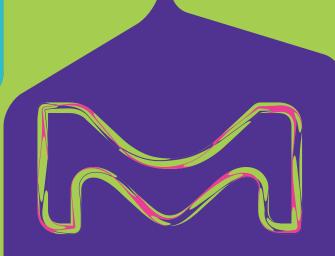
## MERCK KGAA, DARMSTADT, GERMANY -GOLDMAN SACHS FIFTH GERMAN CORPORATE CONFERENCE



Stefan Oschmann, CEO Marcus Kuhnert, CFO

Munich, September 19, 2016



#### Disclaimer

Publication of Merck KGaA, Darmstadt, Germany. In the United States and Canada the group of companies affiliated with Merck KGaA, Darmstadt, Germany operates under individual business names (EMD Serono, Millipore Sigma, EMD Performance Materials). To reflect such fact and to avoid any misconceptions of the reader of the publication certain logos, terms and business descriptions of the publication have been substituted or additional descriptions have been added. This version of the publication, therefore, slightly deviates from the otherwise identical version of the publication provided outside the United States and Canada.

#### **Disclaimer**

#### Cautionary Note Regarding Forward-Looking Statements and financial indicators

This communication may include "forward-looking statements." Statements that include words such as "anticipate," "expect," "should," "intend," "plan," "project," "seek," "believe," "will," and other words of similar meaning in connection with future events or future operating or financial performance are often used to identify forward-looking statements. All statements in this communication, other than those relating to historical information or current conditions, are forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to a number of risks and uncertainties, many of which are beyond control of Merck KGaA, Darmstadt, Germany, which could cause actual results to differ materially from such statements.

Risks and uncertainties include, but are not limited to: the risks of more restrictive regulatory requirements regarding drug pricing, reimbursement and approval; the risk of stricter regulations for the manufacture, testing and marketing of products; the risk of destabilization of political systems and the establishment of trade barriers; the risk of a changing marketing environment for multiple sclerosis products in the European Union; the risk of greater competitive pressure due to biosimilars; the risks of research and development; the risks of discontinuing development projects and regulatory approval of developed medicines; the risk of a temporary ban on products/production facilities or of non-registration of products due to non-compliance with quality standards; the risk of an import ban on products to the United States due to an FDA warning letter; the risks of dependency on suppliers; risks due to product-related crime and espionage; risks in relation to the use of financial instruments; liquidity risks; counterparty risks; market risks; risks of impairment on balance sheet items; risks from product-related and patent law disputes; risks from antitrust law proceedings; risks from drug pricing by the divested Generics Group; risks in human resources; risks from e-crime and cyber attacks; risks due to failure of business-critical information technology applications or to failure of data center capacity; environmental and safety risks; unanticipated contract or regulatory issues; a potential downgrade in the rating of the indebtedness of Merck KGaA, Darmstadt, Germany and its impact on goodwill impairment evaluations; the impact of future regulatory or legislative actions; and the risks and uncertainties detailed by Sigma-Aldrich Corporation ("Sigma-Aldrich") with respect to its business as described in its reports and documents filed with the U.S. Securities and Exchange Commission (the "SEC").

The foregoing review of important factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included elsewhere, including the Report on Risks and Opportunities Section of the most recent annual report and quarterly report of Merck KGaA, Darmstadt, Germany, and the Risk Factors section of Sigma-Aldrich's most recent reports on Form 10-K and Form 10-Q. Any forward-looking statements made in this communication are qualified in their entirety by these cautionary statements, and there can be no assurance that the actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us or our business or operations. Except to the extent required by applicable law, we undertake no obligation to update publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

This quarterly presentation contains certain financial indicators such as EBITDA pre exceptionals, net financial debt and earnings per share pre exceptionals, which are not defined by International Financial Reporting Standards (IFRS). These financial indicators should not be taken into account in order to assess the performance of Merck, KGaA, Darmstadt, Germany in isolation or used as an alternative to the financial indicators presented in the consolidated financial statements and determined in accordance with IFRS. The figures presented in this quarterly statement have been rounded. This may lead to individual values not adding up to the totals presented.

