



# SOLID START TO A CHALLENGING YEAR

Merck KGaA, Darmstadt, Germany Q1 2017 results

Marcus Kuhnert, CFO  
Belén Garijo, CEO Healthcare

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# Agenda

**01** Executive summary

**02** Financial overview

**03** Healthcare update

**04** Guidance



01

## EXECUTIVE SUMMARY

## Highlights

### Operations

- ▶ Healthcare – sound base business, first Bavencio approvals & further pipeline progress
- ▶ Life Science – solid growth against tough comps; Sigma integration on track
- ▶ Performance Materials – Four-pillar platform mitigates softness in Liquid Crystals

### Financials

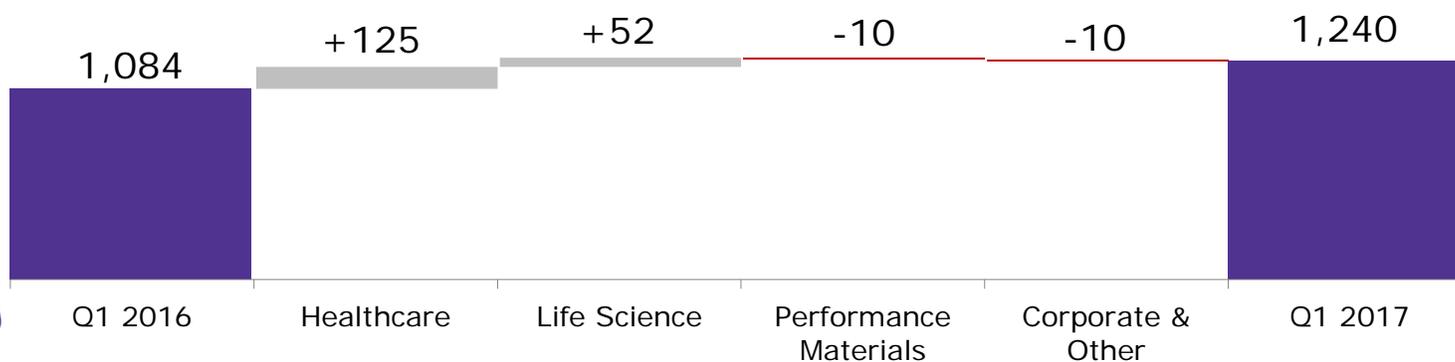
- ▶ Sales growth of 5.3%; EBITDA pre up 14.5% to €1,240 m
- ▶ Deleveraging on track – net financial debt decreases by €400 m
- ▶ FY 2017 guidance – net sales: €15.5 – 16.0 bn & EBITDA pre: €4,400 – 4,600 m

# Healthcare and Life Science fuel increase in EBITDA pre

## Q1 2017 YoY net sales

	Organic	Currency	Portfolio	Total
Healthcare	4.4%	2.0%	-1.0%	<b>5.4%</b>
Life Science	3.3%	2.4%	0.4%	<b>6.1%</b>
Performance Materials	-0.9%	4.5%	0.0%	<b>3.6%</b>
Group	3.1%	2.6%	-0.3%	<b>5.3%</b>

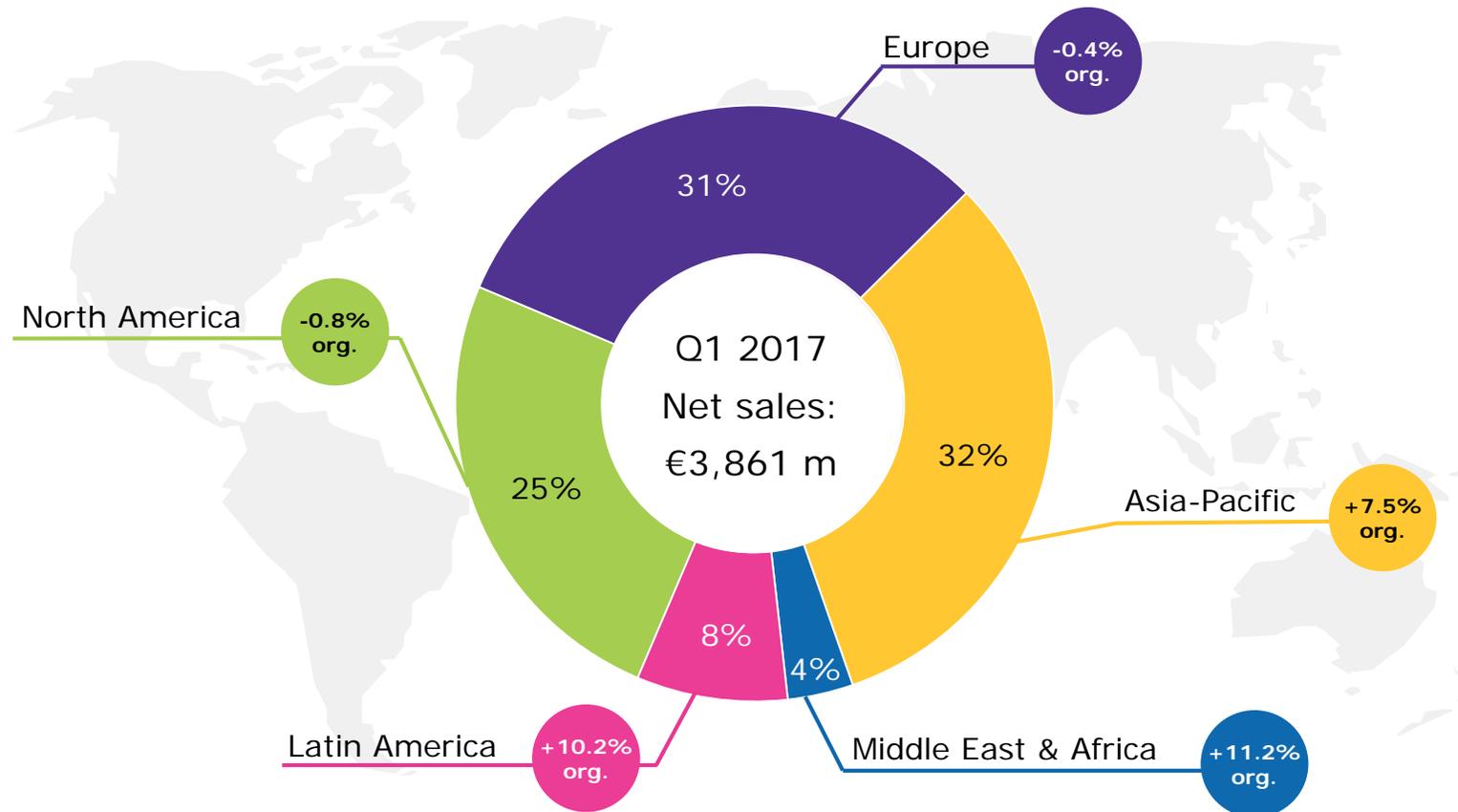
## Q1 YoY EBITDA pre contributors [€ m]



- Healthcare reflects strong growth in General Medicine, especially Glucophage China
- Organic performance in Life Science driven by all business units
- Strong growth of Integrated Circuit Materials and Pigments mitigates LC decline
- HC benefits from first approval milestone, net benefit from royalty swap (~€100m) and organic performance
- Life Science driven by organic growth and ongoing synergy realization
- Performance Materials slightly lower due to business mix and higher R&D
- Corporate EBITDA pre contains hedging and investments in corporate initiatives

