



# GOOD START INTO THE YEAR

Merck KGaA, Darmstadt, Germany, Q1 2016 results

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# Agenda

**01** Executive summary

**02** Financial overview

**03** Guidance



01

## EXECUTIVE SUMMARY

## Highlights

### Operations

- ▶ Healthcare – good organic growth and first avelumab Phase III combination trial
- ▶ Life Science – strong performance continues; Sigma integration on track
- ▶ Performance Materials – healthy profitability amid first supply chain destocking

### Financials

- ▶ Acquisition-driven sales growth of 20.5%; EBITDA pre up 27% to €1,084 m
- ▶ Deleveraging on track – net financial debt decreases by nearly €600 m
- ▶ FY 2016 guidance – net sales: €14.8 – 15.0 bn & EBITDA pre: €4,100 – 4,300 m

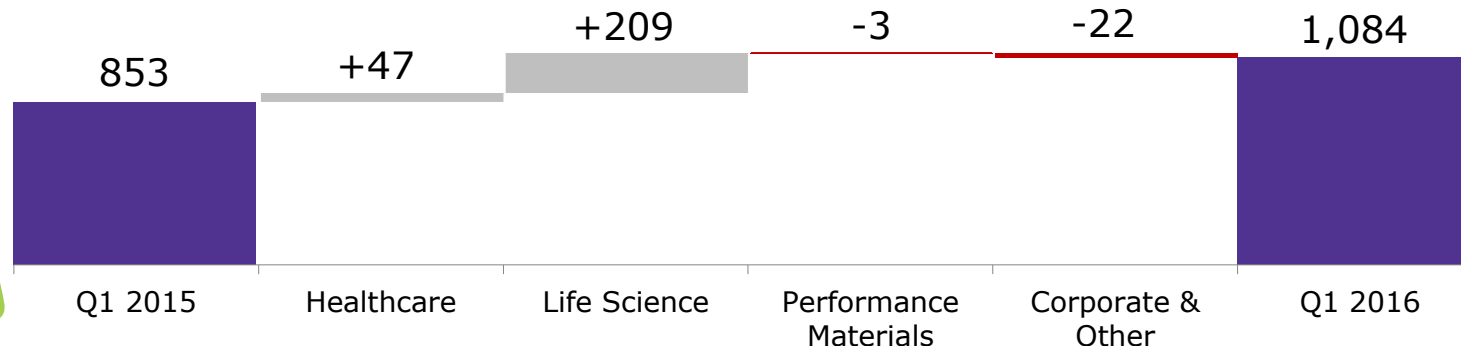
# Life Science and Healthcare drive increase in EBITDA pre

## Q1 2016 YoY net sales

	Organic	Currency	Portfolio	Total
Healthcare	5.4%	-6.8%	-1.0%	<b>-2.4%</b>
Life Science	8.9%	-1.3%	81.6%	<b>89.3%</b>
Performance Materials	-2.4%	0.5%	2.7%	<b>0.9%</b>
Group	4.7%	-4.0%	19.8%	<b>20.5%</b>

- Healthcare growth reflects strong Fertility, GM\* and CH as well as Xalkori commissions
- Strong organic growth in Life Science driven by Process Solutions
- Slight organic decline in Performance Materials confirms expected destocking in display supply chain
- Portfolio reflects Sigma and Kuvan
- HC benefits from solid organic growth, Rebif commission savings and R&D phasing
- Life Science driven by Sigma, strong organic growth and positive product mix
- Performance Materials slightly lower due to product mix
- Corporate EBITDA pre contains hedging and investments in corporate initiatives

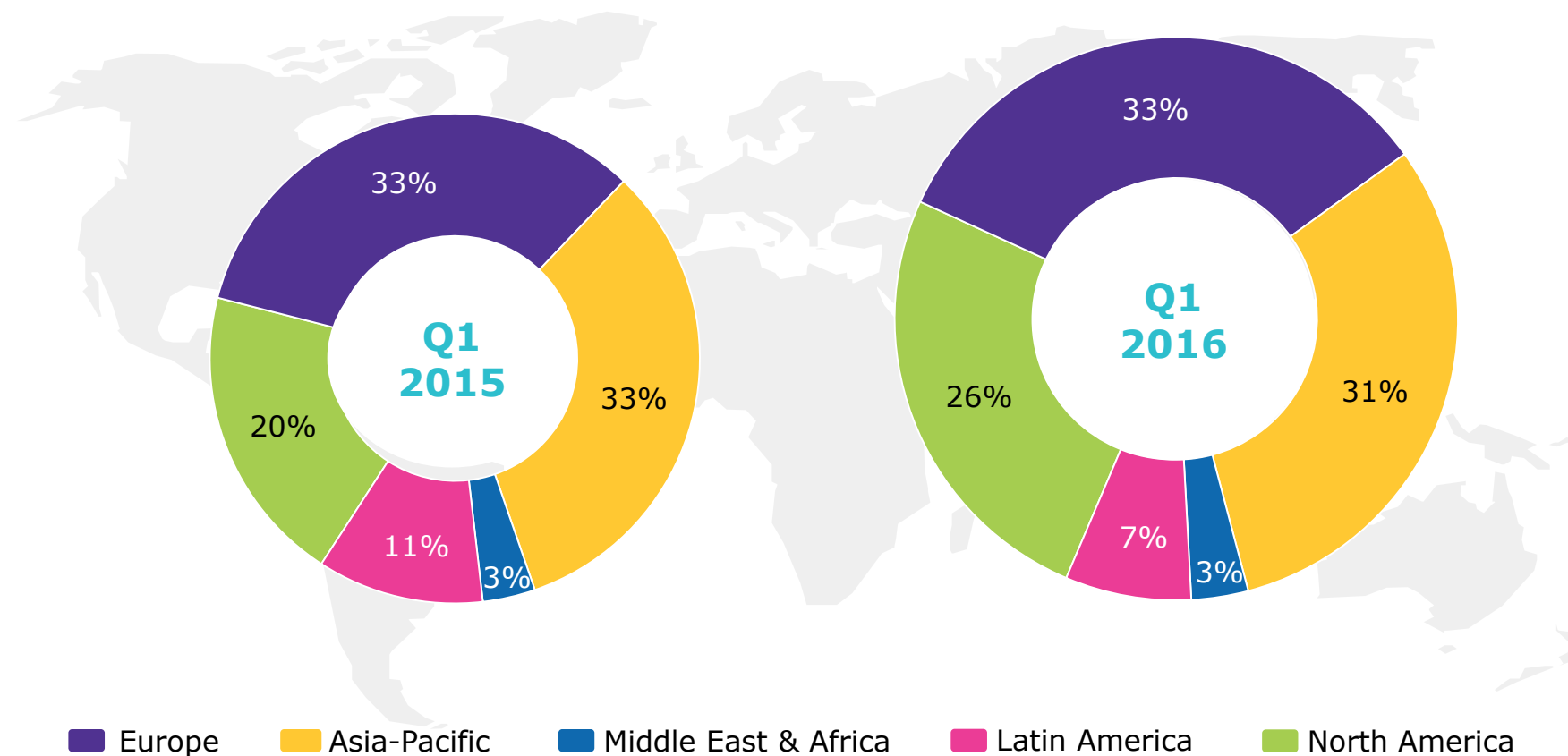
## Q1 YoY EBITDA pre contributors [€ m]



\*General Medicine and CardioMetabolic Care  
Totals may not add up due to rounding