#### Agenda



- **Business overview & strategy recap**
- **O2** Healthcare Funding for success
- **D3** Life Science Focusing on profitable growth
- **Performance Materials Strength and innovation**



**Business and financial review H1 2016** 







#### BUSINESS OVERVIEW & STRATEGY RECAP

# Group Portfolio of three high-tech businesses



## Leading in specialty pharma markets

- Biologics and small-molecules
- Research focus: Oncology, Immunology & Immuno-Oncology
- Over-the-counter medicine



#### Leading life science company

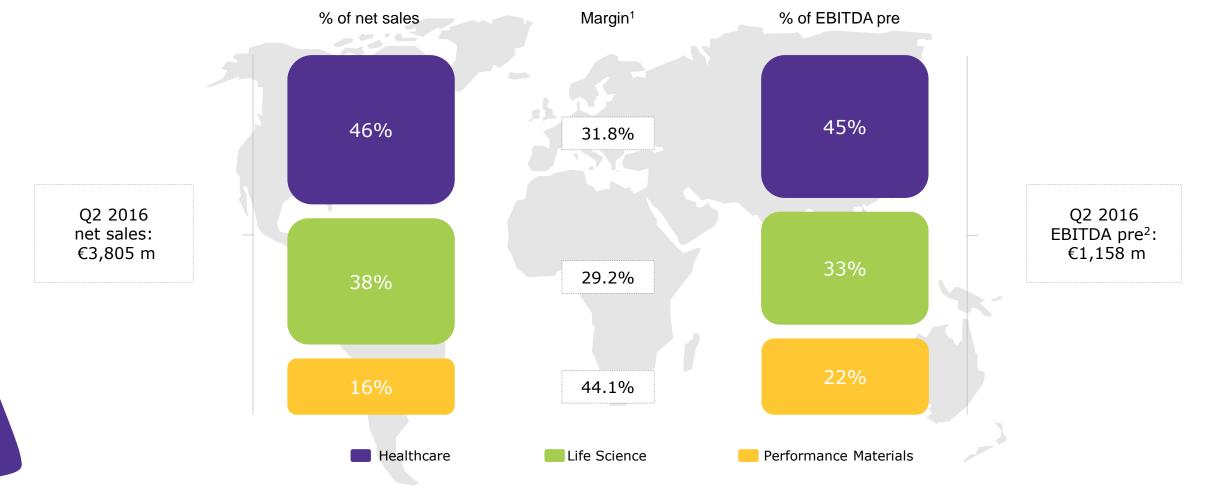
- Tools and services for biotech
   research & production
- Tools and laboratory supply for the academic research and industrial testing



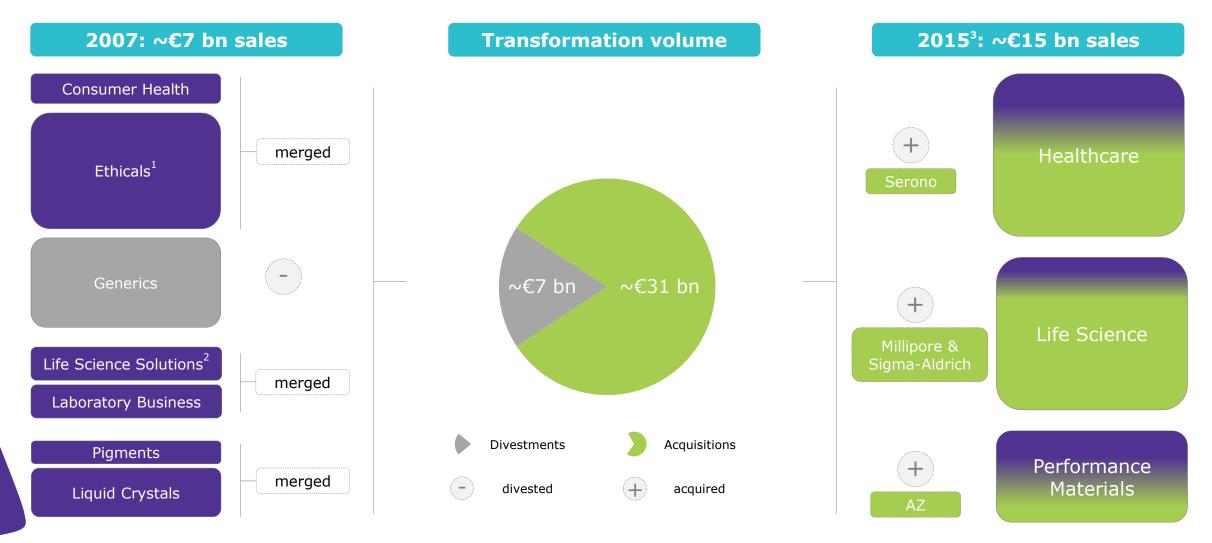
## Market leader in display materials

- Innovative display materials
- Effect pigments and functional materials
- High-tech materials for electronics

#### Group Strong businesses with attractive margins



#### Group We have added scale and strengthened the attractiveness of our portfolio



#### Group We have created three leading businesses

Healthcare

+ Serono

- Leading biotech company
- Global footprint
- Strong presence in growth markets
- Solid underlying business
- Promising pipeline assets