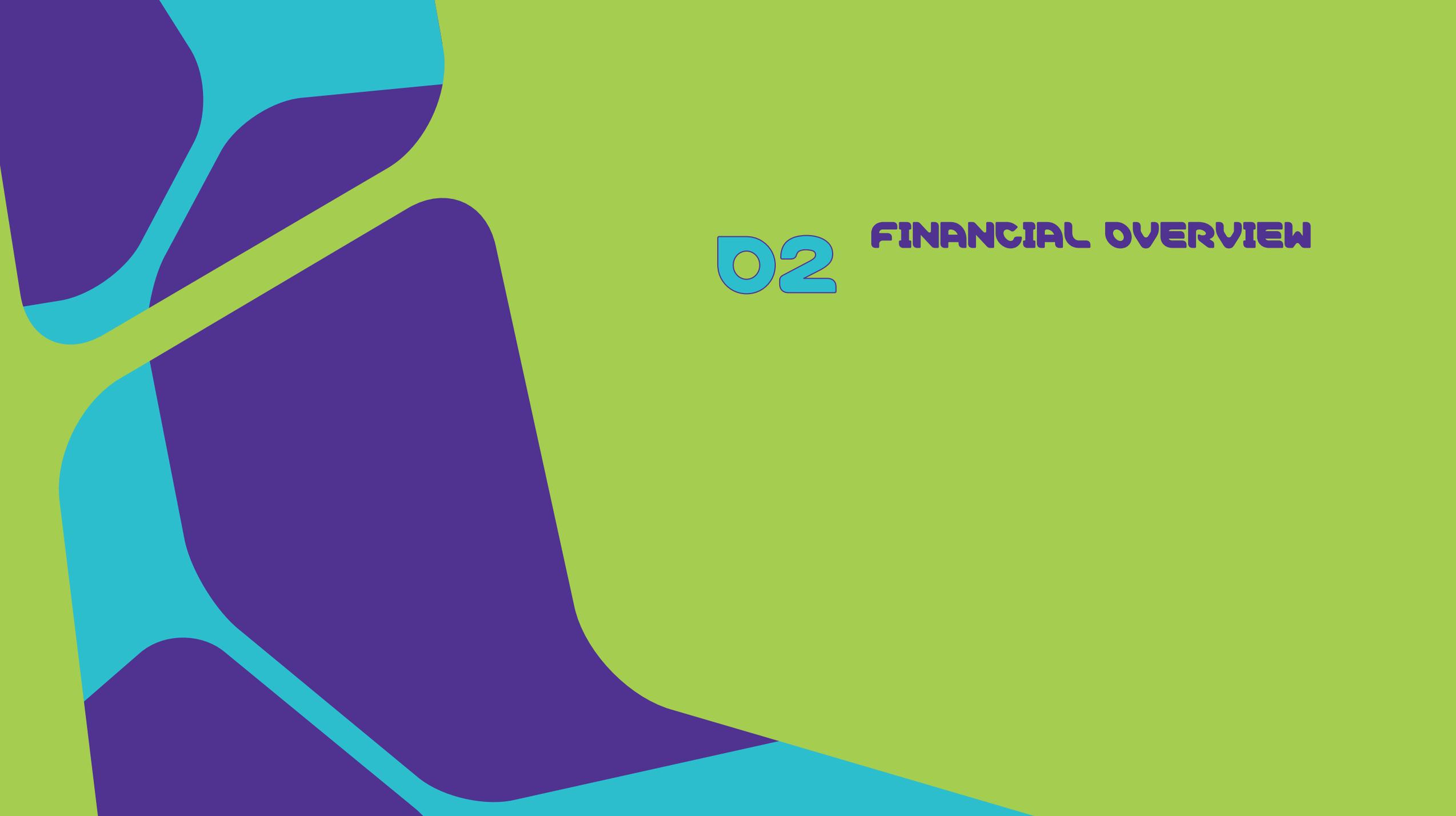
# Organic growth driven by APAC, LATAM and MEA

## Regional breakdown of net sales [€ m]



## Regional organic development

- Slight decline in Europe reflects competition for Rebif, Erbitux and Gonal-f, mitigated by solid demand in Life Science
- North America lower as growth in Life Science is more than offset by Rebif decline and tough Gonal-f comparables
- Good growth in Asia-Pacific mainly driven by Glucophage repatriation in China, strong demand in Process Solutions
- Strong performance in LATAM and MEA across all major businesses



02

## FINANCIAL OVERVIEW

# Q1 2017: Overview

## Key figures

[€m]	Q1 2016	Q1 2017	Δ
Net sales	3,665	<b>3,861</b>	5.3%
EBITDA pre	1,084	<b>1,240</b>	14.5%
Margin (in % of net sales)	29.6%	32.1%	
EPS pre	1.54	<b>1.80</b>	16.9%
Operating cash flow	352	<b>777</b>	120.6%

[€m]	Dec. 31, 2016	March 31, 2017	Δ
Net financial debt	11,513	<b>11,113</b>	-3.5%
Working capital	3,486	<b>3,953</b>	13.4%
Employees	50,414	<b>51,480</b>	2.1%

## Comments

- EBITDA pre & margin increase mainly driven by royalty income swap
- Strong EPS pre growth due to higher EBITDA pre
- Operating cash flow reflects high profit and positive tax effects
- Net financial debt reduction driven by strong operating cash flow
- Working capital reflects increased receivables mainly due to Glucophage repatriation
- Higher headcount due to investments in growth markets and takeover of temporary workers

## Reported figures reflect solid business and royalty income swap

### Reported results

[€m]	Q1 2016	Q1 2017	Δ
EBIT	849	<b>755</b>	-11.1%
Financial result	-68	<b>-71</b>	3.6%
Profit before tax	780	<b>684</b>	-12.4%
Income tax	-187	<b>-161</b>	-14.1%
<i>Effective tax rate (%)</i>	<i>24.0 %</i>	<b>23.5%</b>	
Net income	591	<b>521</b>	-11.8%
EPS (€)	1.36	<b>1.20</b>	-11.8%

### Comments

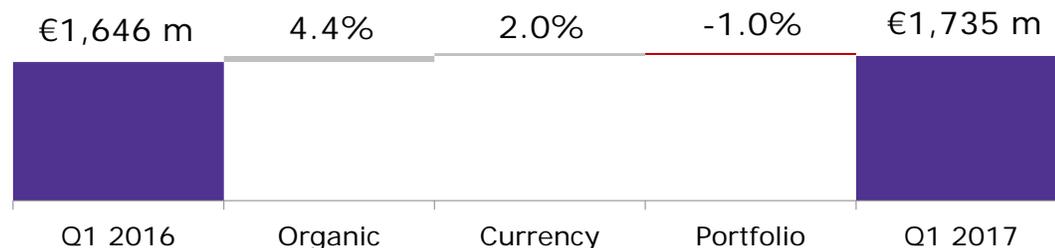
- EBIT decline reflects income from Kuvan sale LY
- Stable financial result – deleveraging compensated by higher interest rates and positive LTIP effect LY
- Effective tax rate within guidance range of ~23-25%

# Healthcare: Solid base business and one-time gains supporting margin

## Healthcare P&L

[€m]	Q1 2016	Q1 2017
Net sales	1,646	<b>1,735</b>
Marketing and selling	- 613	<b>-656</b>
Administration	- 71	<b>-77</b>
Research and development	- 378	<b>-376</b>
EBIT	641	<b>445</b>
EBITDA	829	<b>629</b>
EBITDA pre	508	<b>633</b>
Margin (in % of net sales)	30.9 %	<b>36.5%</b>