# Q1 2016 sales split reflects Sigma's footprint in North America

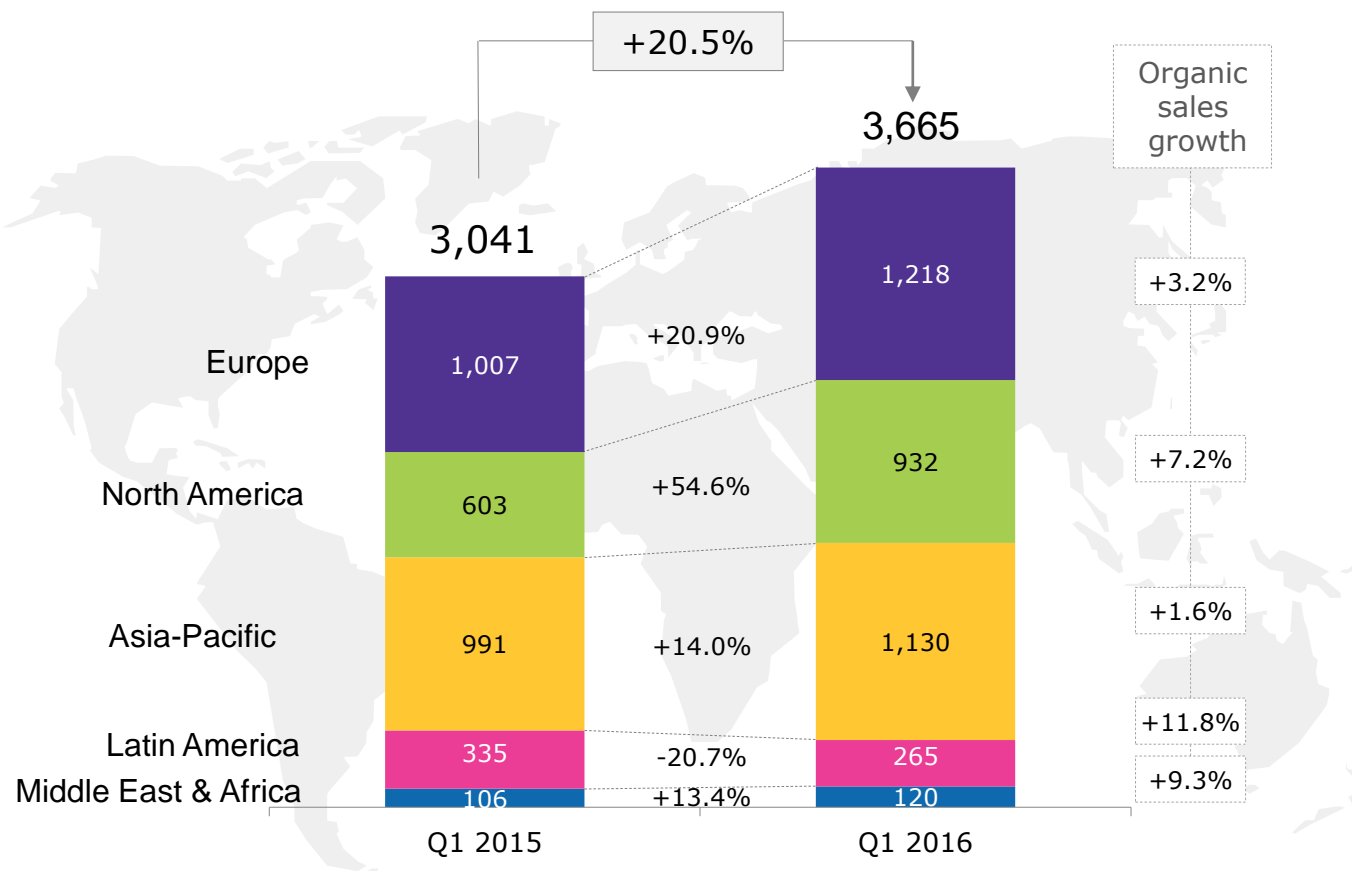
Group Q1 2015 and Q1 2016 net sales by region [in %]





# Organic growth in all regions

## Regional breakdown of net sales [€ m]



Totals may not add up due to rounding

## Regional development

- Organic growth in Europe driven by Life Science, partially offset by Rebif
- North America benefits from strong Fertility franchise and Life Science as well as Rebif price increases
- Asia-Pacific shows slight organic growth as good demand in Fertility is offset by display supply chain destocking
- Strong organic growth in LatAm driven by Consumer Health and new reimbursement for Rebif in Brazil



02

## FINANCIAL OVERVIEW

# Q1 2016: Overview

## Key figures

[€m]	Q1 2015	Q1 2016	Δ
Net sales	3,041	<b>3,665</b>	20.5%
EBITDA pre	853	<b>1,084</b>	27.0%
<i>Margin (in % of net sales)</i>	28.0%	29.6%	
EPS pre	1.12	<b>1.54</b>	37.5%
Operating cash flow	279	<b>352</b>	26.5%

[€m]	Dec. 31, 2015	March 31, 2016	Δ
Net financial debt	12,654	<b>12,072</b>	-4.6%
Working capital	3,448	<b>3,726</b>	8.0%
Employees	49,613	<b>50,262</b>	1.3%

## Comments

- EBITDA pre & margin increase driven by Sigma, end of Rebif commission expenses and organic performance
- Strong EPS pre growth due to higher EBITDA pre; LY financial result burdened by LTIP\* charges
- Operating cash flow reflects strong business performance; LY impacted by one-time tax payment
- Net financial debt reduction driven by cash-in for Kuvan & operating cash flow
- Working capital reflects increase in business activity

## Reported figures reflect solid business performance and Kuvan divestment

### Reported results

[€m]	Q1 2015	Q1 2016	Δ
EBIT	480	<b>849</b>	76.8%
Financial result	-101	<b>-68</b>	-32.1%
Profit before tax	379	<b>780</b>	>100%
Income tax	-94	<b>-187</b>	99.2%
<i>Tax rate (%)</i>	24.8%	<b>24.0%</b>	
Net income	282	<b>591</b>	>100%
EPS (€)	0.65	<b>1.36</b>	>100%

### Comments

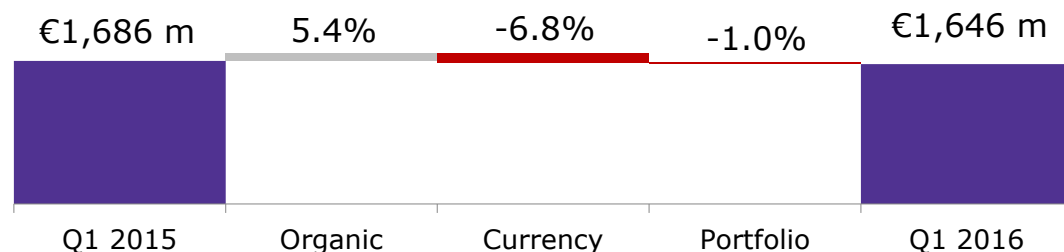
- EBIT reflects increased EBITDA pre and Kuvan disposal gain amid integration costs and D&A from Sigma
- Financial result contains Sigma financing interest expenses; last year adversely affected by LTIP
- Tax rate within guidance range of ~23-25%

# Healthcare: Good organic sales growth amid ramp-up in R&D investments

## Healthcare P&L

[€m]	Q1 2015	Q1 2016
Net sales	1,686	<b>1,646</b>
Marketing and selling	-660	<b>-613</b>
Administration	-66	<b>-71</b>
Research and development	-348	<b>-378</b>
EBIT	268	<b>641</b>
EBITDA	449	<b>829</b>
EBITDA pre	461	<b>508</b>
Margin (in % of net sales)	27.3%	<b>30.9%</b>

## Net sales bridge

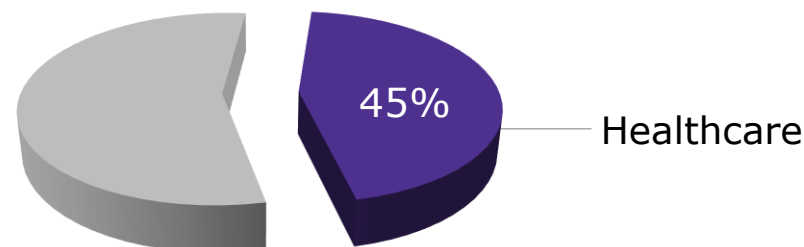


\*Productive Development Partnership  
Totals may not add up due to rounding

## Comments

- Organic growth driven by strong Fertility, GM, CH and Xalkori
- Rebif still impacted by ramp-up of orals in Europe, while U.S. pricing and first contribution from PDP\* in Brazil support performance
- Erbitux shows moderate organic growth benefiting from pick-up in Brazil, but also low comparables; EU remains competitive
- Marketing & selling reflect end of commission expenses for Rebif (U.S.) partially offset by reinvestments in sales force & launch preparations
- R&D spend starts to increase as avelumab Phase III trials progress
- EBIT reflects Kuvan disposal gain of €324 m
- Profitability improves mainly due to good organic growth, ceased Rebif commission expenses amid phased R&D cost ramp-up