## Life science

MilliporeSigma

## performance materials

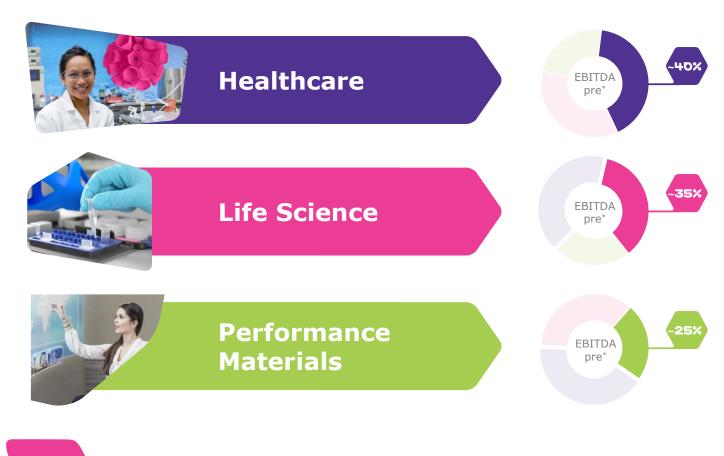
+ AZ

- No. 2 in the world market
- Broad and global product portfolio
- Leading eCommerce platform
- Best-in-class supply chain management

- World market leader
- Technology and innovation leader

Science Technology Innovation Specialties Quality Customer	focus
--	-------

#### Group Each business sector has its specific priorities



#### **Funding for success**

- Invest in pharma pipeline
- Prepare for launches
- Maintain cost discipline

#### Focusing on profitable growth

- Sustain top-line momentum
- Drive underlying earnings
- Integrate Sigma and realize synergies

#### Maintaining superior profitability

- Build on resilient four-pillar platform
- Continuously innovate
- Protect margins with high value-added products

#### We are set for profitable and sustainable growth

\*2015 reported EBITDA pre including Sigma-Aldrich and 100% of expected synergies, excluding Corporate & Other





#### Healthcare Healthcare is set to deliver on promising pipeline candidates

**Deliver** on organic growth

Focus on pipeline



Stable existing business to fuel slight organic growth



Solid pipeline of oncology, immuno-oncology and immunology molecules



Transformation of R&D operating model ongoing



Competitive R&D funding in our focus areas

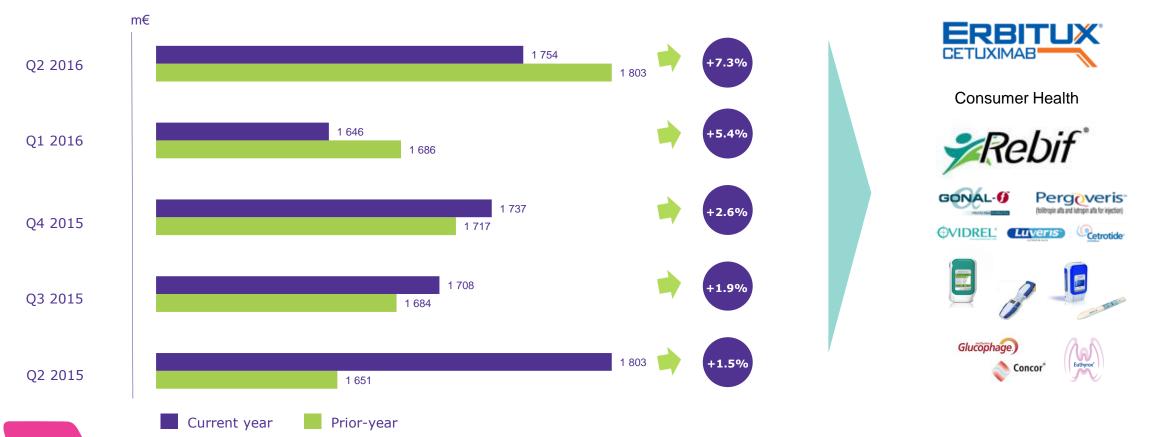


Cost discipline and efficient execution



# Healthcare **Delivered organic sales growth, committed to future performance**

Stable to slight organic growth



Defending the existing product portfolio is a key strength of Healthcare



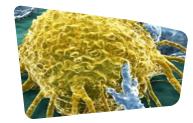
#### Healthcare **Pipeline highlights**

	Immunology	Immuno-Oncology	Oncology
Phase I	BTK inhibitor (SLE)	Avelumab (solid tumors)	Tepotinib (solid tumors)
		• M9241 (NHS-IL12)	<ul> <li>DNA-PK inhibitor (solid tumors)</li> </ul>
		<ul> <li>M7824 (bifunctional immunotherapy)</li> </ul>	
Phase II	Atacicept (SLE)	Avelumab (mMCC)	Tepotinib (HCC, NSCLC)
	• BTK (RA)		
Phase III	<ul> <li>MSB11022 (proposed biosimilar of Adalimumab)</li> </ul>	<ul> <li>Avelumab (Bladder, Gastric 1L&amp;3L, NSCLC 1L&amp;2L, Ovarian 1L&amp;plat res./ref., Renal Cell)</li> </ul>	
Registration	Cladribine tablets (MS) <sup>1</sup>		



