

# SOLID GROWTH AT THE START OF THE YEAR

Merck KGaA, Darmstadt, Germany Q1 2019 results

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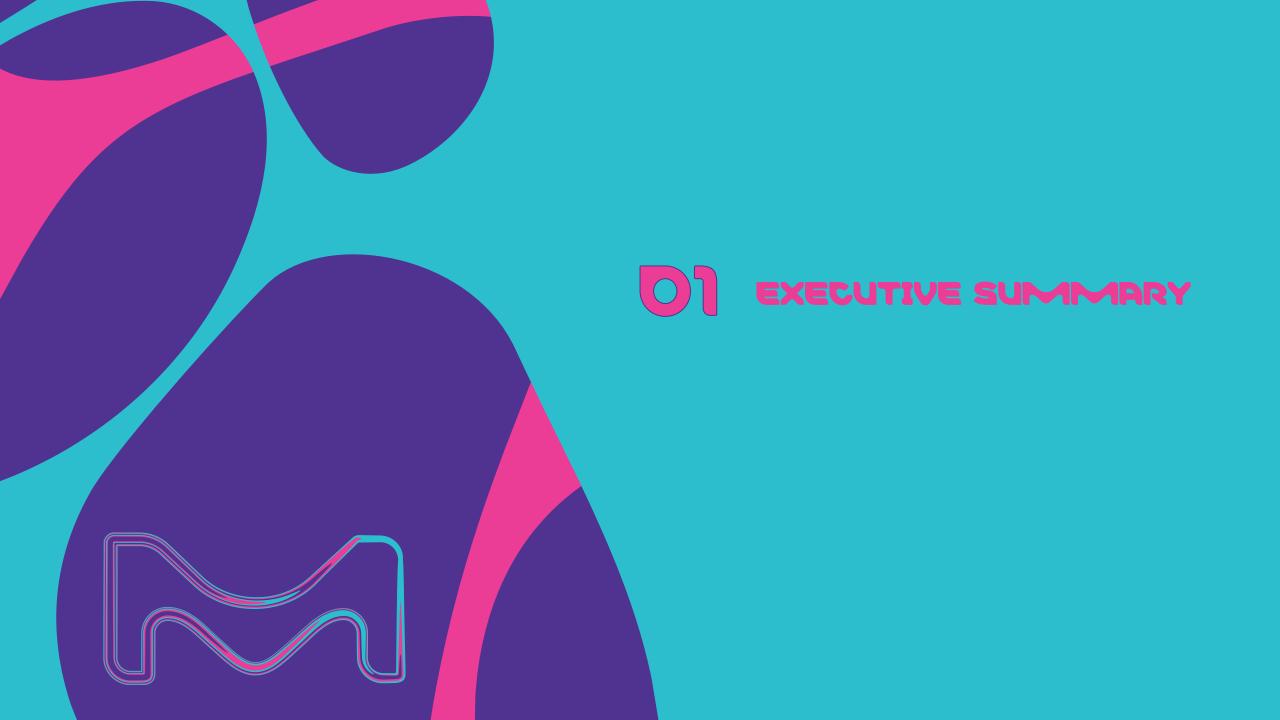
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# **Agenda**

- **Executive summary**
- **©2** Financial overview
- **Guidance**



# **Highlights**



- Healthcare Mavenclad<sup>®</sup> U.S. approval in March 2019, continued strong uptake in ex-US territories and M7824 alliance with GSK announced in February 2019
- Life Science Very strong organic growth fueled by all businesses across all regions
- Performance Materials Ongoing strong demand for LC and OLED; market demand driven softness in Semiconductor Solutions

**Financials** 

- Q1 2019 organic sales growth of +5.7%; Q1 2019 organic EBITDA pre decline of -2.0%
- Full-year 2019 guidance net sales: €15.3 to 15.9 bn; EBITDA pre: € 4,150 to 4,350 m; EPS pre: € 5.30 to 5.65
- Merger agreement with Versum Materials signed\* financing secured

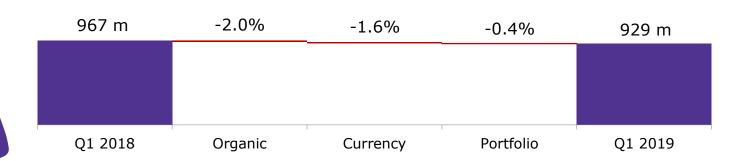
## All business sectors drive organic growth supported by FX tailwinds

## Q1 2019 YoY net sales

	Organic	Currency	Portfolio	Total
Healthcare	2.9%	0.4%	0.0%	3.2%
Life Science	9.4%	2.8%	-0.5%	11.7%
Performance Materials	3.2%	3.9%	0.0%	7.1%
Group	5.7%	2.0%	-0.2%	7.5%

- Healthcare growth driven by General Medicine, Fertility, Mavenclad<sup>®</sup> and Bavencio<sup>®</sup>, offsetting strong Rebif<sup>®</sup> decline
- Life Science with above-market growth driven by all business units
- Performance Materials still driven by temporary
   LC uptake and ongoing strong demand for OLED;
   softer market demand for Semiconductor Solutions