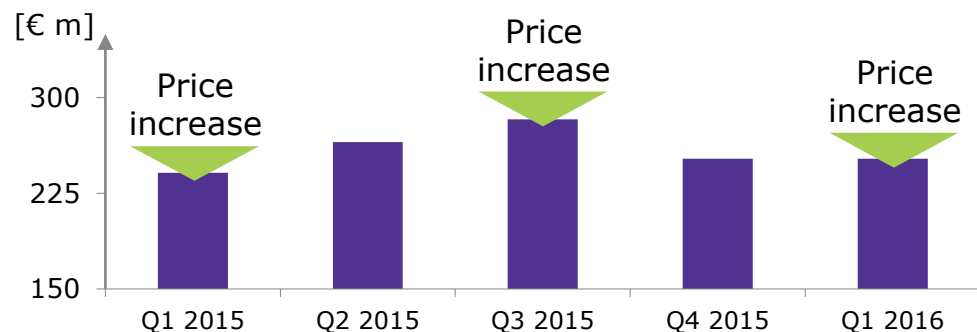
## Q1 2016 share of group net sales



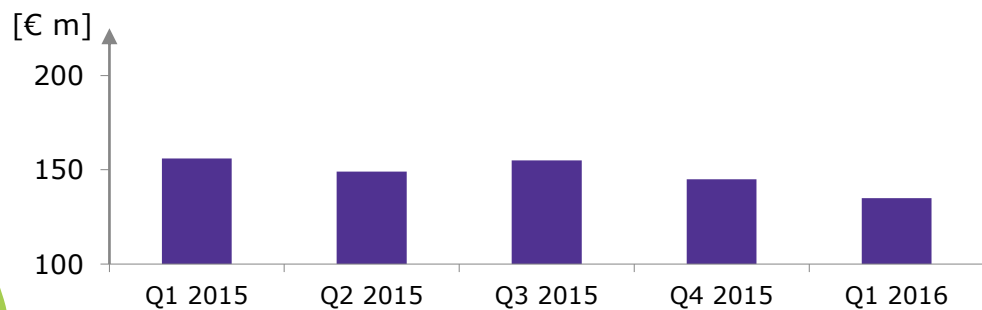
# Rebif: Relief in the U.S. – competitive ramp-up in Europe ongoing

## Rebif sales evolution

### North America



### Europe



### Q1 drivers

1.6% org.



Price



Volume



FX

### Q1 drivers

-13.1% org.



Price



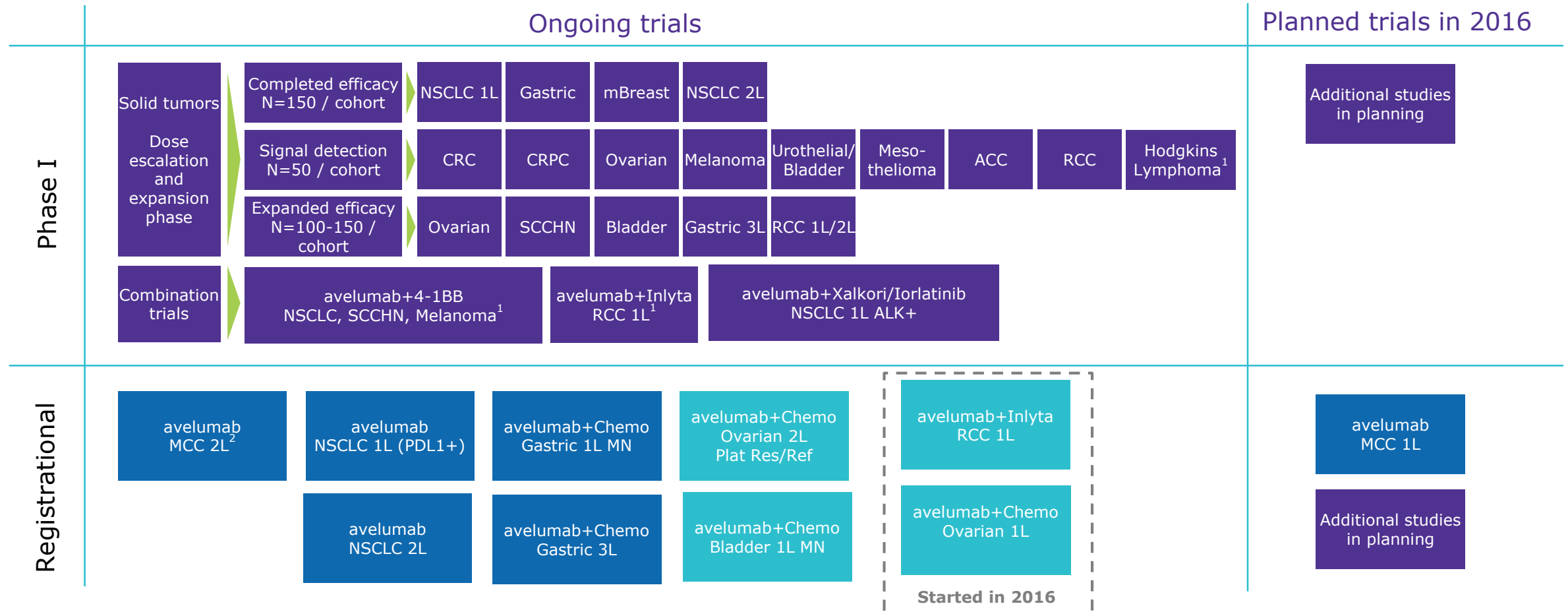
Volume

## Rebif performance

- Rebif sales of €422 m in Q1 2016 reflect organic decline of -1.5% and negative FX effects from LatAm
- Market shares within interferons stable due to high retention rates and known long-term track record
- U.S. price increases and market share stabilization outweigh decline of interferon class
- Phased market entry of orals in Europe causes ongoing volume decline
- Initiation of Productive Development Partnership (PDP) in Brazil supports Rebif growth

# Avelumab: JAVELIN clinical development program initiated as of Oct 2015 and continuously expanded to further indications in 2016

■ Trial led by Merck KGaA Darmstadt, Germany ■ Trial led by Pfizer ■ Both



Acronyms: CRC = colorectal cancer; CRPC = Castrate Resistant Prostrate Cancer; ACC = Adrenocortical Cancer; SCCHN = Squamous Cell Carcinoma of the Head and Neck; RCC = Renal Cell Carcinoma; Avelumab is an investigational agent. Avelumab is the proposed non-proprietary name for the anti-PD-L1 monoclonal antibody (MSB0010718C); <sup>1</sup>Trials currently initiating; <sup>2</sup>Phase II trial

# ASCO: We look forward to presenting the results from our avelumab trials at the upcoming scientific meeting in further detail\*

- 1**  
MCC (2L+)
  - 2**  
NSCLC (1L)
  - 3**  
Ovarian
  - 4**  
Gastric (1L MN & 2L)
  - 5**  
Urothelial / Bladder
  - 6**  
Mesothelioma
  - 7**  
mACC
- Largest trial of a PD(L)1 agent in Merkel cell carcinoma as of today
  - Clinical activity with durable responses in high unmet-need patient population (previously treated with chemotherapy)
  - Single-agent avelumab showed clinical activity
  - Higher trend in PD-L1+ patients suggested
  - Phase 3 trial is underway (JAVELIN LUNG 100)
  - Single-agent avelumab showed clinical activity in heavily pre-treated patients
  - Largest reported dataset of patients with advanced ovarian cancer treated with anti-PD-L1 as of today
  - Phase 3 trials are underway (JAVELIN OVARIAN 100 and 200)
  - Treatment with avelumab as a 1<sup>st</sup> line maintenance and 2<sup>nd</sup> line treatment showed clinical activity
  - Largest reported dataset of patients with advanced gastric cancer treated with anti-PD-L1 as of today
  - Disease control rate was also observed in a SwM (switch-maintenance therapy) group
  - Treatment with avelumab showed clinical activity
  - Phase 3 trial is underway (JAVELIN BLADDER 100)
  - Largest reported dataset of patients with advanced unresectable tumors treated with anti-PD-(L)1 as of today
  - Treatment with avelumab showed clinical activity in pre-treated patients
  - First study to date of an anti-PD-(L)1 agent in this rare tumor type (advanced adrenocortical carcinoma)
  - Treatment with avelumab showed clinical activity in pre-treated patients