#### selected R&D projects

- Atacicept: phase III decision expected in H2 2016
- BTK inhibitor: three phase II trials to be started in 2016 (e.g. RA and SLE) – RA already started
- Cladribine tablets: EMA accepted submission for review of market authorization approval in July 2016
- M7824 (bifunctional PD-L1 + TGFbeta trap): novel, first in-class bifunctional immunotherapy, expansion into phase Ib cohorts started
- Tepotinib: analysis of phase II data for HCC and NSCLC expected in H1 2018



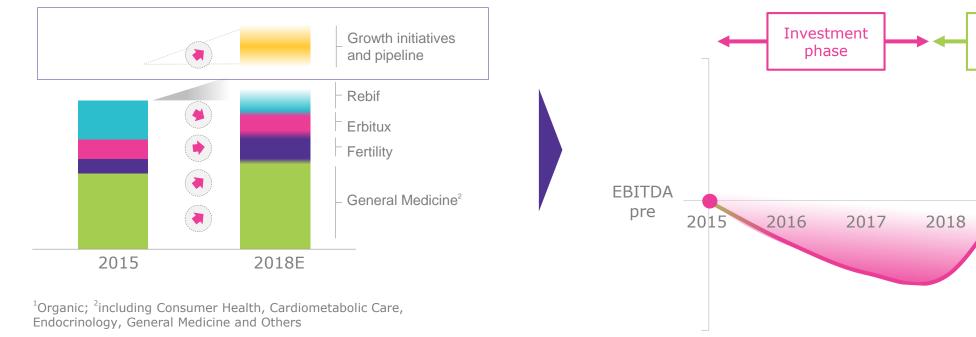
#### avelumab

- Cooperation with Pfizer
- Currently eight phase III trials ongoing
- MCC 2L: encouraging response rates presented at ASCO 2016 – application for market authorization by FDA planned in H2 2016
- Overall, around 30 ongoing therapy programs, spanning approximately 2,200 patients across more than 15 tumor types

(1) As announced on July 18<sup>th</sup>, 2016 the European Medicines Agency (EMA) accepted Merck's KGaA, Darmstadt, Germany Marketing Authorization Application Abbreviations: HCC: hepatocellular cancer | mMCC: metastatic merkel cell carcinoma | NSCLC: non-small cell lung cancer | RA: rheumatoid arthritis | SLE: systematic lupus erythematosus | MS: multiple sclerosis | plat res./ref.: platinum resistant/refractory | 1L: 1<sup>st</sup> line treatment | 2L: 2<sup>nd</sup> line treatment | 3L: 3<sup>rd</sup> line treatment

#### Healthcare Pipeline opportunities will lead to rising investments

## Stable to slightly growing<sup>1</sup> sales until 2018 confirmed



## Should pipeline catalysts materialize, investments will lead to considerable payback as of 2018+

Long-term

EBITDA pre

upside

2019

Rising investments until 2017 to accelerate sales and earnings growth as of 2018

2020

Illustration





#### Life Science Serving customers across the life science industry



- Academic and government institutions
- Biopharma R&D
- Industry R&D



- Pharmaceutical companies
- Small biotech
- Contract manufacturing organizations



- Diagnostic manufacturers
- Clinical testing labs
- Food & Beverage manufacturers

#### Life Science We create sustainable value that is based on strong strategic levers



- A combined portfolio of +300,000 products
- Integrated offerings along the life science value chain
- Complete workflow solutions



- Increased presence in North America
- Accelerating growth momentum in Asia
- Expanded geographic reach in 60+ countries



- Outstanding supply chain management (Ability to deal with complexity)
- Simple e-commerce platform (customer interface with global coverage)
- Expertise to manage regulatory barriers

#### Our capabilities are the foundation for future topline growth in Life Science

#### Life Science Life Science delivers synergies and integrates as planned

## synergies

On track to deliver 2016 synergy target of €90 m:

- HQ measures complete
- 50% of headcount targets met
- 4 site closures in progress
- Procurement actions moving
- Preparing distribution consolidation