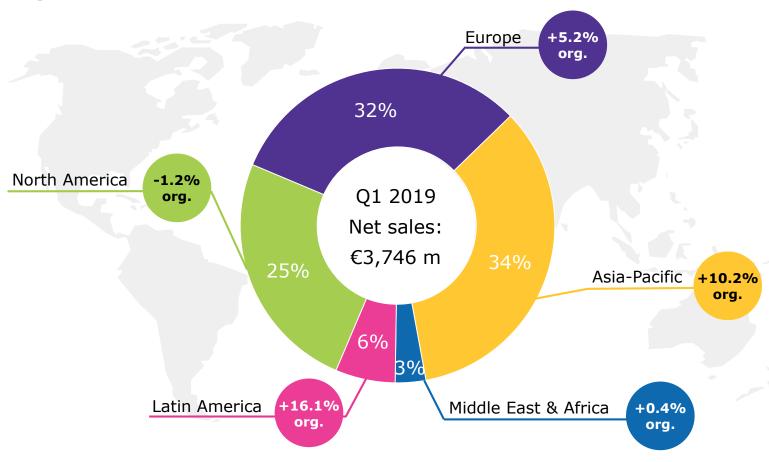
## Q1 YoY EBITDA pre



- Lower organic EBITDA pre reflects strong performance of LS offset by last year milestone payment in HC and ongoing LC price decline
- Negative FX impact on EBITDA pre due to hedging losses related to EUR/USD development

## Organic growth driven by Asia-Pacific, Europe and Latin America

## Regional breakdown of net sales [€ m]



## Regional organic development

- Strong growth in APAC fueled by doubledigit growth of Life Science, Glucophage<sup>®</sup>, Erbitux<sup>®</sup> and OLED; LC still benefitting from temporary capacity ramp-up in China
- Europe with solid growth due to ongoing strong demand in Life Science; strong Mavenclad<sup>®</sup> ramp-up offsets Rebif<sup>®</sup> decline
- North America reflects robust demand in Life Science offset by double-digit decline of Rebif<sup>®</sup>
- Double-digit growth in LATAM due to strong demand for General Medicine and Life Science
- About stable Middle East and Africa driven by solid demand in Life Science offsetting softer Healthcare

Merck KGaA

Darmstadt, Germany



## Q1 2019: Overview

## Key figures

[€m]	Q1 2018*	Q1 2019	Δ
Net sales	3,486	3,746	7.5%
EBITDA pre Margin (in % of net sales)	967 <i>27.7%</i>	<b>929</b> 24.8%	-4.0%
EPS pre	1.33	1.13	-15.4%
Operating cash flow	380	493	29.5%
[€m]	Dec. 31, 2018	March 31, 2019	Δ
Net financial debt	6,701	7,089	5.8%
Working capital	3,486	3,782	8.5%
Employees	51,749	52,140	1.0%

#### Comments

- Net sales reflect organic sales growth across all business sectors fueled by FX tailwinds
- EBITDA pre & margin decrease due to hedging losses and LC price decline; last year contained Peg-Pal milestone (€50 m)
- Lower EPS pre driven by impairment of asset from F-star collaboration (~€27 m) and D&A from IFRS 16 effect (~€32 m)
- LY operating cash flow driven by higher income tax payments
- Working capital reflects increased business activity
- Higher net financial debt mainly due to IFRS
   16 reclassification

## **Reported figures**

## Reported results

[€m]	Q1 2018*	Q1 2019	Δ
EBIT	502	379	-24.6%
Financial result	-61	-113	83.9%
Profit before tax	441	266	-39.6%
Income tax	-108	-67	-37.8%
Effective tax rate (%)	24.5%	25.2%	
Net income	341	189	-44.7%
EPS (€)	0.78	0.43	-44.9%

#### Comments

- Lower EBIT reflects hedging losses and LC price decline; last year EBIT included Peg-Pal milestone
- •Lower financial result driven by revaluation of F-Star purchase option (-€45 m)
- Effective tax rate within guidance range of ~24-26%
- Lower net income and EPS reflect lower financial result and lower EBIT

# Healthcare: Solid core business and strong Mavenclad weighed down by last year's Peg-Pal milestone payment

#### Healthcare P&L

[€m]	Q1 2018*	Q1 2019
Net sales	1,435	1,481
Marketing and selling	-550	-550
Administration	-77	-88
Research and development	-379	-380
EBIT	195	128
EBITDA	379	329
EBITDA pre	381	332
Margin (in % of net sales)	26.6%	22.4%

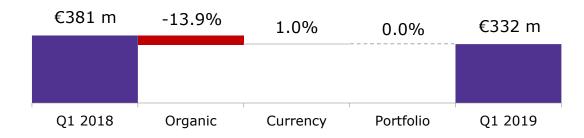
#### Net sales bridge



#### Comments

- Organic growth driven by double-digit growth of General Medicine and ongoing strong demand in Fertility
- Mavenclad<sup>®</sup> with continued strong uptake and U.S. approval in March 2019, mitigating ongoing Rebif<sup>®</sup> decline
- Bavencio<sup>®</sup> ramp-up on track; Erbitux<sup>®</sup> benefitting from China reimbursement, still facing ongoing competition and price pressure in major markets
- Flat M&S reflects pre-launch investments attributable to Mavenclad  $^{\otimes}$  and Bavencio  $^{\otimes}$  as well as investments to drive growth in China offset by lower investments in mature products
- Last year EBITDA pre higher due to Peg-Pal milestone payment (€50 m)