## Net sales bridge

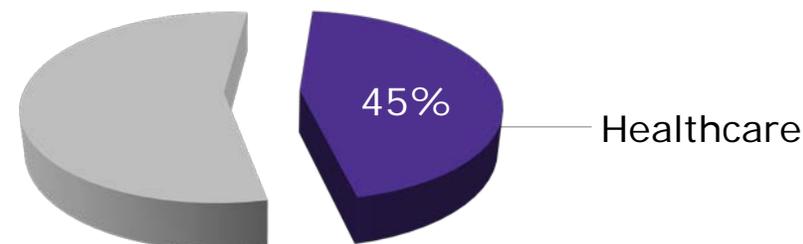


\*Productive Development Partnership  
Totals may not add up due to rounding

## Comments

- Organic growth supported by Glucophage repatriation in China
- Rebif with ongoing volume and price declines in Europe outweighing U.S. pricing and contribution from PDP\* in Brazil
- Erbitux shows moderate organic growth benefiting from demand in growth markets; competitive pressure in Europe persists
- Marketing & selling reflects investments for launch preparations and costs for Glucophage repatriation in China
- R&D costs phased – ramp-up towards coming quarters
- EBIT last year contained Kuvan disposal gain of €324 m
- Profitability spike mainly driven by net benefit of royalty income swap (~€100m) and Bavencio milestone, outweighing negative product mix

## Q1 2017 share of group net sales



# Progress in Q1 sets course for future success in 2017

## Business performance



- Rebif: 5.5% U.S. price increase in January 2017
- Erbitux: NICE recommendation for 1L mCRC
- Fertility: Approval of new fertility pen for Pergoveris
- General Medicine: Repatriated Glucophage business from BMS in China

## Pipeline delivering



- Avelumab: Accelerated approval for both mMCC (U.S.) and UC\* 2L (U.S.); 9<sup>th</sup> Phase III started (LA/SCCHN)
- DNA Damage & Repair: four oncology programs in-licensed from Vertex
- BTK-i: 3<sup>rd</sup> Phase II study initiated (RRMS)
- Anti-IL-17 A/F nanobody partnered with Avillion in unique development model
- Biosimilars divestment announced

Acronyms: NICE = National Institute for Health and Care Excellence (UK); mCRC = Metastatic colorectal cancer; CHMP = Committee for Medicinal Products for Human Use; BMS = Bristol-Myers Squibb; mMCC = Metastatic Merkel Cell Carcinoma; UC = Urothelial Cancer; LA/SCCHN = Locally advanced squamous cell carcinoma of the head and neck; RRMS = Relapsing Remitting Multiple Sclerosis;

\*The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) metastatic Merkel cell carcinoma (mMCC) in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy therapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

## Key ASCO abstracts at a glance (two oral presentations)

### MCC (1L)

- Initial results from a cohort of chemotherapy-naïve pts with mMCC (ongoing study)
- Manageable safety profile, consistent with findings for 2L+ cohort
- **Unconfirmed ORR: 64.0%** (≥6 weeks follow-up) / **Confirmed ORR: 56.3%** (≥3 months follow-up)
- Avelumab is associated with early responses; preliminary results suggest that responses mature to become durable

### NSCLC

- Exposure-response and PD-L1 expression analysis of NSCLC 2L (Phase I cohort)
- Patients in upper half of increased exposure ( $C_{\text{troughfirst}}$ -dose quartiles Q3-Q4) showed increasing ORR (by higher PD-L1-staining level); **ORR: 25% (≥1%); 26% (≥5%); 33% (≥50%); 43% (≥80%)\***
- Analysis provides rationale for the modification of the NSCLC 1L Phase III trial

### Urothelial

- Updated efficacy and safety data of avelumab in metastatic urothelial carcinoma 2L (pooled Phase Ib)
- Durable responses in heavily pretreated patients, irrespective of tumor PD-L1 expression status
- **Confirmed ORR: 17.4%**; 6.2% CR (≥6m follow-up)

### RCC (oral presentation)

- First line avelumab + axitinib therapy in patients with advanced renal cell carcinoma 1L (Phase Ib)
- Preliminary findings confirm manageable safety profile and consistent with agents administered as monotherapy
- **Confirmed ORR: 54.5%**, based on 2 CR and 28 PR (follow-up ongoing)

### Anti PD-L1/ TGF-beta trap (oral presentation)

- Preliminary results from Phase I dose-escalation study (bifunctional fusion protein targeting PD-L1 and TGF-β)
- Manageable safety profile in patients with heavily pre-treated advanced solid tumors
- Early signs of clinical efficacy: **1 ongoing confirmed CR** (cervical) and **1 durable PR** (pancreatic), a 25% reduction in the sum of diameters of target lesions after 2 doses of M7824 (cervical), and 2 cases of prolonged stable disease (pancreatic; carcinoid).

Source: ASCO abstracts; Acronyms: ORR: Objective Response Rate | PFS: Progression-free survival | OS: Overall Survival | CR: complete response | PR: partial response

\*These ORRs are higher compared to the lower half

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.

## Newsflow: Upcoming pipeline catalysts

Avelumab	▶ Expected EMA decision (MCC)	▶ H2 2017
BTK inhibitor (RA)	▶ Phase IIa signal confirmation <sup>1</sup>	▶ Q2 2017
M7824 (anti PD-L1 – TGF-beta trap)	▶ Phase I interim data <sup>1</sup>	▶ mid 2017
Cladribine tablets	▶ Expected EMA decision	▶ Q3 2017
Sprifermin	▶ Final Phase II data readout <sup>1</sup>	▶ Q3 2017
Avelumab	▶ Phase III data readout (Gastric 3L) <sup>1</sup> ▶ Phase III data readout (NSCLC 2L) <sup>1</sup>	▶ Q1 2018 ▶ H1 2018
Atacicept	▶ Phase III decision	▶ Subject to interaction with authorities

Note: Timelines are event-driven and may change; Acronyms: MCC = Merkel cell carcinoma | RA: Rheumatoid Arthritis | NSCLC: Non small cell lung cancer  
(1) Data-read out is internal date. Data to be presented at upcoming scientific congress.

# Life Science: Ongoing synergy realization drives margin progression

## Life Science P&L

[€m]	Q1 2016	Q1 2017
Net sales	1,397	<b>1,481</b>
Marketing and selling	- 421	<b>-449</b>
Administration	- 63	<b>-70</b>
Research and development	- 62	<b>-62</b>
EBIT	105	<b>236</b>
EBITDA	284	<b>430</b>
EBITDA pre	393	<b>445</b>
Margin (in % of net sales)	28.1 %	<b>30.1%</b>

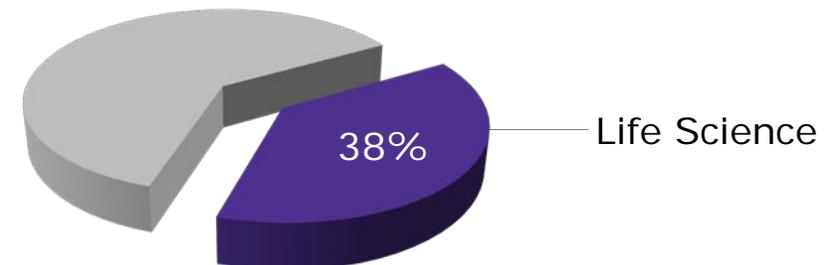
## Net sales bridge



## Comments

- Process Solutions benefits from robust demand for single-use and upstream, but against tough comps & soft start at some larger accounts
- Applied Solutions shows solid organic growth, fueled by robust demand for food & beverage testing and lab water platform
- Research Solutions posts slight organic growth from solid demand in growth markets outweighing challenging U.S. market environment
- Marketing & selling increase in line with sales progression
- Q1 2016 EBIT affected by inventory step-up for Sigma-Aldrich
- Profitability reflects ongoing synergy realization and organic growth