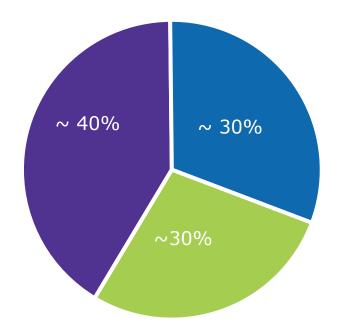
### Integration

Smooth integration ongoing with early achievements:

- Organization structure implemented
- High engagement from organization
- Common definition and implementation of processes well underway, e.g. pricing, customer excellence

No disruption of growth momentum during integration

#### Life Science Expected synergies identified and fully confirmed

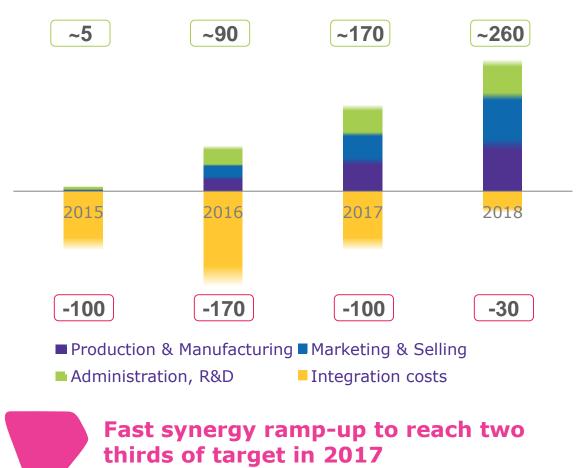


Sources of synergies (3<sup>rd</sup> full year 2018)

Production & Manufacturing Marketing & SellingAdministration, R&D

Three major areas for delivering the synergies

Timing of expected synergies and related costs [€m]



#### Life Science We aim to be the profitability champion of the sector

New sales breakdown as of Q2 2016

#### Profitability champion including synergies\* **Applied Solutions Research Solutions** Mid single digit growth Low single digit growth Company A Millipore Sigma 36% 26% SIAL MM Company B Company C Company D **Process Solutions** Company E High single digit growth Industry average ~25%

Above industry margin levels

Life Science is well set for sustainable growth and profitability





#### Performance Materials The four pillars are set for future profitable growth



#### ~50-60% of total sales,

- liquid crystals (LC) and photoresists for TVs, smartphones and tablet computers
- other display and non-display applications (e.g. LC Windows)

#### ~15-20% of total sales,

- effect pigments and functional materials for coatings, plastics, printing and cosmetics
- functional materials for cosmetics and special applications

#### ~15-20% of total sales,

- dielectrics, colloidal silica, lithography materials (photo resists), yield enhancers, edge-bead removers
- polyimide raw materials and printing materials

#### ~5-10% of total sales,

 organic (OLED) and inorganic (LED) light emitting diodes and functional materials for electronics and energy solutions, especially OLED is providing first substantial sales

#### Performance Materials Innovation leadership is the backbone of future profitability and growth



Incremental product adjustments - only minor investments

LC	New singles for PSVA technology, new mode SA-VA
pigments	Meoxal luminous metal effect pigments
ICM	low defect CMP <sup>2</sup> slurries
advanced tech.	Organic Photovoltaics



#### Fundamental research - more substantial investments needed

LC	Smart windows, smart antennas
pigments	Counterfeiting prevention applications
ICM	Directed self-assembly (DSA) in lithography
advanced tech.	OLED printing technology

#### Performance Materials Sound platform to deliver high earnings

#### Four-pillar platform diversifies earnings stream

- Liquid Crystals remain key earnings contributor
- AZ\* expertise is being leveraged to develop innovative value-added solutions for customers
- OLED is becoming a visible growth driver
- Pigments continue to grow with high-end products



#### Continuous innovation as key profitability driver

- New products contribute high growth and profitability
- LC\* technology mode UB-FFS\* launched in 2014 is the most recent example

#### **Balanced sales and consistently high earnings**



# We are the innovation leader IPS\* "Improved picture quality" 1996 VR\* "Large TVs" 2000 DS\* "Display cost reduction & advanced performance" 2008 VR\* "Superior image resolution and boxer energy consumption" 2014

Diversification of portfolio and ongoing innovation lead to strong profitability

Merck KGaA

Darmstadt, Germany

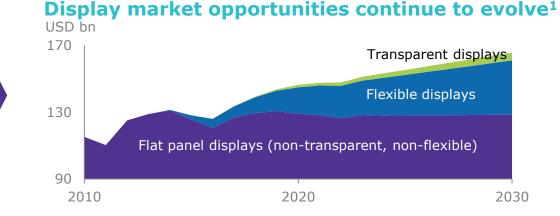
#### **Performance Materials**

#### Long-term growth and profitability drivers are intact



#### Macroeconomics and electronics remain buoyant

- Global consumer electronics market expected to grow above GDP\*
- Mobile data, Internet of Things and Big Data are key growth drivers for LC and IC
- Display market continues to grow