## Newsflow: Upcoming pipeline catalysts

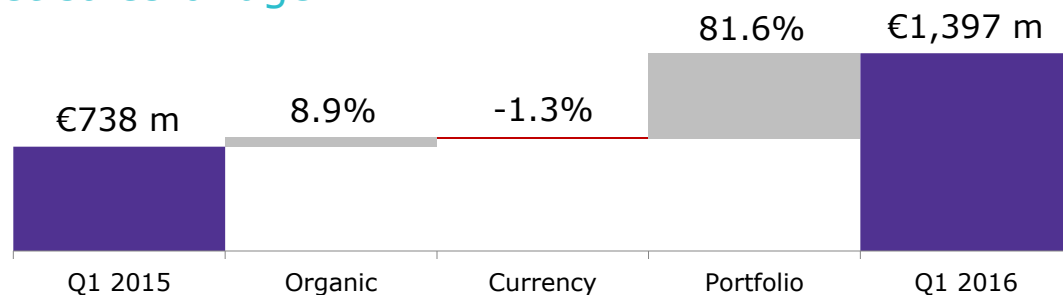
<b>AVELUMAB</b>	▶ Data readout Phase II MCC	▶ H1 2016
<b>CLADRIBINE</b>	▶ Expected EMA filing	▶ H1 2016
<b>SPRIFERMIN</b>	▶ Data readout Phase II	▶ H2 2016
<b>ATACICEPT</b>	▶ Data readout Phase II	▶ H2 2016
<b>M7824</b> (PD-L1 – TGF-beta)	▶ Dose escalation outcome	▶ H2 2016
<b>TEPOTINIB</b>	▶ Data readout Phase II	▶ H1 2017

# Life Science: A strong start to 2016

## Life Science P&L

[€m]	Q1 2015	Q1 2016
Net sales	738	<b>1,397</b>
Marketing and selling	-233	<b>-421</b>
Administration	-31	<b>-63</b>
Research and development	-45	<b>-62</b>
EBIT	83	<b>105</b>
EBITDA	164	<b>284</b>
EBITDA pre	184	<b>393</b>
Margin (in % of net sales)	25.0%	<b>28.1%</b>

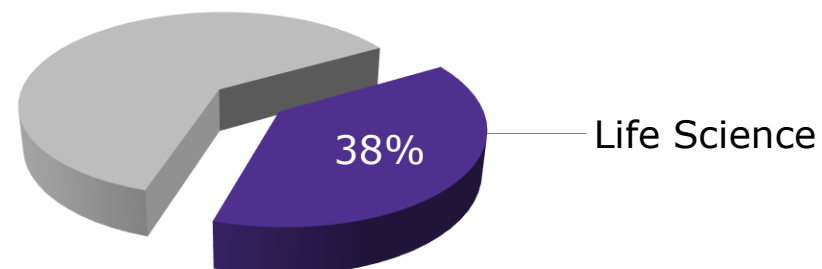
## Net sales bridge



## Comments

- Very strong growth of Process Solutions driven by increasing production of large molecules across global and regional accounts
- Applied Solutions shows moderate organic growth, driven by bio-monitoring products for pharma & demand for analytical testing
- Research Solutions benefits from increased research on biologics as well as solid demand for high-value chemicals
- Absolute costs higher due to Sigma, but improve in relation to sales
- Profitability reflects Sigma, favorable product mix and synergies

## Q1 2016 share of group net sales

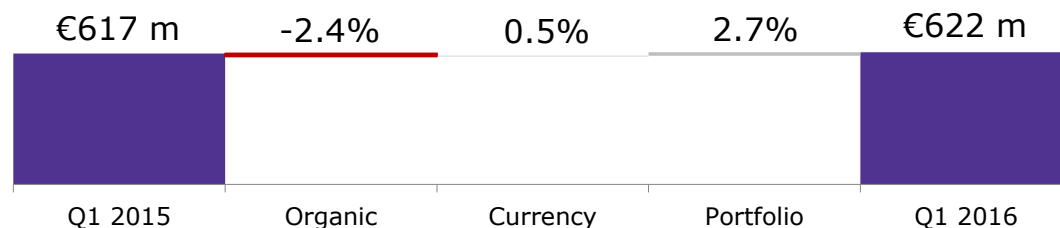


# Performance Materials: Healthy profitability amid destocking of display industry inventories

## Performance Materials P&L

[€m]	Q1 2015	Q1 2016
Net sales	617	<b>622</b>
Marketing and selling	-46	<b>-58</b>
Administration	-18	<b>-16</b>
Research and development	-47	<b>-48</b>
EBIT	214	<b>207</b>
EBITDA	273	<b>267</b>
EBITDA pre	277	<b>273</b>
Margin (in % of net sales)	44.8%	<b>43.9%</b>

