors: Rozlytrek</li> </ul> <p><b>6. Other oncology</b></p> <ul style="list-style-type: none"> <li>• Melanoma: Tecentriq, Cotellic, Zelboraf</li> <li>• OC: Tecentriq, Avastin</li> <li>• HCC: Tecentriq, Avastin</li> </ul>	<p><b>9. Immunology</b></p> <ul style="list-style-type: none"> <li>• Lupus nephritis: Gazyva</li> <li>• Ulcerative colitis: etrolizumab</li> <li>• Crohn's disease: etrolizumab</li> <li>• Food allergy: Xolair</li> <li>• Nasal polyps: Xolair</li> </ul>
	<p><b>6. Hemophilia A</b></p> <ul style="list-style-type: none"> <li>• Hemlibra</li> </ul>	<p><b>8. Infectious diseases</b></p> <ul style="list-style-type: none"> <li>• Influenza A/B: baloxavir marboxil</li> </ul>
	<p><b>7. Neuroscience</b></p> <ul style="list-style-type: none"> <li>• MS: Ocrevus update</li> <li>• SMA: risdiplam</li> <li>• NMOSD: satralizumab</li> <li>• Huntington's disease: HTT-ASO</li> <li>• Autism: balovaptan</li> <li>• Parkinson's disease: prasinezumab</li> </ul>	<p><b>6. Ophthalmology</b></p> <ul style="list-style-type: none"> <li>• DME, nAMD: faricimab</li> <li>• AMD: Port Delivery System</li> <li>• GA: ASO factor B</li> <li>• Choroideremia: Gene therapy</li> </ul>

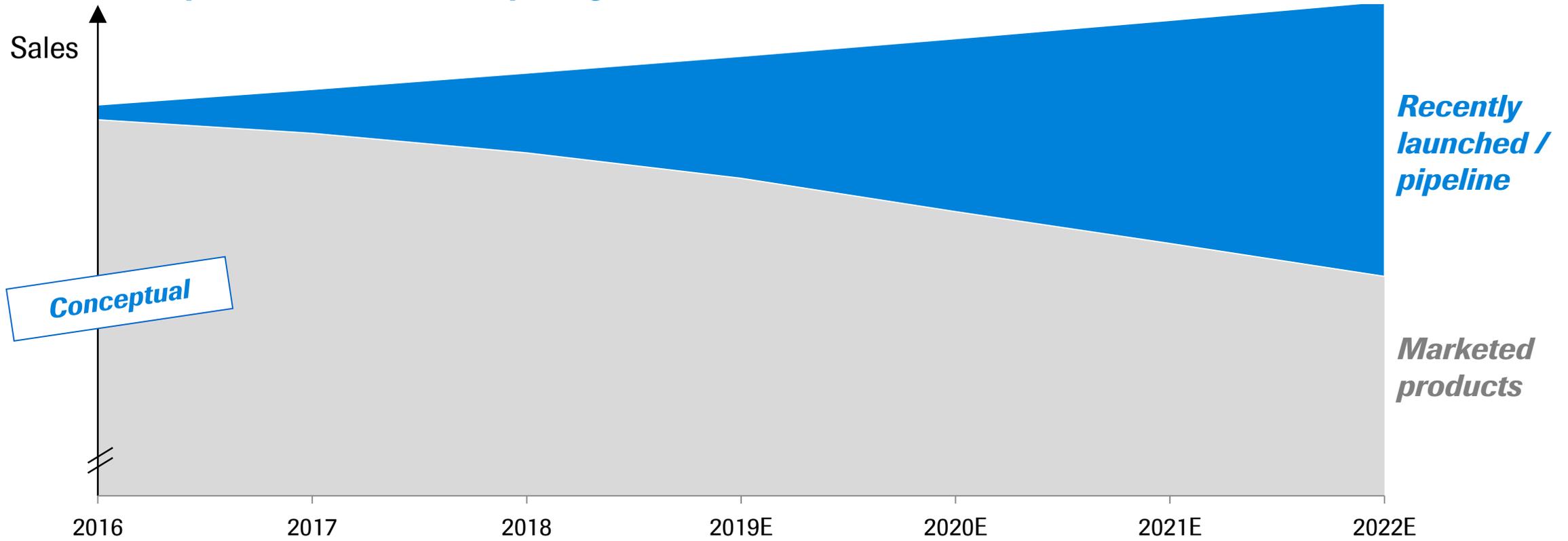
	Oncology / Hematology		1	Topics main presentations
	Neuroscience	1		Topics break-out sessions
	Ophthalmology			
	Infectious diseases			
	Immunology			

\* For further information on target patient populations please consult the appendix; For further details on the late stage pipeline please consult the HY 18 results presentation appendix or visit the IR homepage