## EBITDA pre bridge

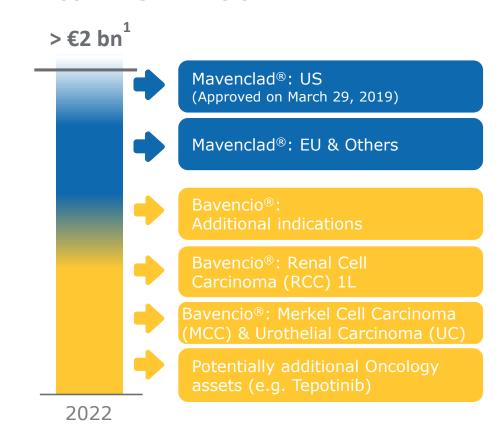


# Mavenclad® and Bavencio® are on track and support the €2 bn pipeline target

#### Global launches gaining traction ...

- Approved in 55 countries since 2017 (incl. USA, Canada, EU, Australia and Switzerland)
- Reimbursed in approx. 50% of markets, payer negotiations ongoing
- Global peak sales: 1 1.4 bn € 2019 sales: up to mid-triple-digit m €
- Approved: Merkel cell carcinoma (US, EU, JP) and urothelial carcinoma (US)
- Regulatory submission on track: Priority Review granted by US FDA, filing validated by EMA, filing submitted in Japan
- Upcoming Ph III read outs: Gastric 1L and NSCLC 1L

#### ... and supporting €2 bn pipeline sales ambition



MAVENCLAD

# Broad Multiple Sclerosis (MS) portfolio positions Merck KGaA, Darmstadt, Germany as a key player both now and in the future





#### Launch



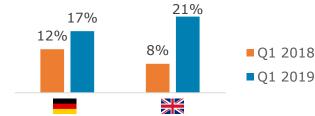
# EVODRULINIO (BTK-Inhibitor)





- First BTKi demonstrating Proofof-concept in MS: 48 week data
  presented at AAN 2019 and
  published in the New England
  Journal of Medicine, demonstrating
  rapid lesion reductions on MRI
  maintained through week 48, with
  no new safety signals
- Upcoming milestones: Initiation of Ph III (MS) to follow in H2 2019

- US Approval: Received US approval on March 29, 2019 for both RRMS and active SPMS
- US Market Access: Attained coverage by Express Scripts<sup>1</sup> (leading US pharmacy benefits manager) within just one week of approval
- **Ex-US Market Penetration:** Achieving increase in market shares despite growing competition<sup>2</sup>

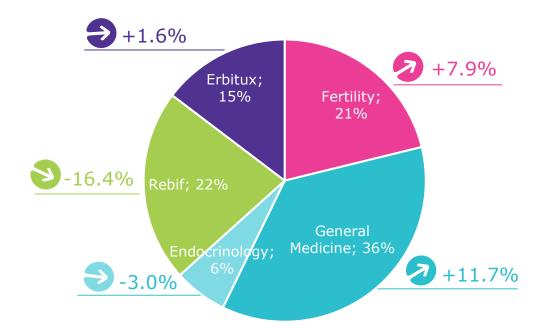


- Stable market share: within the declining interferon class
- **Expanding patient population:** Planned pregnancy label update (end of 2019) removes contraindication & need for contraception, allows use in pregnancy & lactation<sup>3</sup>

<sup>1 &</sup>gt;80 mn members nationally; 2 share of dynamic high efficacy market, UK data source: HMSL, German data source: IQVIA; 3 relevant for ~40% of MS patients (women of childbearing age); Acronyms: AAN = American Academy of Neurology, BTKi = Bruton's tyrosine kinase inhibitor, MRI = Magnetic Resonance Imaging, RRMS = Relapsing Remitting MS. SPMS = Secondary Progressive MS

# Highly resilient core business sustains impressive growth rates despite competitive landscape

## Sales contribution of core business & organic growth rates<sup>1</sup>



# Emerging markets & innovative business models

rentility

- Market leader posting strong growth in Europe and APAC
- Sustainable growth ensured through innovation (e.g. successful launch of Pergoveris<sup>®</sup> pen in 13 countries with mid double-digit annual sales growth YoY)

General Medicine & Endocrinology

- Glucophage's position reinforced through pre-diabetes, now approved in 48 markets vs 19 in Q1 2018
- Concor and Euthyrox growth (18.2% and 13.0% org. YoY) further boosting sales, especially in China and LATAM

Erbitux

- Absolute sales almost stable despite ongoing competition, price reductions and shrinking market
- Inclusion in China's NRDL (National Reimbursement Drug List) driving strong growth in APAC of 29.8% (org.), mitigating decline in Europe and Middle East & Africa