## Q1 2017 share of group net sales

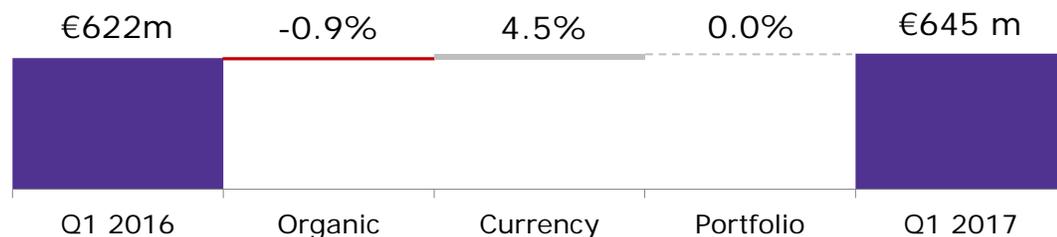


# Performance Materials: Top line recovery despite still declining Liquid Crystals

## Performance Materials P&L

[€m]	Q1 2016	Q1 2017
Net sales	622	<b>645</b>
Marketing and selling	-58	<b>-62</b>
Administration	-16	<b>-18</b>
Research and development	-48	<b>-58</b>
EBIT	207	<b>195</b>
EBITDA	267	<b>257</b>
EBITDA pre	273	<b>263</b>
Margin (in % of net sales)	43.9 %	<b>40.9%</b>

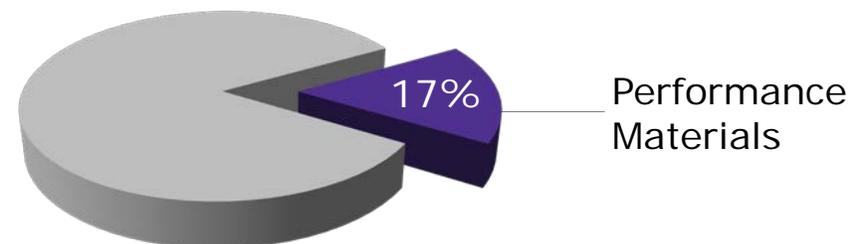
## Net sales bridge



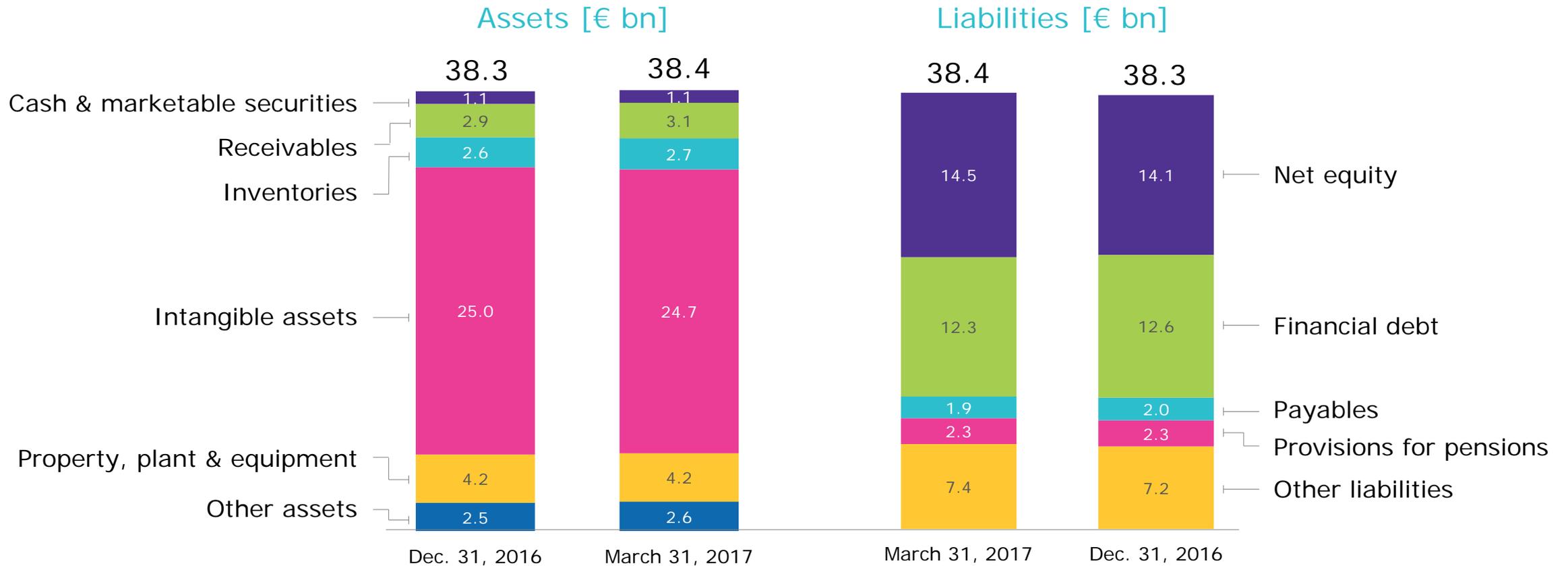
## Comments

- Organic growth of Integrated Circuit Materials, Pigments and OLED mitigate LC softness
- Liquid Crystals impacted by further market share normalization
- Integrated Circuit Materials with record quarter and above market growth due to strong demand from key accounts
- Pigments & Functionals post solid organic growth mainly driven by coatings applications especially automotive
- R&D increase reflects investments in LC technologies beyond displays
- Sound profitability despite negative business mix & higher R&D

## Q1 2017 share of group net sales



# Balance sheet – focus on rapid deleveraging



- Total assets about stable, while equity ratio increases to 37.8%
- Reduction of intangible assets reflects D&A and FX, more than offsetting new assets from Vertex licensing deal

- Net equity increase driven by profit after tax
- USD250 m bond repayment reduces financial debt

## Strong operating cash flow benefits from royalty swap and tax effects

### Q1 2017 – cash flow statement

[€m]	Q1 2016	Q1 2017	Δ
Profit after tax	593	<b>523</b>	-70
D&A	433	<b>448</b>	15
Changes in provisions	21	<b>51</b>	30
Changes in other assets/liabilities	-34	<b>134</b>	168
Other operating activities	-394	<b>-11</b>	383
Changes in working capital	-266	<b>-368</b>	-102
Operating cash flow	352	<b>777</b>	425
Investing cash flow	284	<b>-402</b>	-686
thereof Capex on PPE	-160	<b>-201</b>	-41
Financing cash flow	-572	<b>-290</b>	282

### Cash flow drivers

- LY profit after tax includes gain from Kuvan sale, which is neutralized in other operating activities
- Changes in other assets/liabilities benefit from positive tax effects
- Changes in working capital reflect new Glucophage China business and higher R&D receivables from Pfizer
- Investing cash flow contains increased Capex and Vertex licensing deal; LY included sale of Kuvan
- Financing cash flow reflects repayment of USD250 m bond



04

**GUIDANCE**

## Full-year 2017 guidance

▶ Net sales: ~ €15.5 – 16.0 bn ◀

▶ EBITDA pre: ~ €4,400 – 4,600 m ◀

▶ EPS pre: ~ €6.15 – 6.50 ◀



## 2017 business sector guidance



### Net sales

- Slight organic growth
- Ongoing organic Rebif decline
- Other franchises growing; repatriation of Glucophage/China supportive

### EBITDA pre

~ €1,900 – 2,000m



### Net sales

- Organic growth slightly above market, driven by Process Solutions
- First minor contribution of top-line synergies

### EBITDA pre

~ €1,780 – 1,850m



### Net sales

- Slight organic decline
- Volume increases in all businesses
- Further market share normalization in Liquid Crystals