## Net sales bridge

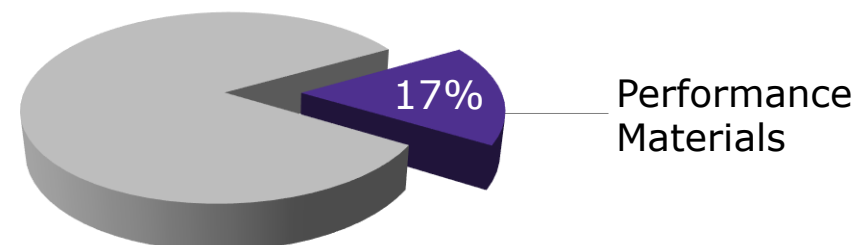


\*Active pharmaceutical ingredient  
Totals may not add up due to rounding

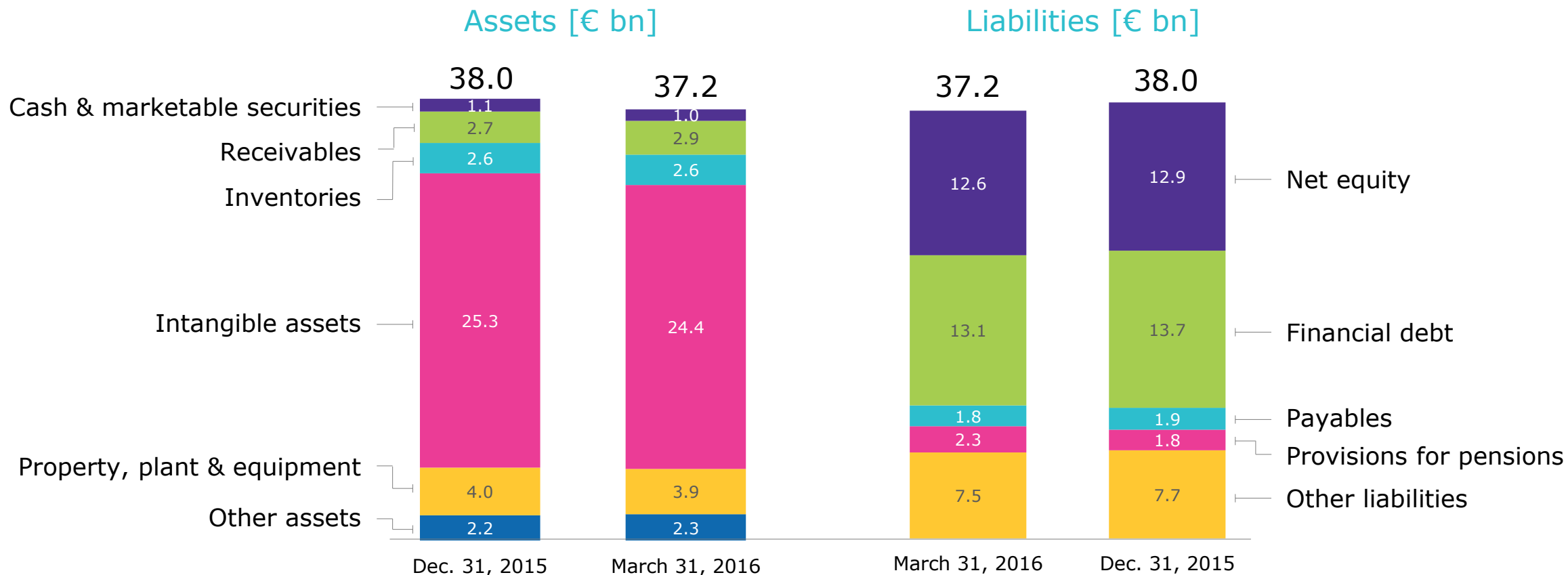
## Comments

- Organic growth of OLED, ICM, and Pigments mitigates LC softness
- Liquid Crystals impacted by indicated inventory correction in supply chain
- OLED continues to grow on industry capacity expansion & investments
- Integrated Circuit Materials (ICM) show solid growth mainly driven by dielectric materials for chip production
- Pigments & Functionals post moderate growth esp. due to cosmetic API\*
- Marketing & selling reflect contribution from Sigma's SAFC Hitech and sales force IT initiative
- Healthy profitability reflects leading market position with highly differentiated products, despite destocking and negative mix effects

## Q1 2016 share of group net sales



## Balance sheet – deleveraging initiated after Sigma acquisition



- Total assets decline by 2.2%, equity ratio remains at 33.8%
- Reduction of intangible assets reflects D&A (€0.3 bn) and FX (€0.6 bn)
- FX development accounts for ~€0.6 bn total equity decrease
- Net financial debt reduced by €0.6 bn
- Decline of interest rates increases pension provisions

# Healthy operating cash flow enables first deleveraging measures

## Q1 2016 – cash flow statement

[€m]	Q1 2015	Q1 2016	Δ
Profit after tax	285	<b>593</b>	308
D&A	325	<b>433</b>	108
Changes in provisions	90	<b>21</b>	-69
Changes in other assets/liabilities	-231	<b>-34</b>	197
Other operating activities	-20	<b>-394</b>	-374
Changes in working capital	-172	<b>-266</b>	-94
Operating cash flow	279	<b>352</b>	73
Investing cash flow	392	<b>284</b>	-108
thereof Capex on PPE	-75	<b>-160</b>	-85
Financing cash flow	2,288	<b>-572</b>	-2,860

## Cash flow drivers

- Profit after tax includes gain from Kuvan divestment, which is neutralized in other operating activities
- D&A increases due to Sigma
- Tax payment (Pfizer upfront) burdened changes in other assets/liabilities LY
- Changes in working capital reflect lower payables (Pfizer-Rebif) and higher R&D receivables from Pfizer (avelumab)
- Investing cash flow contains increased Capex and Kuvan divestment; LY with sale of financial assets
- Financing cash flow reflects first repayments of Sigma-related bank loans; LY contains USD bond issuance



# 03 GUIDANCE

## Full-year 2016 guidance

Group guidance for 2016, including Sigma-Aldrich

▶ **Net sales:** ~ €14.8 – 15.0 bn ◀

▶ **EBITDA pre:** ~ €4,100 – 4,300 m ◀

▶ **EPS pre:** ~ €5.65 – 6.00 ◀



## 2016 business sector guidance



### Net sales

- Slight organic growth
- Organic Rebif decline
- Other franchises growing

### EBITDA pre

~ €1,800 – 1,900m



### Net sales

- Mid single-digit organic growth
- Main driver Process Solutions
- High double-digit contribution from Sigma

### EBITDA pre

~ €1,620 – 1,670m



### Net sales

- Organically about stable
- Including moderate destocking in liquid crystals
- Growing demand in all businesses

### EBITDA pre

~ €1,100 – 1,150m





The background features a vibrant, abstract design. On the left side, there are overlapping, organic shapes in shades of purple and cyan. The rest of the page is a solid, bright lime green. The word 'APPENDIX' is centered in the upper right quadrant of the green area.

## APPENDIX

# Additional financial guidance 2016

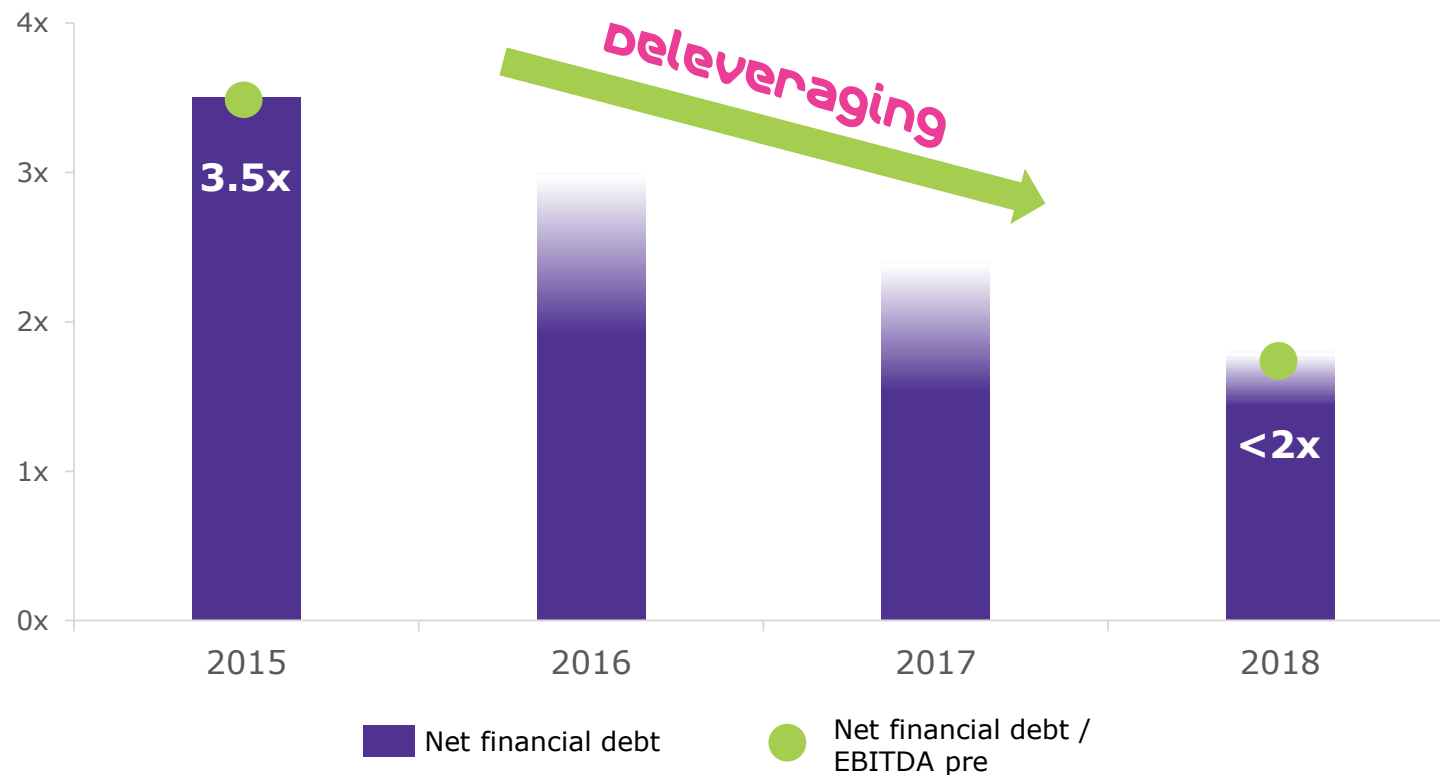
## Further financial details

Corporate & Other EBITDA pre	~ -€370 – -400 m
Interest result	~ -€270 – -300 m
Intangibles amortization from Sigma PPA	~ €250 – 300 m p.a.
Underlying tax rate	~23% to 25%
Capex on PPE	~€750 – 800 m
Hedging/USD assumption	<b>2016 &amp; 2017 hedge rate ~40-45% at EUR/USD ~1.10 to 1.15</b>
2016 Ø EUR/USD assumption	~1.07 – 1.12