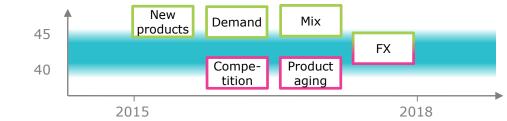


#### High value-added products yield superior profitability

- High market share in liquid crystals expected to prevail
- Strong differentiation by innovation inherent mature of business

#### Sustainable profitability drivers





Unique differentiation and market position will continue to lead to strong profitability and maintain low single-digit growth trajectory



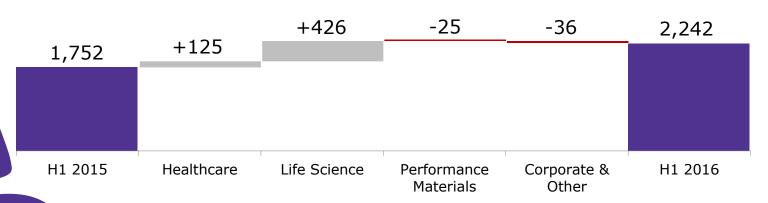


#### Life Science and Healthcare drive growth and profitability

#### H1 2016 YoY net sales

	Organic	Currency	Portfolio	Total
Healthcare	6.4%	-7.9%	-1.0%	-2.6%
Life Science	8.5%	-2.1%	80.6%	87.1%
Performance Materials	-3.5%	-0.8%	2.9%	-1.4%
Group	4.9%	-5.1%	19.5%	19.3%

#### H1 YoY EBITDA pre contributors [€ m]



•Growth in Healthcare driven by strong Fertility, GM\* as well as Xalkori commissions

• Strong organic growth in Life Science driven by Process Solutions

• Organic decline in Performance Materials reflects destocking in display supply chain

Portfolio reflects Sigma and Kuvan

• HC benefits from good organic growth, Rebif commission savings and R&D phasing

- Life Science driven by Sigma, strong organic growth and positive business mix
- Performance Materials slightly lower due to Liquid Crystal sales decrease
- Corporate EBITDA pre contains hedging and investments in corporate initiatives

#### H1 2016: Overview

#### Key figures

[€m]	H1 2015	H1 2016	Δ
Net sales	6,261	7,470	19.3%
EBITDA pre Margin (in % of net sales)	1,752 <i>28.0%</i>	<b>2,242</b> 30.0%	27.9%
EPS pre	2.43	3.09	27.2%
Operating cash flow	605	663	9.6%
[€m]	Dec. 31, 2015	Jun. 30, 2016	Δ
Net financial debt	12,654	12,510	-1.1%
Working capital	3,448	3,813	10.6%
Employees	49,613	50,456	1.7%

#### Comments

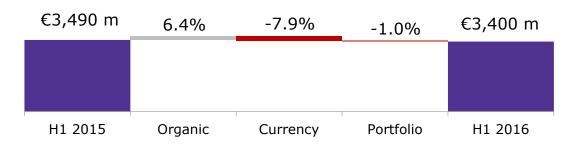
- EBITDA pre & margin increase driven by Sigma, organic performance and end of Rebif commission expenses
- EPS pre grows in line with EBITDA pre
- Healthy operating cash flow driven by strong business performance
- Net financial debt reflects cash-in for Kuvan & operating cash flow partially offset by dividend payments
- Working capital shows increase in business activity – further room for improvement

#### Healthcare: Good organic growth and product mix drive profitability

#### Healthcare P&L

[€m]	H1 2015	H1 2016
Net sales	3,490	3,400
Marketing and selling	-1,390	-1,256
Administration	-135	-137
Research and development	-706	-756
EBIT	536	939
EBITDA	910	1,387
EBITDA pre	941	1,065
Margin (in % of net sales)	27.0%	31.3%

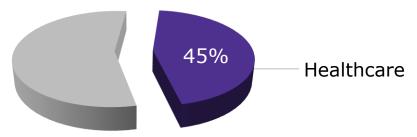
#### Net sales bridge



#### Comments

- Rebif still impacted by ramp-up of competition in Europe, while U.S. pricing, Russian tender and PDP\* in Brazil support performance
- Erbitux shows solid organic growth benefiting from volume increase in all regions, but also low comparables; EU remains competitive
- Marketing & selling reflects end of commission expenses for Rebif (U.S.) partially offset by reinvestments in sales force & launch preparations
- R&D spend increases as pipeline development progresses
- EBIT reflects Kuvan disposal gain of €324 m in Q1 2016
- Profitability improves due to good organic growth, end of Rebif commissions and ~€30m disposal gain from Merck KGaA, Darmstadt, Germany Ventures minority