#### **Upcoming catalysts** A year of continued pipeline development<sup>1</sup> Completed Oncology Immuno-Oncology Immunology **ASCO** Neurology R&D Update Call (June 14) Q2 2019 03 2019 **Q4 2019** Q1 2020 Evobrutinib **Tepotinib** (BTK-inhibitor) (c-Met–inhibitor) Ph IIb 48 week data (MS) Expected presentation of PhIII data Expected presentation of IA results (Gastric 1L) presentation at AAN 2019 (NSCLC, MET Exon 14) Evobrutinib Evobrutinib (BTK-inhibitor) (BTK-inhibitor) Expected FDA decision, Expected presentation of Phase II PDUFA date: June 2019 data (SLE and RA) Initiation of PhIII (MS) trial Tepotinib (c-Met-inhibitor) Presentation of advanced IA results (NSCLC, MET Exon 14) at ASCO 2019 Initiation of PhII study of EGFR-mutant NSCLC Initiation of four additional studies including Gastric, 1L BTC, TNBC and HPV related cancers

<sup>&</sup>lt;sup>1</sup> Note: All timelines are event-driven and may be subject to change; <sup>2</sup> proposed International Nonproprietary Name (INN); Acronyms: BTC = Biliary Tract Cancer, BTKi = Bruton's Tyrosine Kinase Ínhibitor, FDA = US Food & Drug Administration, IA = Interim Analysis, MS = Multiple Sclerosis, NSCLC = Non-small Cell Lung Cancer, RCC = Renal Cell Carcinoma, RA = Rheumatoid Arthritis, SLE = Systemic Lupus Erythematosus, TNBC = Triple-Negative Breast Cancer

# Life Science: Strong organic sales growth across all businesses drives margin expansion

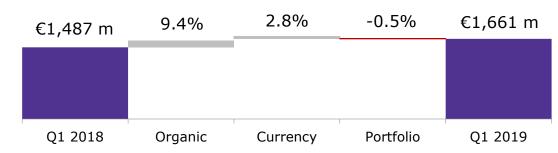
#### Life Science P&L

[€m]	Q1 2018	Q1 2019
Net sales	1,487	1,661
Marketing and selling	-409	-470
Administration	-78	-88
Research and development	-59	-62
EBIT	273	313
EBITDA	442	507
EBITDA pre	455	516
Margin (in % of net sales)	30.6%	31.0%

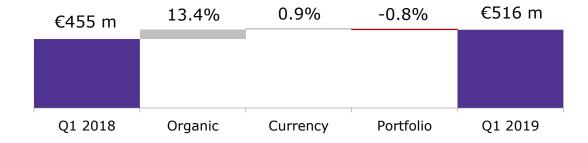
#### Comments

- Ongoing strong demand in Process Solutions with double-digit growth driven by all businesses and all major regions
- Applied Solutions shows high-single digit growth fueled by all businesses across all regions, especially Advanced Analytical and Lab Water
- Research Solutions posts moderate organic growth fueled by ongoing strong demand for lab chemicals and workflow tools across all regions
- M&S increase reflects volume growth, investments in eCommerce and strategic initiatives
- EBITDA pre reflects strong topline and IFRS 16 effect

#### Net sales bridge



### EBITDA pre bridge



# Performance Materials: Organic growth mainly driven by ongoing strong demand for OLED and support from LC capacity ramp-up and low comps

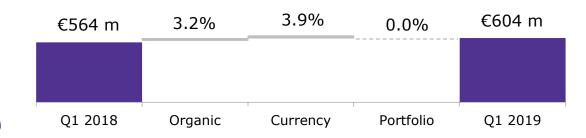
#### Performance Materials P&L

[€m]	Q1 2018	Q1 2019
Net sales	564	604
Marketing and selling	-60	-66
Administration	-22	-23
Research and development	-59	-72
EBIT	136	95
EBITDA	192	157
EBITDA pre	196	193
Margin (in % of net sales)	34.7%	31.9%

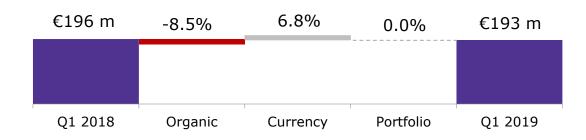
#### Comments

- Performance Materials with moderate organic growth reflecting strong demand for OLED, LC support from new panel plant ramp-up projects in China and low comps
- About stable Semiconductor Solutions reflects observed market slowdown
- Increased R&D due to provisions related to Bright Future program; underlying decrease in R&D reflecting cost control
- EBITDA pre reflects negative business mix and ongoing Liquid Crystals price decline