# 2019: Positive outlook re-iterated

## ***NME launches***

*Ocrevus, Perjeta, Hemlibra, Tecentriq, Venclexta, Gazyva, Alecensa, Xofluza, Polivy, Rozlytrek, idasanutlin, ipatasertib, PI3Ka inhibitor, SERD, etrolizumab, faricimab, PDS, satralizumab, risdiplam, HTT-ASO, balovaptan, gantenerumab, etc.*



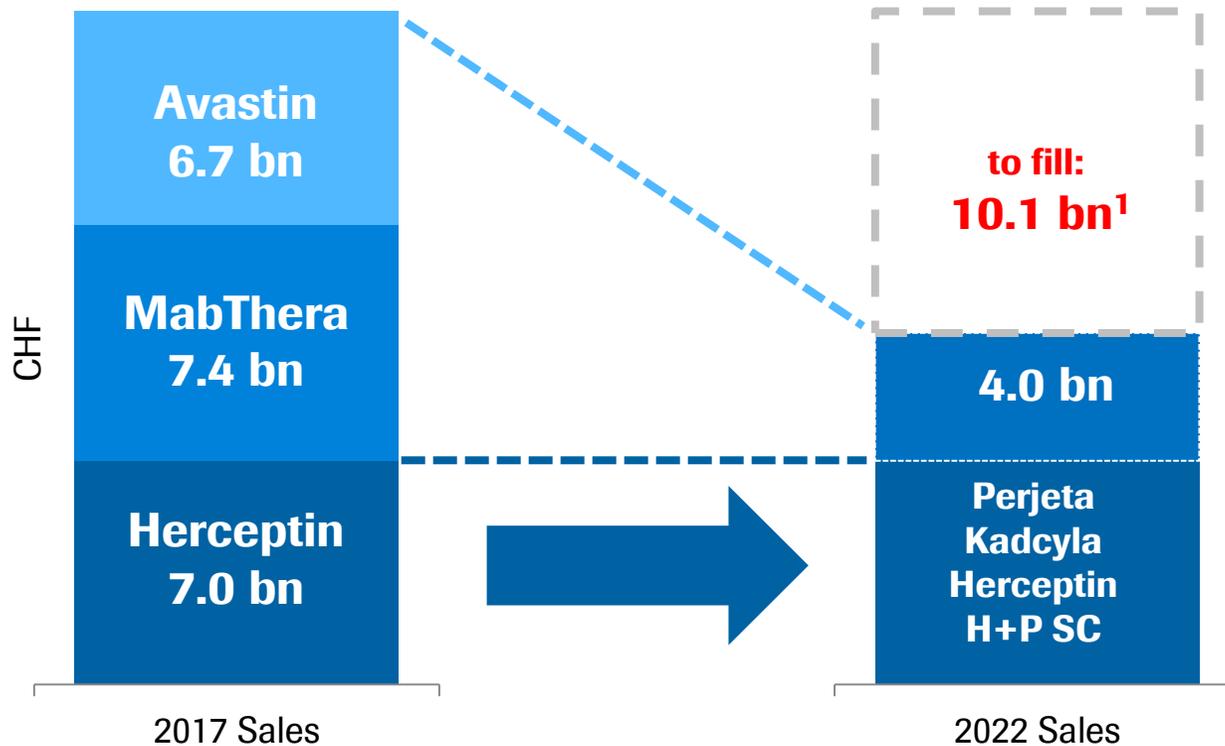
# *Backup Slides*

# New product growth expected to show strong momentum

## Considerable optionality

**Pharma Day 2018**

**Sensitivity analysis:** Assuming conservative planning assumptions of 60-70% erosion from biosimilars



### 2017-2022 consensus sales growth\* (CHF)

Ocrevus	4.5 bn
Tecentriq	2.3 bn
Hemlibra	2.1 bn
Gazyva	1.0 bn
Alecensa	1.1 bn
In-market & mature <sup>2</sup>	(0.6) bn
Pipeline value <sup>3</sup>	0.4 bn

**Total 10.8 bn**

**Up-side potential to consensus above are:**  
**Venclexta, SMA** (risdiplam), **Huntington** (HTT-ASO), **Autism** (balovaptan), **Alzheimer** (gantenerumab & crenezumab), **Ophthalmology** (Port Delivery System), **Infectious disease** (baloxavir marboxil), **Oncology** (idasanutlin, ipatasertib, mosunetuzumab)

\* Source: Roche post-HY 2018 consensus; <sup>1</sup> Gap value including the total HER2 franchise change from 2017 to 2022, assuming Lucentis will be replaced by faricimab; <sup>2</sup> Esbriet, Tarceva, Xolair, Pulmozyme, Rocephin, CellCept, Mircera, NeoRecormon/Epogin, Activase/TNKase, Xeloda, Valcyte/Cymevene, Actemra/RoActemra, Tamiflu, Madopar, Pegasys; <sup>3</sup> etrolizumab

*Doing now what patients need next*