# Strong focus on cash generation to ensure swift deleveraging

## Net debt and leverage development

[Net debt/  
EBITDA pre]

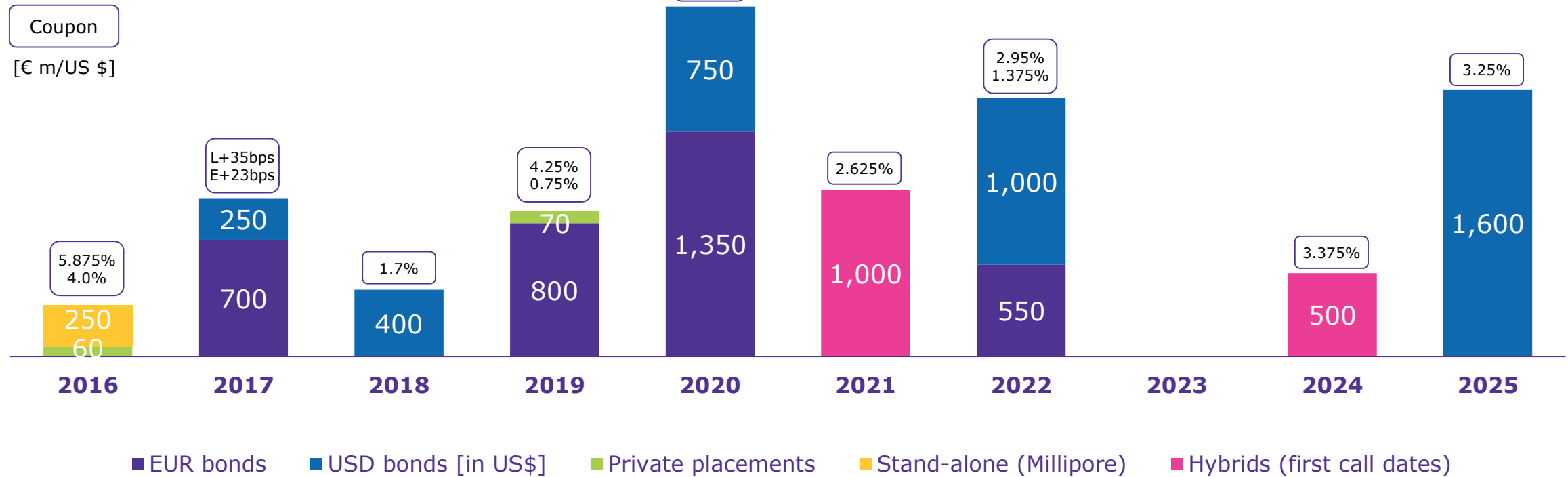


## Focus on deleveraging

- Commitment to swift deleveraging to ensure a strong investment grade rating and financial flexibility
- Strong cash flow will be used to drive down leverage to expected <2x net debt/EBITDA pre in 2018
- Larger acquisitions (>€500 m) ruled out for the next two years
- Interest result in 2016: ~-€270 – -300 m