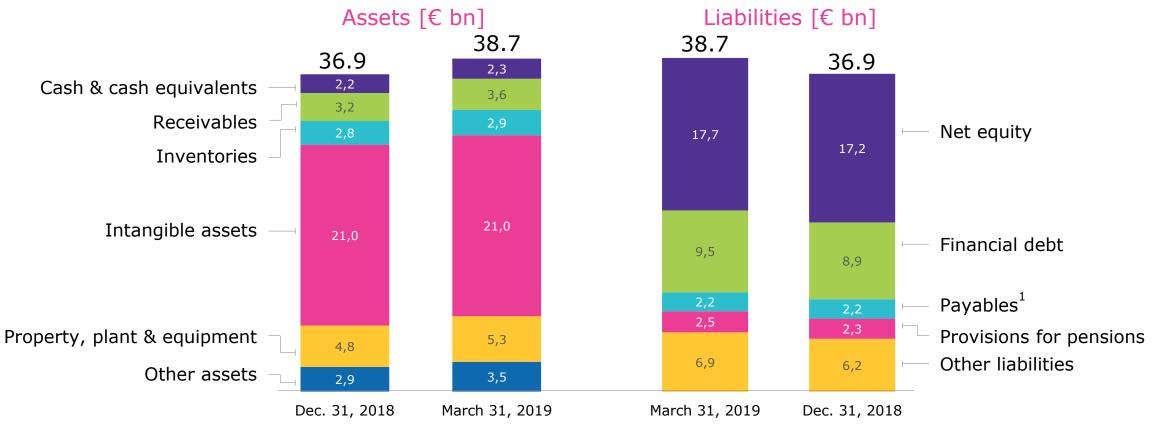
## Net sales bridge



## EBITDA pre bridge



## **Balance sheet – Changes due to IFRS 16 adoption**



- Property, plant and equipment increase mainly driven by IFRS 16 adoption
- Other assets reflect temporary investment of cash proceeds from Consumer Health disposal
- GSK collaboration included in receivables and other liabilities

- Increase in equity driven by currency translation effects and profit after tax (equity ratio of 45.7%)
- Higher financial debt due to IFRS 16 reclassification of lease liabilities

## **Cash flow statement**

## Q1 2019 – cash flow statement

[€m]	Q1 2018	Q1 2019	Δ
Profit after tax	342	190	-152
D&A	428	474	46
Changes in provisions	17	100	83
Changes in other assets/liabilities	-235	-89	146
Other operating activities	-10	-5	5
Changes in working capital	-161	-178	-17
Operating cash flow	380	493	113
Investing cash flow	-213	-329	-116
thereof Capex on PPE	-228	-209	19
Financing cash flow	-3	-3	0

#### Cash flow drivers

- Profit after tax in line with lower EBIT
- D&A increase mainly due to IFRS 16 reclassification
- Changes in provisions driven by build up for transformation program
- Changes in other assets/liabilities reflects lower income tax payment
- Increased investing cash flow due to temporary investment of cash proceeds from Consumer Health disposal



# Group

## **Key earnings drivers to remember for 2019**



# EBITDA1-supporting factors

- Strong sales contribution from Mavenclad® ramp-up and Bavencio®; first contribution from Mavenclad® US by Q2 2019
- Ongoing strength in Life Science with 6% to 7% organic above-market net sales growth and 20-30 bps underlying margin progression
- Successful partnering of bintrafusp alfa with ~€100 m of deferred income from upfront payment recognized as other operating income starting Q2 2019
- Income from milestones and management of pipeline (part of operating business in Healthcare) starting to materialize as of Q2 2019
- Lower expected license payments for Erbitux®
- · High level of cost consciousness and prioritization
- Adoption of IFRS 16 contributes ~€130 m<sup>2</sup> to organic growth YoY
- Positive FX impact: Emerging market currencies remain weak but offset by favorable EUR/USD development (range 2019: 1.13-1.17)



## EBITDA1-reducing factors

- Slight absolute increase in R&D costs budgeted for Healthcare but decrease as % of sales (actual development will be subject to clinical data outcome of priority projects and prioritization decisions)
- Healthcare underlying margins negatively impacted by product mix
- Performance Materials sales and earnings reaching trough due to expected decline in Liquid Crystals

# Group

## Full-year 2019 guidance<sup>1</sup>



# Group

## 2019 business sector guidance<sup>1</sup>



#### Net sales

- Moderate organic growth +4% to +6%
- Base business at least stable organically
- Strong contributions from launches incl. Mavenclad® US

## EBITDA pre<sup>2</sup>

- Organic +19% to +23% YoY
- FX -2% to +3% YoY
- ~ €1,820 1,950 m



#### Net sales

- Organic growth +6% to +7% above expected market growth
- All businesses contributing; Process Solutions remains main growth driver

# EBITDA pre<sup>2</sup>

- Organic +10% to +12% YoY
- FX +0% to +3% YoY
- ~ €2,000 2,100 m with 20-30 bps³
   underlying margin progression



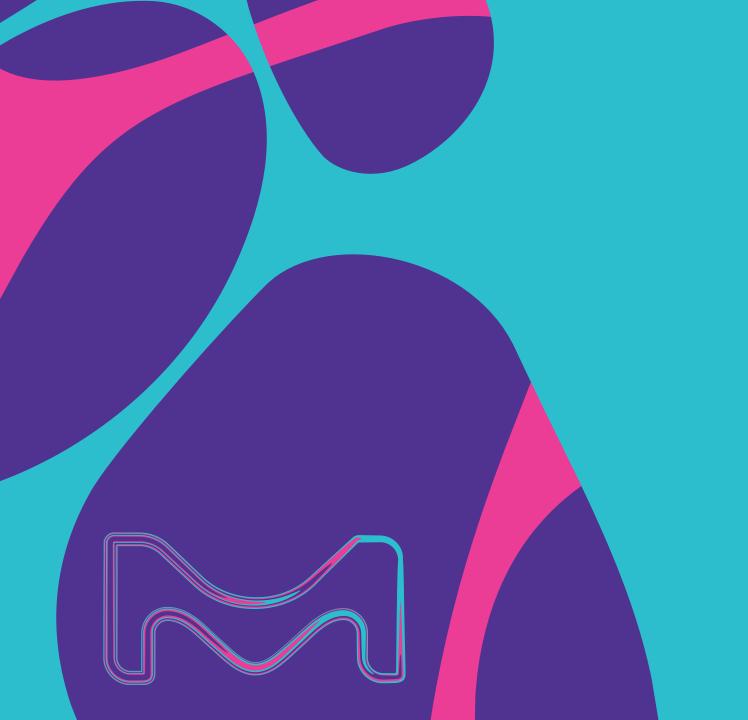
#### Net sales

- Moderate organic decline -3% to -6%
- Liquid Crystals benefiting from temporary capacity ramp-up in China