### EBITDA pre

~ €1,050 – 1,130m



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## APPENDIX

# Additional financial guidance 2017

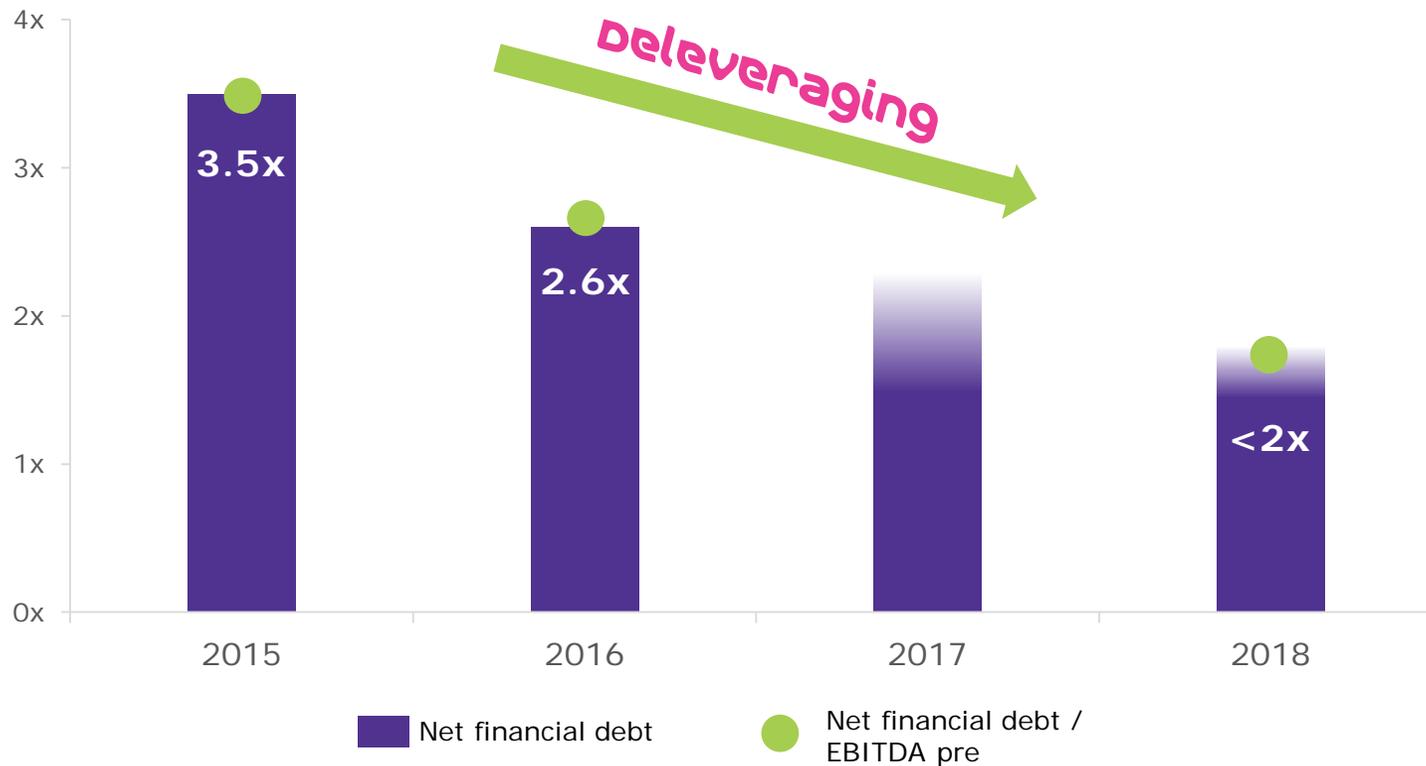
## Further financial details

Corporate & Other EBITDA pre	~ -€350 – -400m
Interest result	~ -€250 – -260 m
Effective tax rate	~ 23% to 25%
Capex on PPE	~ €850 – 900 m
Hedging/USD assumption	<b>2017 hedge ratio ~60% at EUR/USD ~ 1.11 to 1.12</b>
2017 Ø EUR/USD assumption	~ 1.06 – 1.10

# Strong focus on cash generation to ensure swift deleveraging

## Net financial debt\* and leverage development

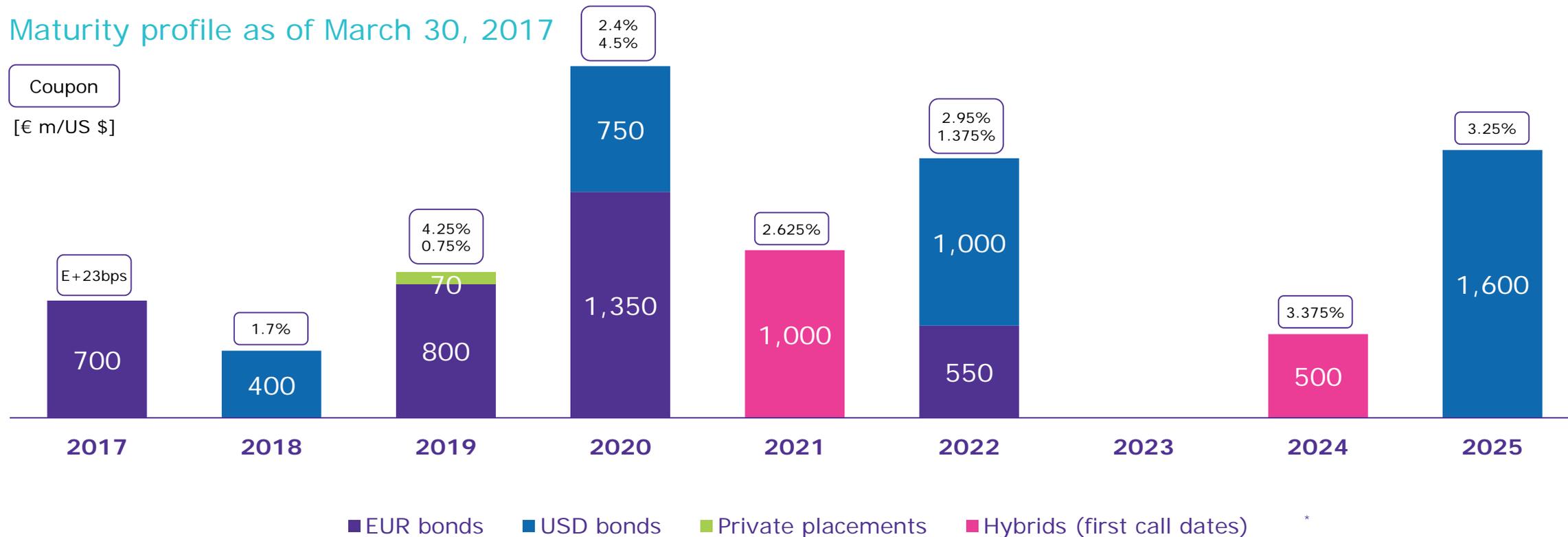
[Net financial debt/  
EBITDA pre]



## Focus on deleveraging

- Commitment to swift deleveraging to ensure a strong investment grade credit 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 (or financed by divestments)