# Well-balanced maturity profile reflects capital markets transactions related to Sigma-Aldrich

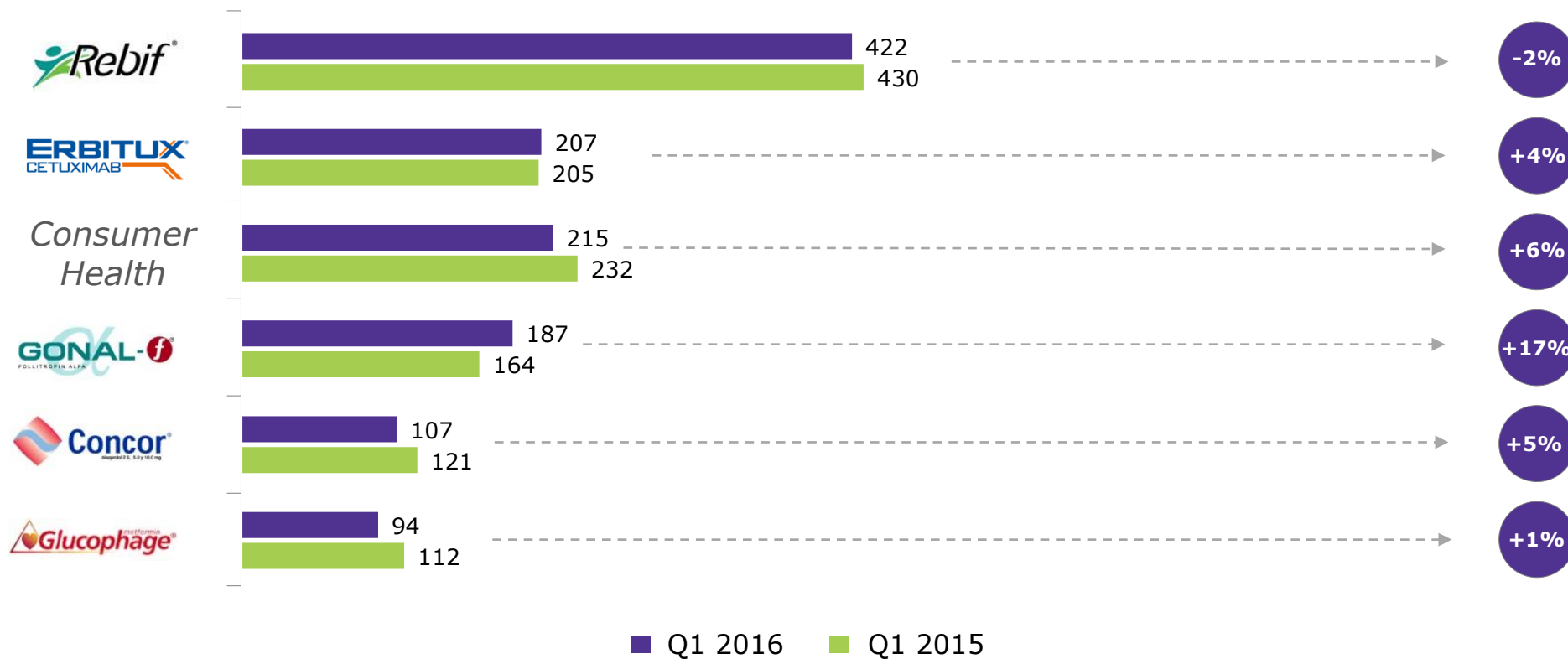
Maturity profile as of March 31, 2016



Financing structure enables flexible and swift deleveraging

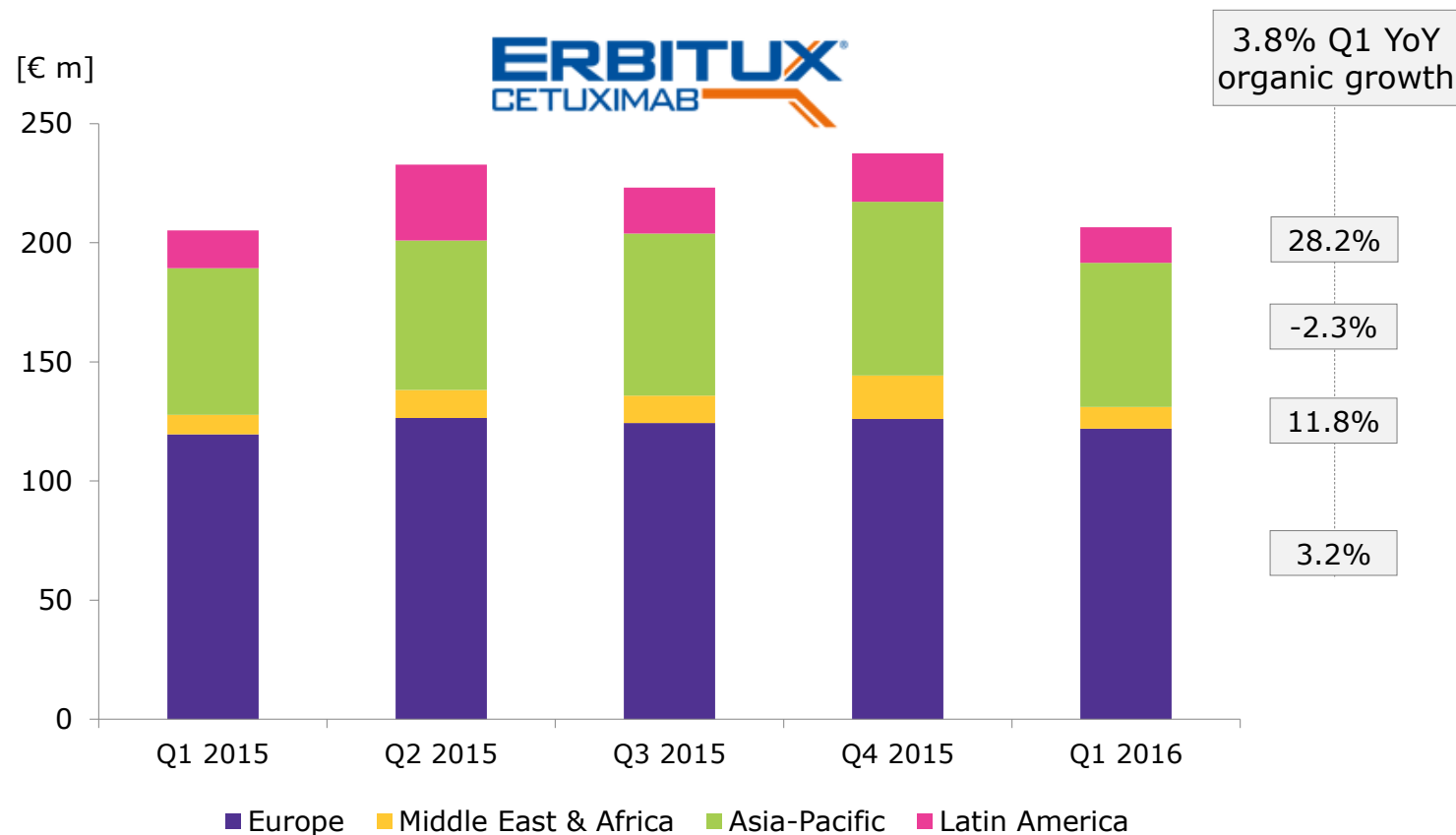
# Healthcare organic growth by franchise/product

Q1 2016 organic sales growth [%] by key franchise/products [€ m]



# Erbitux: A challenging market environment

## Erbitux sales by region



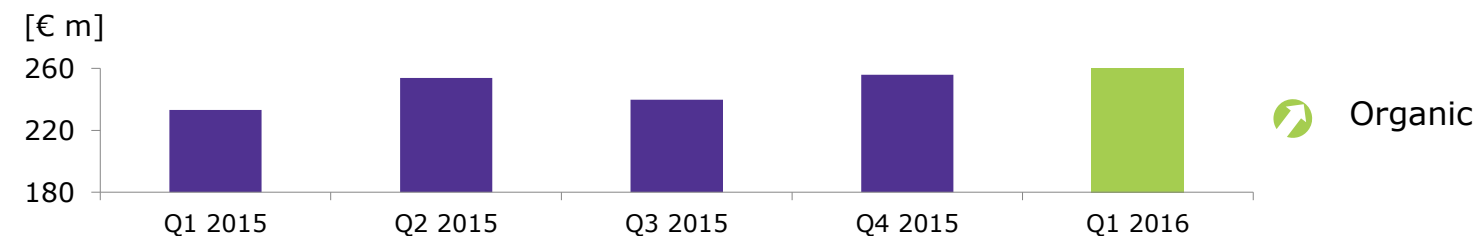
## Erbitux performance

- Sales increase to €207 m due to solid volume development, but low base last year
- Europe impacted by mandatory price cuts & increasing competition offset by uptake in Russia
- Latin America shows strong growth esp. in Brazil after weak 2015
- APAC mainly reflects reduction of patient population due to label change in Japan (April 2015)

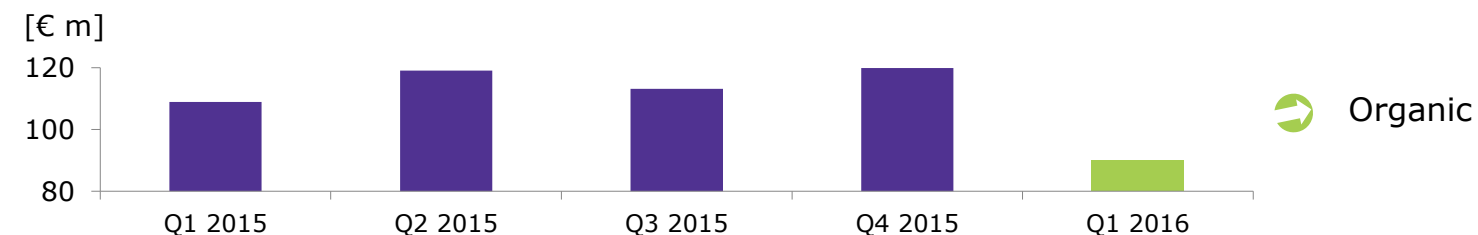
# Strong organic growth in Fertility, General Medicine and Endocrinology

## Sales evolution

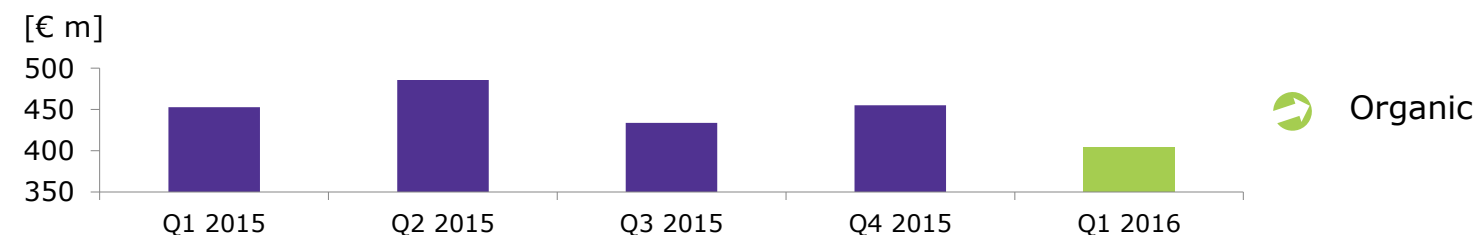
### Fertility



### Endocrinology



### General Medicine\*



## Q1 drivers

- Record quarter for Fertility (17% org.) driven by favorable competitive situation in U.S. and strong China
- Sales drop in Endocrinology reflects Kuvan divestment; remaining portfolio (Saizen, Serostim) growing organically
- General Medicine sales burdened by FX headwinds from LatAM, organic performance sustainably healthy
- Euthyrox posts strong growth driven by ongoing demand from China
- Glucophage benefits from successful repatriation in Russia; very strong comparables last year



# Clinical pipeline

## Phase I

### Tepotinib c-Met kinase inhibitor

Solid tumors

**M2698**

### p70S6K & Akt inhibitor

Solid tumors

**M3814**

### DNA-PK inhibitor

Solid tumors

### Beigene-283

### BRAF inhibitor

Solid tumors

### Avelumab<sup>1</sup>

### Anti-PD-L1 mAb

Solid tumors

### M9241 (NHS-IL12)<sup>2</sup>

### Cancer immunotherapy

Solid tumors

**M7824**

### Bifunctional immunotherapy

Solid tumors

### M1095 (ALX-0761)

### Anti-IL-17 A/F nanobody

Psoriasis

**M2951**

### BTK inhibitor

Systemic lupus erythematosus

## Phase II

### M2736 (ATX-MS-1467) Immune tolerizing agent

Multiple sclerosis

### Tepotinib c-Met kinase inhibitor

Non-small cell lung cancer

### Tepotinib

### c-Met kinase inhibitor

Hepatocellular cancer

### Avelumab<sup>1</sup>

### Anti-PD-L1 mAb

Merkel cell carcinoma

### Sprifermin

### Fibroblast growth factor 18

Osteoarthritis

### Atacicept

### Anti-Blys/anti-APRIL fusion protein

Systemic lupus erythematosus

## Phase III

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Non-small cell lung cancer 1L<sup>3</sup>