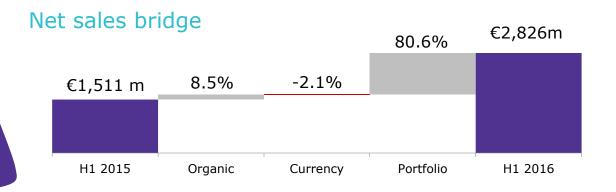
#### H1 2016 share of group net sales



#### Life Science: A strong first half of 2016

#### Life Science P&L

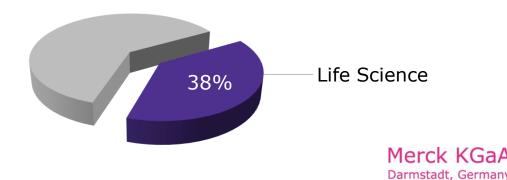
[€m]	H1 2015	H1 2016
Net sales	1,511	2,826
Marketing and selling	-477	-833
Administration	-59	-121
Research and development	-94	-126
EBIT	170	271
EBITDA	334	627
EBITDA pre	384	810
Margin (in % of net sales)	25.4%	28.6%



#### Comments

- Very strong growth of Process Solutions driven by increasing biopharma production and single-use demand across all regions
- Applied Solutions shows moderate organic growth, driven by biomonitoring products for pharma & demand for analytical testing
- Research Solutions benefits from increased research on biologics as well as solid demand for high-value chemicals
- Cost base contains Sigma, but improves in relation to sales
- Profitability reflects Sigma, business mix and synergies



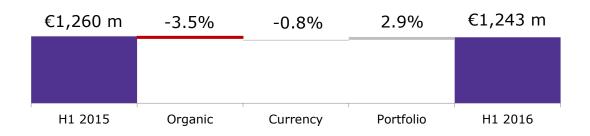


## **Performance Materials: Healthy profitability amid destocking of display industry inventories**

#### Performance Materials P&L

[€m]	H1 2015	H1 2016
Net sales	1,260	1,243
Marketing and selling	-99	-116
Administration	-32	-31
Research and development	-95	-101
EBIT	452	399
EBITDA	572	534
EBITDA pre	572	547
Margin (in % of net sales)	45.4%	44.0%

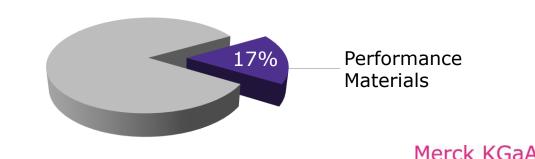
#### Net sales bridge



#### Comments

- LC impacted by volume declines of mature TN-TFT and indicated inventory correction in supply chain, expected to continue into H2
- OLED continues to grow on industry capacity expansion & investments
- Integrated Circuit Materials (ICM) shows solid above-market growth mainly driven by dielectric materials for chip production
- Pigments & Functionals post solid growth esp. due to cosmetic API\*
- Marketing & selling reflects contribution from Sigma's SAFC Hitech
- Healthy profitability due to leading market position with highly differentiated products, despite destocking in display supply chain

#### H1 2016 share of group net sales



Darmstadt, Germany





#### Group We are well set for profitable and sustainable growth



Maximize growth of existing franchises Deliver on pipeline

Focus on seamless integration and deliver cost synergies Leverage strategic capabilities for value creation

Drive innovation and technology leadership across all businesses Innovate in applications beyond displays



Group Upgrade of full-year 2016 guidance

Guidance for 2016









# Appendix

















## 2016 business sector guidance



# Additional financial guidance 2016

### Further financial details

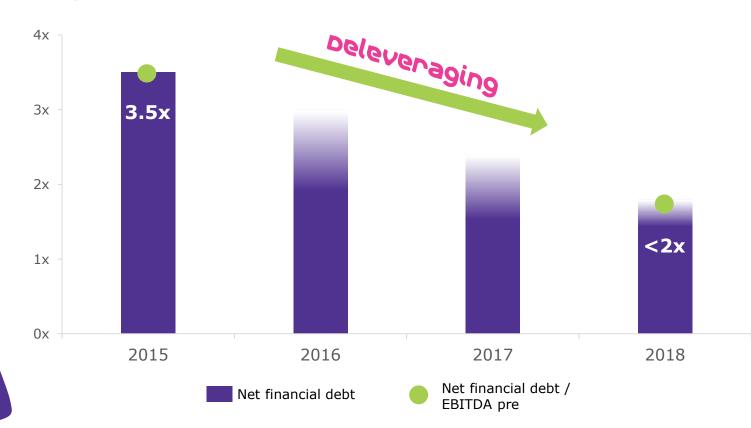
Corporate & Other EBITDA pre	~ -€370 – -400 m
Interest result	~ -€270 – -300 m
Intangibles amortization from Sign	na PPA ~ €250 – 300 m p.a.
Underlying tax rate	~23% to 25%
Capex on PPE	~€750 – 800 m
Hedging/USD assumption	2016 & 2017 hedge ratio ~40%-45% at EUR/USD ~1.10 to 1.15
2016 Ø EUR/USD assumption	~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 (or financed by divestments)