## EBITDA pre<sup>2, 4</sup>

- Organic -7% to -11% YoY
- FX +0% to +4% YoY
- ~ €700 760 m





# **APPENDIX**

# **Additional financial guidance 2019**

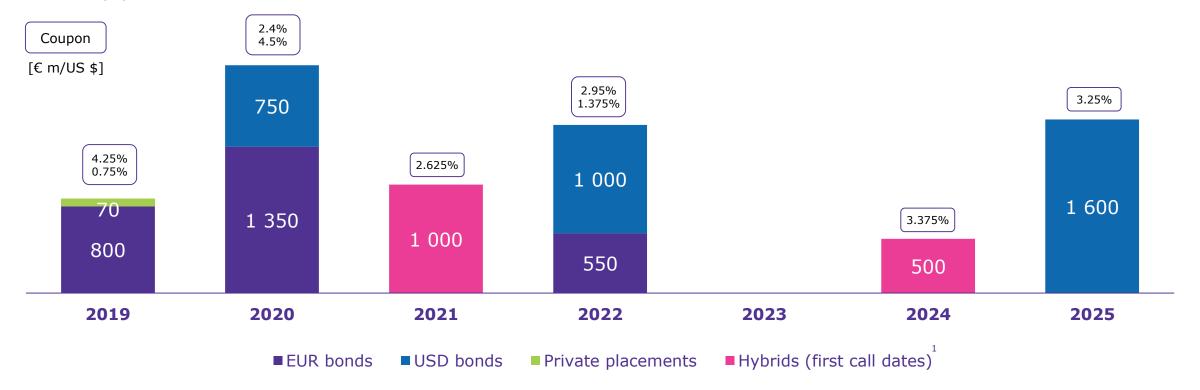
#### Further financial details

Corporate & Other EBITDA pre*	~ -€420 – -480 m
Interest result	~ -€220 – -240 m
Effective tax rate	~ 24% to 26%
Capex on PPE	~ €1.1 bn - 1.2 bn
Hedging/USD assumption	FY 2019 hedge ratio ~60% at EUR/USD ~1.20
2019 Ø EUR/USD assumption	~ 1.13 – 1.17

# Well-balanced maturity profile reflects Sigma-Aldrich financing transactions



Maturity profile as of Dec. 31, 2018

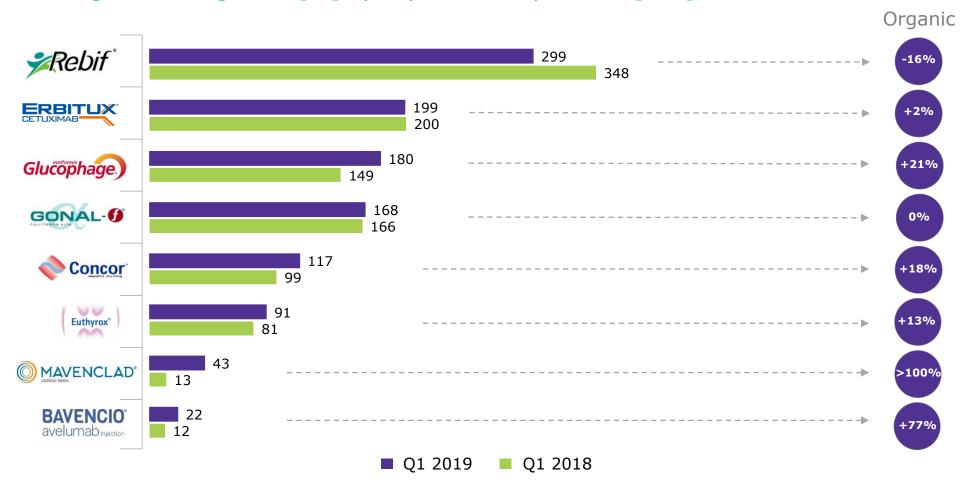




Financing structure enables flexible and swift deleveraging

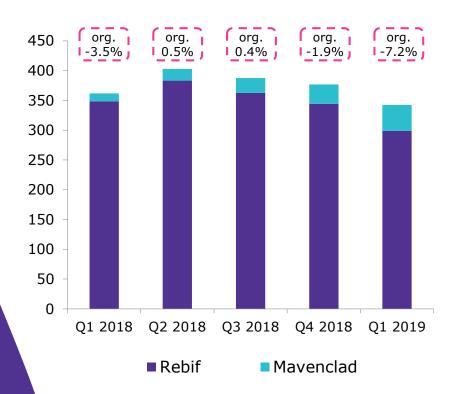
# Healthcare organic growth by franchise/product

Q1 2019 organic sales growth [%] by key franchise/products [€ m]