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Non-small cell lung cancer 2L<sup>4</sup>

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Gastric cancer 1L<sup>3</sup>

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Gastric cancer 3L<sup>5</sup>

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Bladder cancer 1L<sup>3</sup>

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Ovarian cancer platinum resistant/refractory

### Avelumab<sup>1</sup> – Anti-PD-L1 mAb

Renal cell carcinoma 1L<sup>3</sup>

### MSB11022

### Proposed biosimilar of Adalimumab

Chronic plaque psoriasis

## Registration

### Cladribine Tablets<sup>6</sup> – Lymphocyte targeting agent

Relapsing-remitting multiple sclerosis

■ Neurodegenerative Diseases

■ Oncology

■ Immunology

■ Immuno-Oncology

■ Biosimilars

Pipeline as of May 19, 2016

Pipeline products are under clinical investigation and have not been proven to be safe and effective.

There is no guarantee any product will be approved in the sought-after indication.

<sup>1</sup>Avelumab is the proposed International Non-proprietary Name (INN) for the anti-PD-L1 monoclonal antibody (previously known as MSB 0010718C);

<sup>2</sup>Sponsored by the National Cancer Institute (USA); <sup>3</sup> 1st line treatment; <sup>4</sup> 2nd line treatment; <sup>5</sup> 3rd line treatment

<sup>6</sup>As announced on September 11, 2015 Merck KGaA Darmstadt, Germany is preparing a regulatory submission to the European Medicines Agency

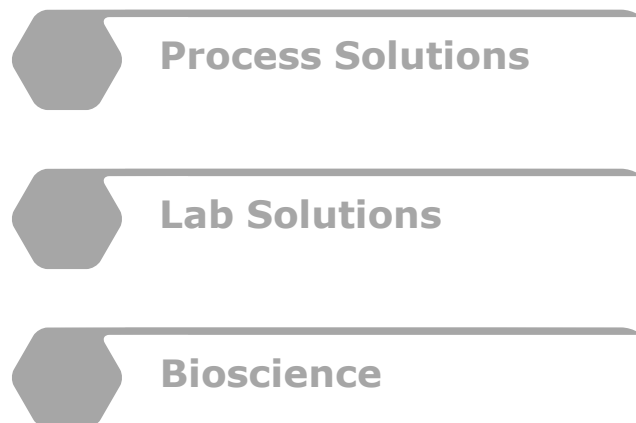
# Exceptionals in Q1 2016

## Exceptionals in EBIT

[€m]	Q1 2015		Q1 2016	
	Exceptionals	thereof D&A	Exceptionals	thereof D&A
Healthcare	12	0	-321	0
Life Science	20	0	109	0
Performance Materials	4	0	6	0
Corporate & Other	12	0	7	0
Total	48	0	-198	0

# Life Science: New reporting structure reflects customer-centric approach

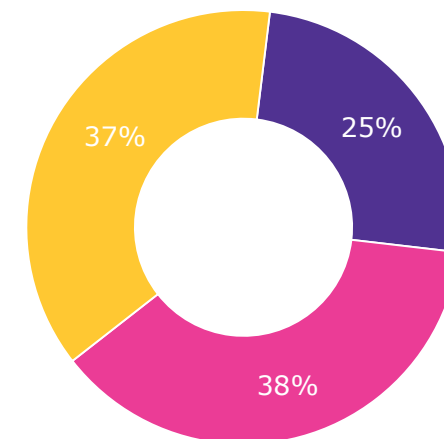
## 2015 product-centric structure



## New 2016 customer-centric structure



New sales breakdown as of Q1 2016

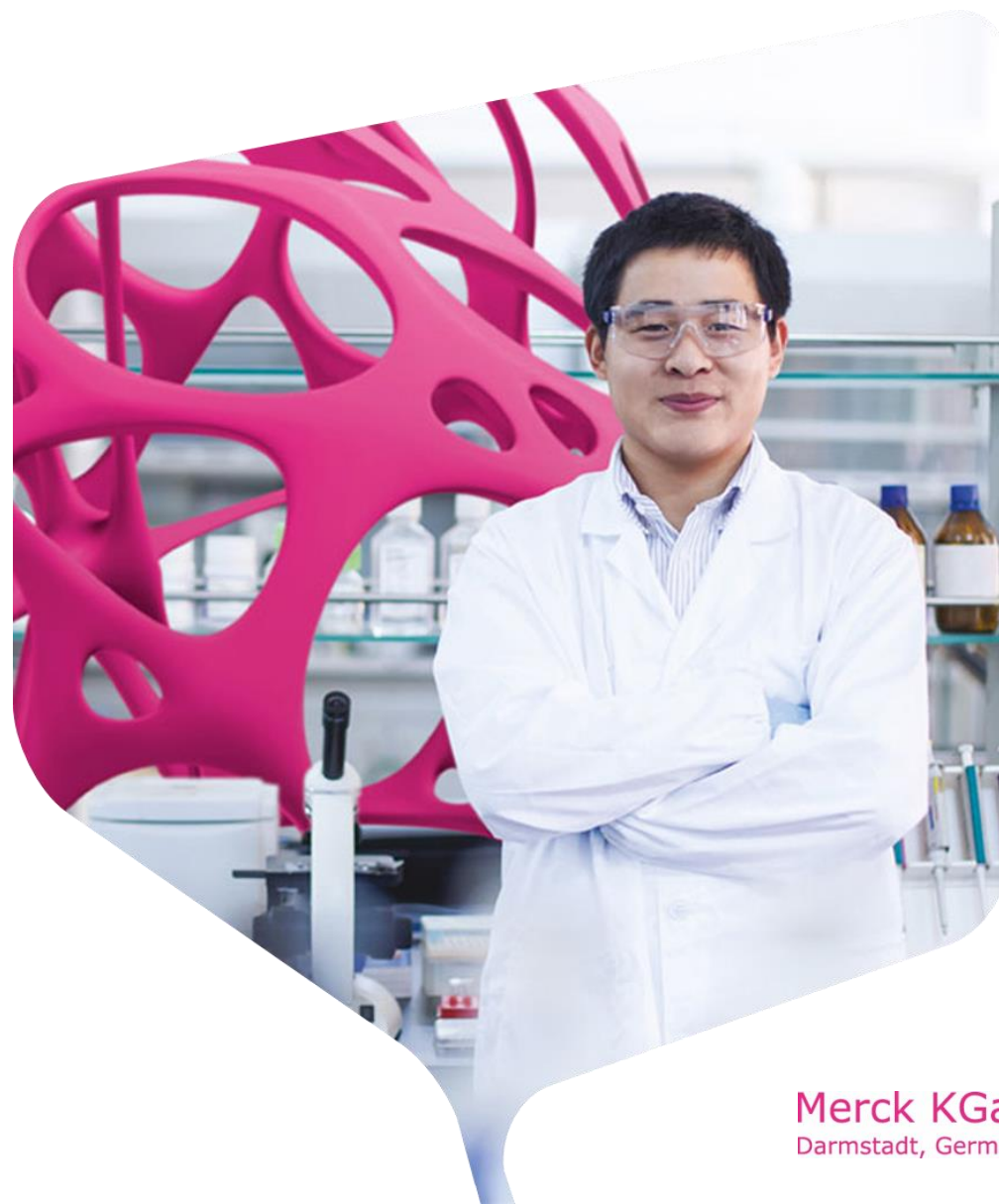


### Customer-centric business approach:

- Enhanced emphasis on customers' unique needs
- Customized solutions for the specific needs of each segment from the start of product development to its completion

## Financial calendar

Date	Event
June 20, 2016	R&D Update Call
August 4, 2016	Q2 2016 Earnings release
November 15, 2016	Q3 2016 Earnings release



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