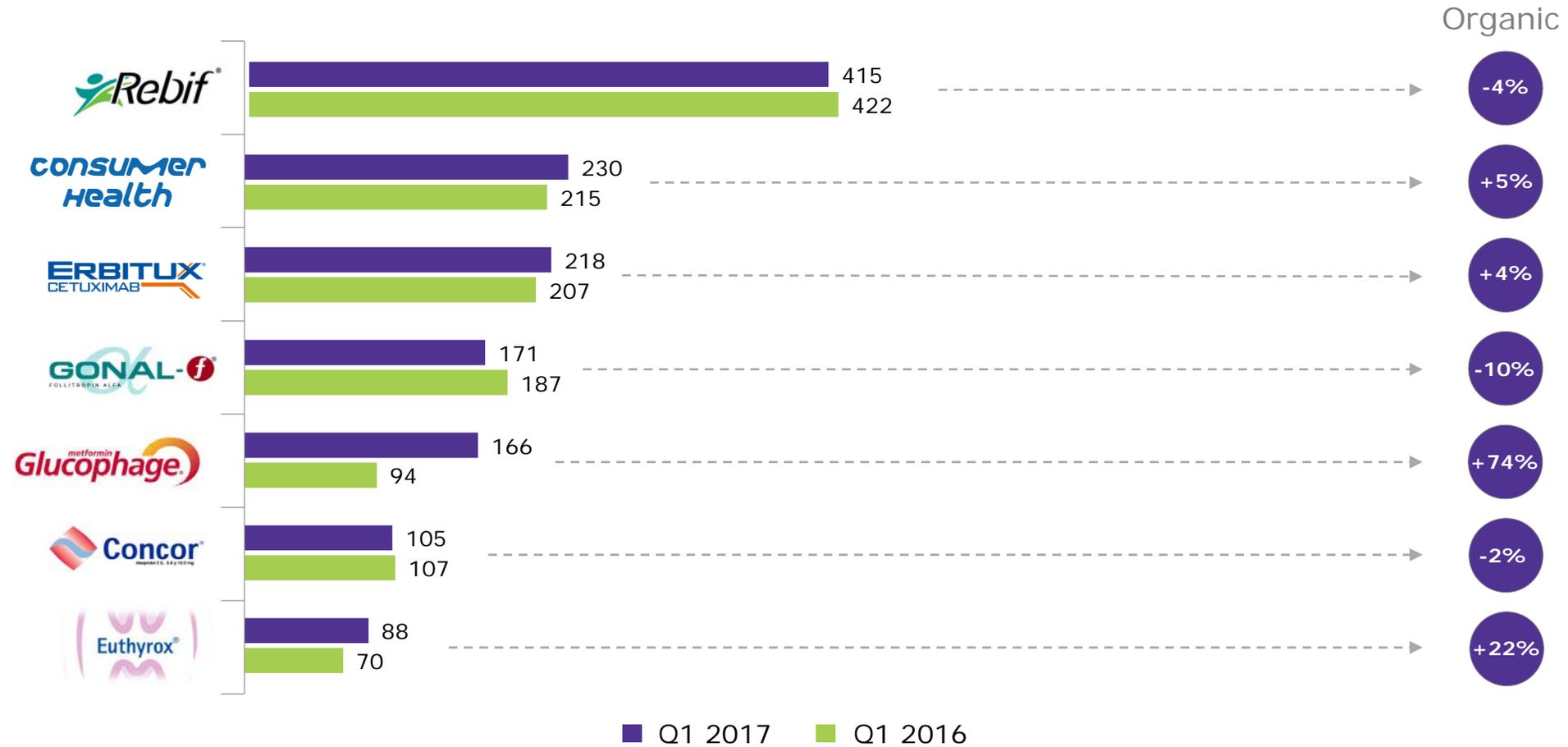
# Well-balanced maturity profile reflects capital market transactions related to Sigma-Aldrich



Financing structure enables flexible and swift deleveraging

# Healthcare organic growth by franchise/product

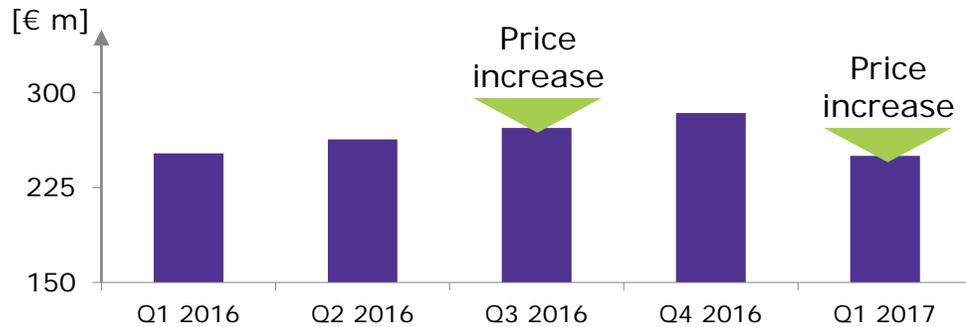
Q1 2017 organic sales growth [%] by key franchise/products [€ m]



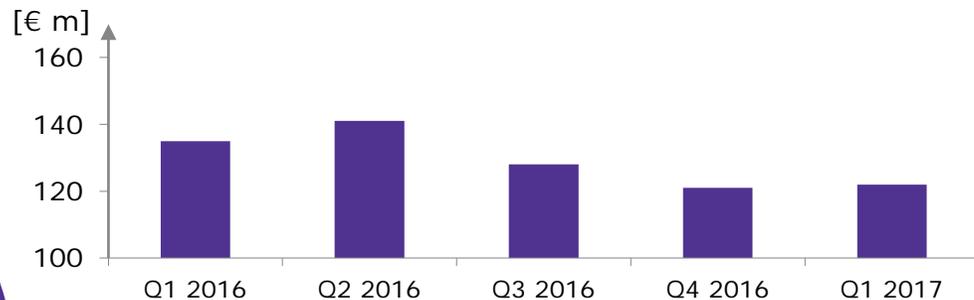
# Rebif: Relief in the U.S. – competitive ramp-up in Europe ongoing

## Rebif sales evolution

### North America



### Europe



### Q1 drivers

-4.6% org.



Price



Volume



FX

### Q1 drivers

-9.3% org.