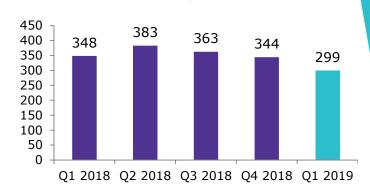


# **Neurodegenerative Diseases: Strong growth of Mavenclad<sup>®</sup> mitigates Rebif<sup>®</sup> decline**

## Sales development NDI, [€m]

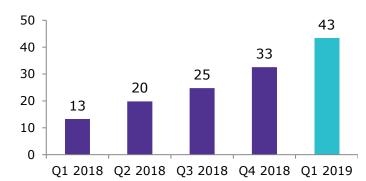


# Rebif<sup>®</sup> net sales, [€m]



- Rebif<sup>®</sup> sales of €299 m in Q1 2019 reflects organic decline of -16.4% mitigated by FX effect of +2.1%
- U.S. and European volume decline mainly due to competition
- U.S. decline in line with IFN market dynamics

## Mavenclad<sup>®</sup> net sales, [€m]



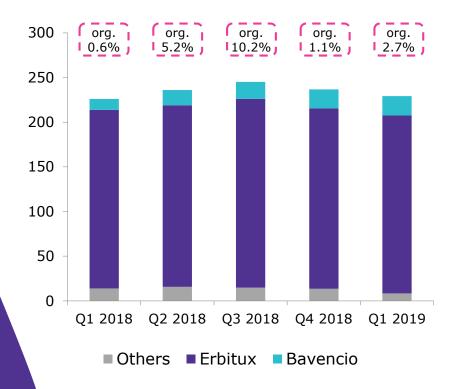
Mavenclad<sup>®</sup> launch on track with increasing contribution

FY 2019 guidance of up to mid triple-digit €m

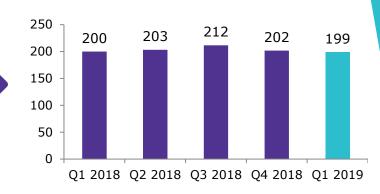
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# Oncology: Organic growth driven by Bavencio<sup>®</sup> ramp up and strong demand for Erbitux<sup>®</sup> in China

## Sales development Oncology, [€m]

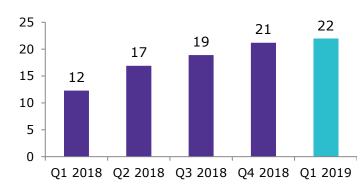


# Erbitux<sup>®</sup> net sales, [€m]



- Absolute sales almost stable with €199 m (org. 1.6%; FX -1.9%)
- Decline in Europe reflects ongoing competition, price reductions and shrinking market size
- MEA decline driven by tender phasing due to importation permit
- APAC with organic growth mainly driven by strong demand in China due to reimbursement recognition

## Bavencio<sup>®</sup> net sales, [€m]



Bavencio<sup>®</sup> with strong market position in MCC

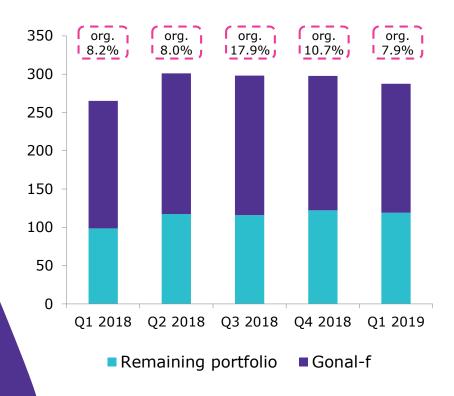
FY 2019 guidance of high double-digit €m

Merck KGaA

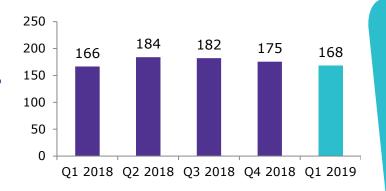
Darmstadt, Germany

# Fertility: High single digit organic growth reflects ongoing strong demand across the portfolio

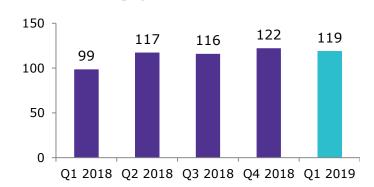
## Sales development Fertility, [€m]



# Gonal-f<sup>®</sup> net sales, [€m]



## Remaining portfolio net sales, [€m]

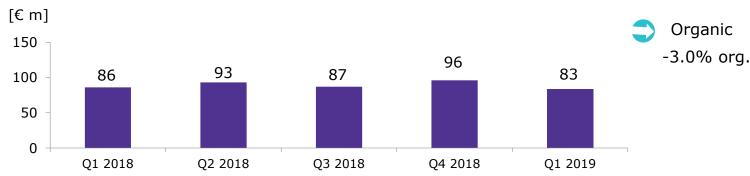


- Fertility posts high single digit growth driven by growth across all regions, mainly Europe and APAC
- Gonal-f<sup>®</sup> about stable reflecting tough comps last year
- Remaining portfolio shows ongoing strong demand, especially in China and Europe
- Continued and successful launch of Pergoveris<sup>®</sup> pen in 13 European countries