Price



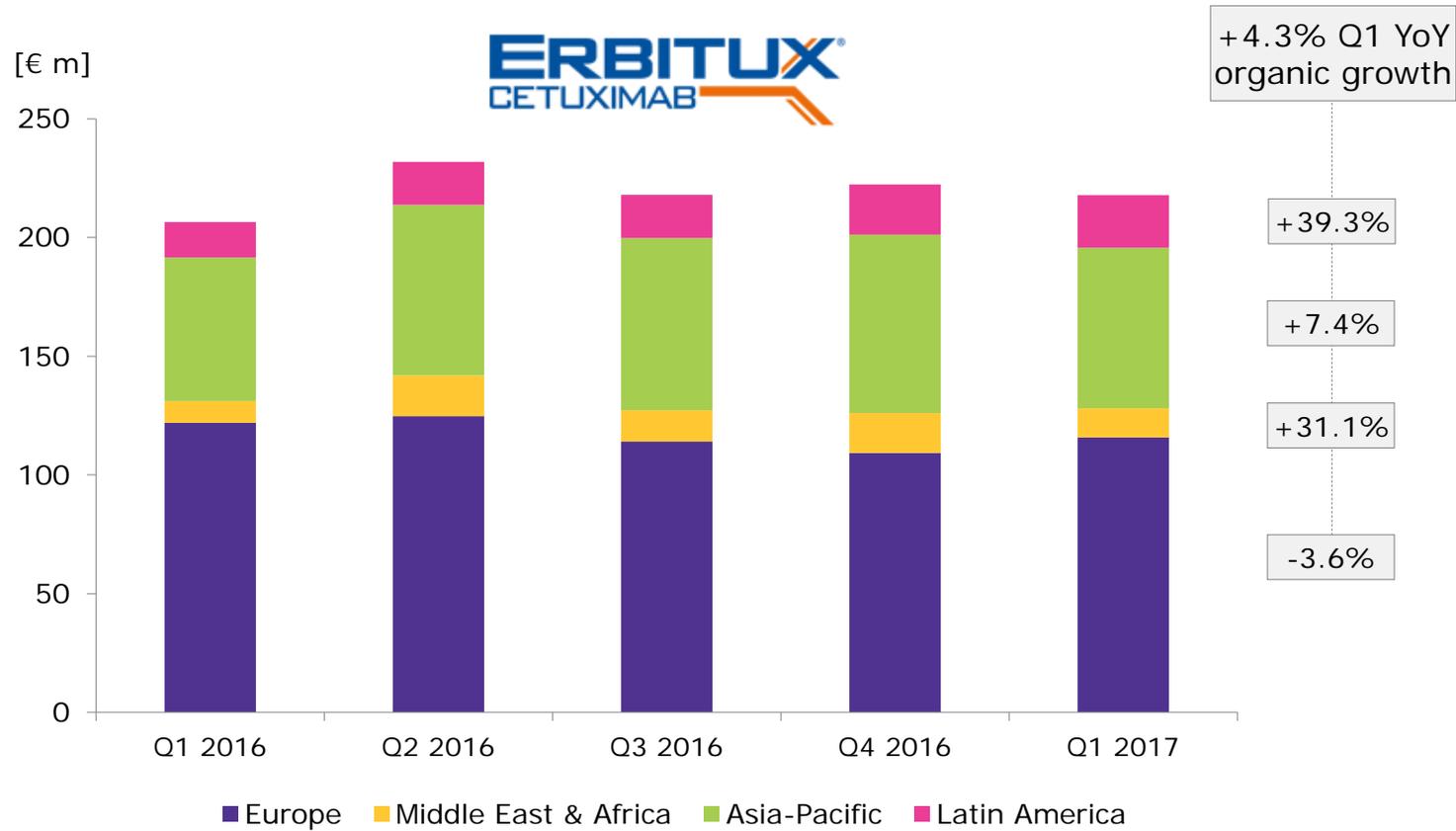
Volume

## Q1 2017 Rebif performance

- Rebif sales of €415 m in Q1 2017 reflect organic decline of -4.0% and positive FX effects from the U.S.
- U.S. price increase in January, partially offsets U.S. volume erosion
- Market shares within interferons stable due to high retention rates and known long-term track record
- Phased market entry of orals and mandatory price cuts in Europe cause ongoing organic decline
- Productive Development Partnership (PDP) in Brazil supports Rebif growth in LATAM

# Erbitux: A challenging market environment

## Erbitux sales by region



## Q1 2017 Erbitux performance

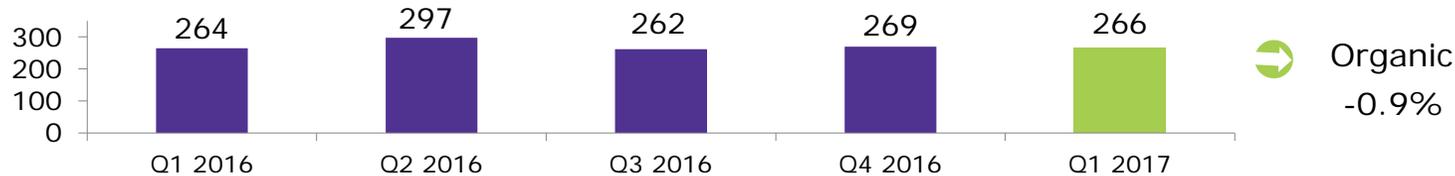
- Sales increase to €218m due to solid volume development in growth markets and slight FX tailwinds
- Europe impacted by competition and shrinking market size due to increasing Immuno-Oncology trials
- APAC with healthy organic growth driven by higher volumes in China
- LATAM and MEA shows strong growth from higher demand, but also benefited from tender phasing

# Strong organic growth of General Medicine driven by Glucophage repatriation

## Sales evolution

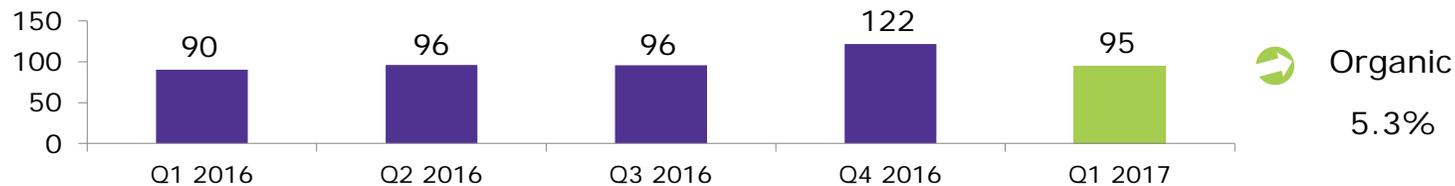
### Fertility

[€ m]



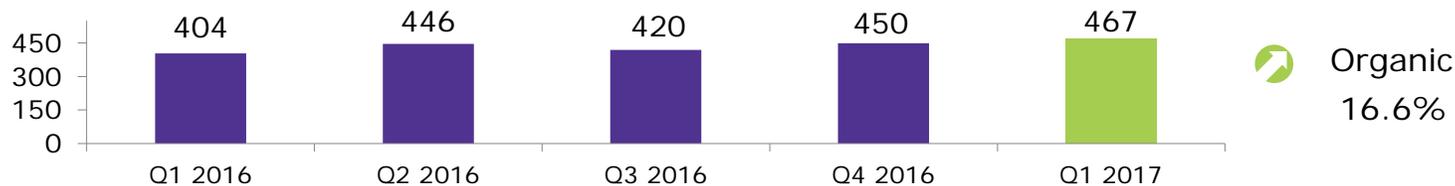
### Endocrinology

[€ m]



### General Medicine\*

[€ m]



## Q1 2017 organic drivers

- Fertility slightly lower, mainly due to Gonal-f facing tough comps and competition from biosimilars in Europe
- Other fertility drugs continue to grow across all major regions
- Release of accruals for rebates for Saizen supports Endocrinology growth
- General Medicine growth benefits from Glucophage China repatriation
- Euthyrox posts strong growth driven by ongoing strong demand from China
- Concor slightly negative due to order phasing in Russia

# Clinical pipeline

## Phase I

**M2698 – p70S6K & Akt inhibitor**  
Solid tumors

**M3814 – DNA-PK inhibitor**  
Solid tumors

**M9831 (VX-984) – DNA-PK inhibitor**  
Solid tumors

**M6620<sup>7</sup> (VX-970) – ATR inhibitor**  
Solid tumors

**M4344 (VX-803) – ATR inhibitor**  
Solid tumors

**M7583 – BTK inhibitor**  
Hematological malignancies

**Avelumab – Anti-PD-L1 mAb**  
Solid tumors

**Avelumab – Anti-PD-L1 mAb**  
Hematological malignancies

**M9241 (NHS-IL12)  
Cancer immunotherapy**  
Solid tumors

**M7824 - anti-PD-L1/TGF-beta trap**  
Solid tumors

**M1095<sup>9</sup> (ALX-0761)  
Anti-IL-17 A/F nanobody**  
Psoriasis

## Phase II

**Tepotinib  
c-Met kinase inhibitor**  
Non-small cell lung cancer

**Tepotinib  
c-Met kinase inhibitor**  
Hepatocellular cancer

**Avelumab – Anti-PD-L1 mAb**  
Merkel cell carcinoma 1L<sup>1</sup>

**Sprifermin  
Fibroblast growth factor 18**  
Osteoarthritis

**Atacicept  
Anti-Blys/anti-APRIL fusion protein**  
Systemic lupus erythematosus

**Atacicept  
Anti-Blys/anti-APRIL fusion protein**  
IgA nephropathy

**Evobrutinib  
BTK inhibitor**  
Rheumatoid arthritis

**Evobrutinib  
BTK inhibitor**  
Systemic lupus erythematosus

**Abituzumab  
anti-CD 51 mAb**  
Systemic sclerosis with interstitial lung disease

**Evobrutinib  
BTK inhibitor**  
Multiple sclerosis

## Phase III

**Avelumab – Anti-PD-L1 mAb**  
Non-small cell lung cancer 1L<sup>1</sup>

**Avelumab – Anti-PD-L1 mAb**  
Non-small cell lung cancer 2L<sup>2</sup>

**Avelumab – Anti-PD-L1 mAb**  
Gastric cancer 1L<sup>TM</sup>

**Avelumab – Anti-PD-L1 mAb**  
Gastric cancer 3L<sup>3</sup>

**Avelumab – Anti-PD-L1 mAb**  
Urothelial cancer 1L<sup>TM</sup>

**Avelumab – Anti-PD-L1 mAb**  
Ovarian cancer platinum resistant/refractory

**Avelumab – Anti-PD-L1 mAb**  
Ovarian cancer 1L<sup>1</sup>

**Avelumab - Anti-PD-L1 mAb**  
Renal cell cancer 1L<sup>1</sup>

**Avelumab - Anti-PD-L1 mAb**  
Locally advanced head and neck cancer

**MSB11022<sup>8</sup>  
Proposed biosimilar of Adalimumab**  
Chronic plaque psoriasis

## Registration

**Cladribine<sup>4</sup> Tablets –  
Lymphocyte targeting agent**  
Relapsing-remitting multiple sclerosis

**Avelumab<sup>5</sup> – Anti-PD-L1 mAb**  
Merkel cell carcinoma

## Recently registered

**Avelumab<sup>5</sup> – Anti-PD-L1 mAb**  
Merkel cell carcinoma

**Avelumab<sup>6</sup> – Anti-PD-L1 mAb**  
Urothelial cancer 2L<sup>2</sup>

- Neurology
- Oncology
- Immunology
- Immuno-Oncology
- Biosimilars

Pipeline as of May 11<sup>th</sup>, 2017

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> 1st line treatment; <sup>TM</sup> First Line maintenance treatment; <sup>2</sup> 2nd line treatment; <sup>3</sup> 3rd line treatment; <sup>4</sup> European Medicines Agency (EMA) accepted Marketing Authorization Application (MAA) from Merck KGaA, Darmstadt, Germany in July 2016; <sup>5</sup> EMA accepted MMA from Merck KGaA, Darmstadt, Germany in July 2016 and on March 23, 2017, the US FDA has approved avelumab for the treatment of adults and pediatric patients 12 years and older; <sup>6</sup> On May 9, 2017 the US FDA approved avelumab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy therapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; <sup>7</sup> Includes expansion cohorts in non small cell lung cancer, small cell lung cancer and triple negative breast cancer; <sup>8</sup> On April 24, 2017 Merck KGaA, Darmstadt, Germany announced the divestment of its Biosimilars business to Fresenius, closing is expected in H2 2017, subject to regulatory approvals and other conditions; <sup>9</sup> As announced on March 30, 2017 in an agreement with Avillion, anti-IL-17 A/F nanobody will be developed by Avillion for plaque psoriasis and commercialized by Merck KGaA, Darmstadt, Germany

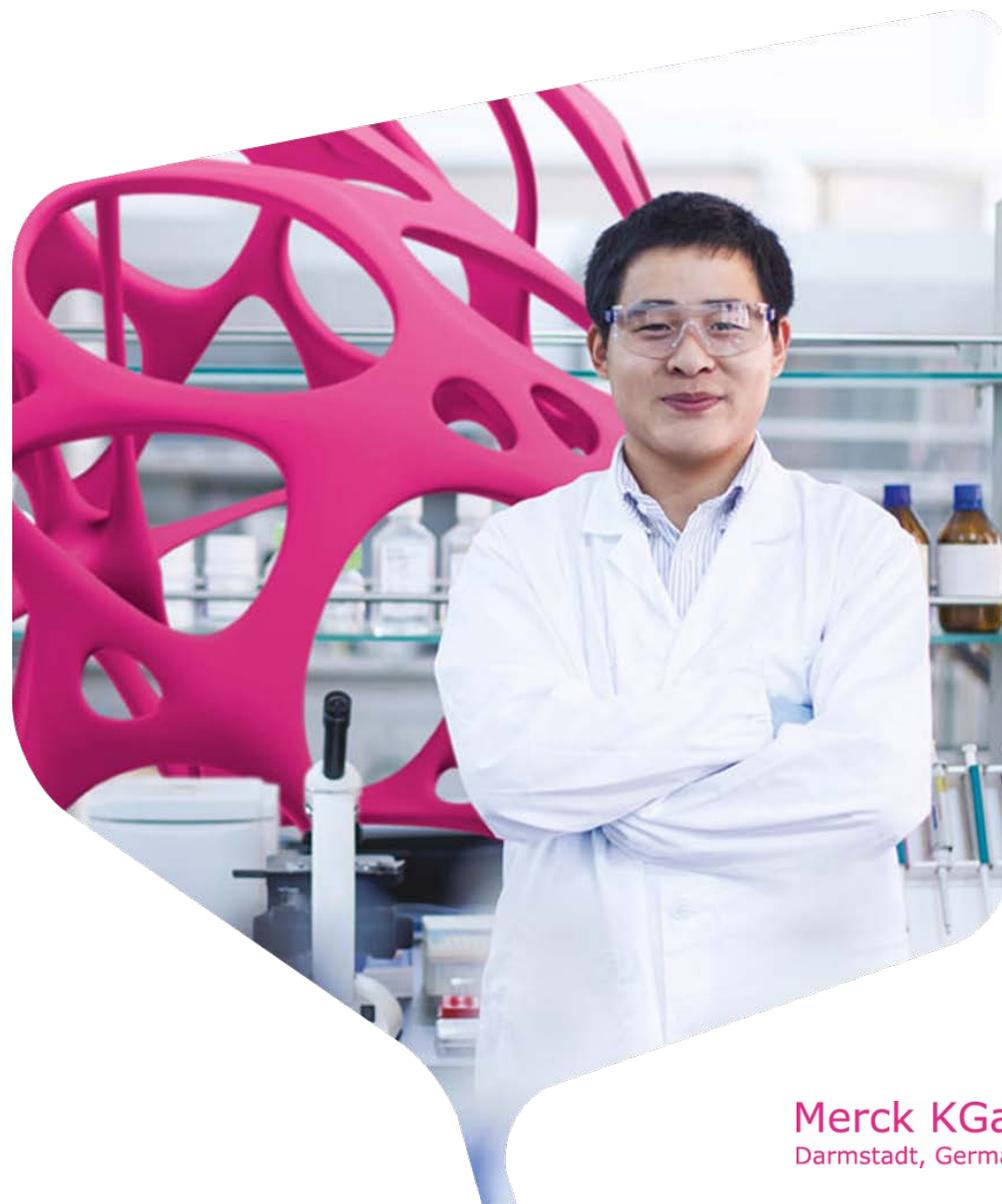
# Exceptionals in Q1 2017

## Exceptionals in EBIT

[€m]	Q1 2016		Q1 2017	
	Exceptionals	thereof D&A	Exceptionals	thereof D&A
Healthcare	-321	0	4	1
Life Science	109	0	16	0
Performance Materials	6	0	7	0
Corporate & Other	7	0	15	3
Total	-198	0	41	4

## Financial calendar

Date	Event
June 12, 2017	R&D Update Call
August 3, 2017	Q2 2017 Earnings release
November 9, 2017	Q3 2017 Earnings release
March 8, 2018	Q4 2017 Earnings release
April 27, 2018	Annual General Meeting
May 15, 2018	Q1 2018 Earnings release



## CONSTANTIN FEST



Head of Investor Relations  
+49 6151 72-5271  
constantin.fest@emdgroup.com

## SVENJA BUNDSCHUH



Assistant Investor Relations  
+49 6151 72-3744  
svenja.bundschuh@emdgroup.com

## ALESSANDRA HEINZ



Assistant Investor Relations  
+49 6151 72-3321  
alessandra.heinz@emdgroup.com

## ANNETT WEBER



Institutional Investors /  
Analysts  
+49 6151 72-63723  
annett.weber@emdgroup.com

## NILS VON BOTH



Institutional Investors /  
Analysts  
+49 6151 72-7434  
nils.von.both@emdgroup.com

## EVA STERZEL



Private Investors / AGM /  
CMDs / IR Media  
+49 6151 72-5355  
eva.sterzel@emdgroup.com

## OLLIVER LETTAU



Institutional Investors /  
Analysts  
+49 6151 72-34409  
olliver.lettau@emdgroup.com

**EMAIL:** [investor.relations@emdgroup.com](mailto:investor.relations@emdgroup.com)  
**WEB:** [www.emdgroup.com/investors](http://www.emdgroup.com/investors)  
**FAX:** +49 6151 72-913321