# Double digit organic growth of General Medicine fueled by China and LATAM

#### Sales evolution

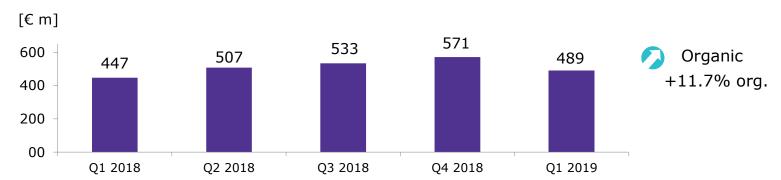
## Endocrinology



## Q1 2019 organic drivers

• Endocrinology declines organically due to lower demand and higher sales deductions in the U.S. mitigated by higher demand in Europe and APAC

#### General Medicine\*



•General Medicine reflects double digit growth of Glucophage<sup>®</sup>, Euthyrox<sup>®</sup> and Concor<sup>®</sup> driven by China and LATAM

## **Healthcare** pipeline

#### Phase I

M2698 p70S6K & Akt inhibitor Solid tumors

M3541 ATM inhibitor Solid tumors

M3814 DNA-PK inhibitor Solid tumors<sup>1</sup>

M4344 (VX-803) ATR inhibitor Solid tumors

M6620 (VX-970) ATR inhibitor Solid tumors

M7583 BTK inhibitor Hematological malignancies

M8891 MetAP2 inhibitor Solid tumors avelumab anti-PD-L1 mAb Solid tumors

bintrafusp alfa
TGFbeta trap/anti-PD-L1
Solid tumors

M9241 (NHS-IL12) Cancer immunotherapy Solid tumors<sup>1</sup>

M5049
Immune receptor inhibitor
Immunology

M6495 anti-ADAMTS-5 nanobody Osteoarthritis

M5717 PeEF2 inhibitor Malaria

#### Phase II

tepotinib MET kinase inhibitor Non-small cell lung cancer

tepotinib MET kinase inhibitor Hepatocellular cancer

M3814 DNA-PK inhibitor Rectal cancer

M6620 (VX-970) ATR inhibitor Ovarian cancer<sup>1</sup>

abituzumab<sup>2</sup>
pan-av integrin inhibiting mAb
Colorectal cancer 1L

avelumab anti-PD-L1 mAb Merkel cell cancer 1L

avelumab anti-PD-L1 mAb Solid tumors<sup>3</sup>

avelumab anti-PD-L1 mAb Non-small cell lung cancer<sup>3</sup>

avelumab anti-PD-L1 mAb Urothelial cancer<sup>3</sup>

evobrutinib BTK inhibitor Multiple sclerosis bintrafusp alfa
TGFbeta trap/anti-PD-L1
Non-small cell lung cancer 1L

bintrafusp alfa TGFbeta trap/anti-PD-L1

Non-small cell lung cancer 1L/2L **bintrafusp alfa** 

TGFbeta trap/anti-PD-L1
Locally advanced non-small cell lung cancer

bintrafusp alfa TGFbeta trap/anti-PD-L1 Biliary tract cancer 2L

atacicept
anti-BlyS/APRIL fusion protein
Systemic lupus erythematosus

atacicept
anti-BlyS/APRIL fusion protein
IgA nephropathy

evobrutinib BTK inhibitor Rheumatoid arthritis

evobrutinib BTK inhibitor

Systemic lupus erythematosus

sprifermin fibroblast growth factor 18 Osteoarthritis

M1095 (ALX-0761)<sup>4</sup> anti-IL-17 A/F nanobody Psoriasis **Phase III** 

**avelumab - anti-PD-L1 mAb** Non-small cell lung cancer 1L

avelumab - anti-PD-L1 mAb Gastric cancer 1L-M

avelumab - anti-PD-L1 mAb
Urothelial cancer 1L-M

avelumab - anti-PD-L1 mAb
Locally advanced head and neck cancer

#### Registration

avelumab anti-PD-L1 mAb Renal cell cancer 1L<sup>5</sup>

Oncology

Immuno-Oncology

Immunology

Neurology

Global Health

1L, first-line treatment; 1L-M, first-line maintenance treatment; 2L, second-line treatment, ¹ Includes studies in combination with avelumab. ² As announced on May 2 2018, in an agreement with SFJ Pharmaceuticals Group, abituzumab will be developed by SFJ for colorectal cancer through Phase II/III clinical trials. ³ Avelumab combination studies with talazoparib, axitinib, ALK inhibitors, cetuximab, chemotherapy, or novel immunotherapies. ⁴ 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. ⁵ The US Food and Drug Administration (FDA) accepted for Priority Review the supplemental Biologics License Application (sBLA) (February 11 2019) and the European Medicines Agency (EMA) validated for review the Type II variation application (March 8 2019) for avelumab in combination with axitinib for patients with advanced renal cell carcinoma. 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.

# **Adjustments in Q1 2019**

## Adjustments in EBIT

[€m]	Q1 2018		Q1 20	019
	Adjustments	thereof D&A	Adjustments	thereof D&A
Healthcare	3	0	3	0
Life Science	13	0	9	0
Performance Materials	3	0	35	0
Corporate & Other	24	0	28	0
Total	43	0	76	0

# **Financial calendar**

Date	Event
August 8, 2019	Q2 2019 Earnings release
November 14, 2019	Q3 2019 Earnings release
March 5, 2020	FY 2019 Earnings release



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