# Group We have clear financial priorities for the next two years



- **Strong cash flow** will be used to drive down gearing to <2x net debt / EBITDA pre in 2018
- Larger acquisitions (>€500m) ruled out for the next two years (or financed by divestments)
- **Dividend policy** reflects sustainable earnings trend
- Synergy generation is utmost priority
- Cost discipline continues in all business sectors
- Further efficiency gains from ongoing improvement and harmonization of processes and systems
- All our businesses have growth potential
- **Decisions on growth investments** are based on sound business cases and robust clinical data

Near-term financial priorities will secure our profitable growth path

# High cost base in strong currencies and hedging losses partially offset FX tailwinds



#### Sales

- Global presence
- ~40% of sales in Europe

#### Costs

- High Swiss franc cost base due to manufacturing sites
- R&D hub and notable sales force in U.S.

#### **FX** Impact





• Balanced regional sales split between EU, NA and RoW

#### Costs

- Extensive manufacturing and research footprint in the U.S.
- Global customer proximity requires broad-based sales force

#### **FX** Impact



#### Sales

- ~80% of sales in Asia-Pacific
- Industry is USD-driven

#### Costs

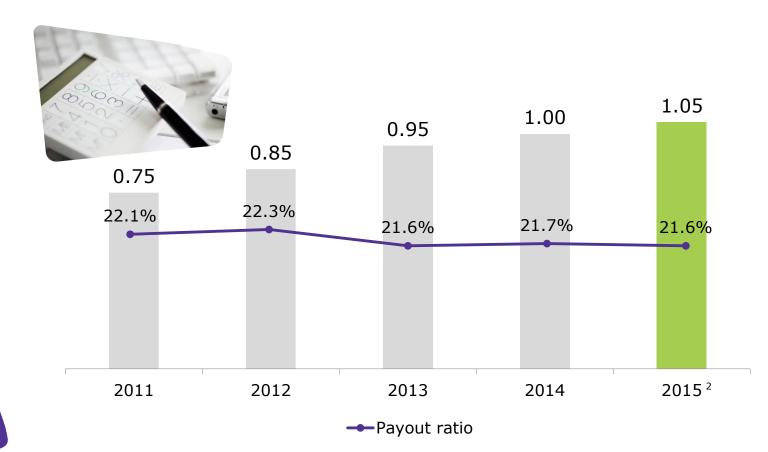
- Main production sites in Germany
- Several R&D and mixing facilities in Asia

#### **FX** Impact



# **Sustainable dividend development**

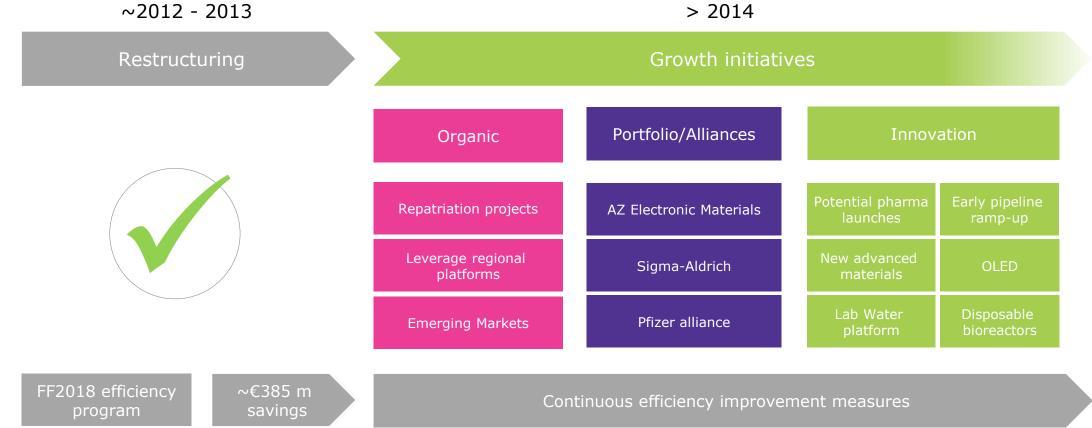
#### Dividend<sup>1</sup> development 2011-2015



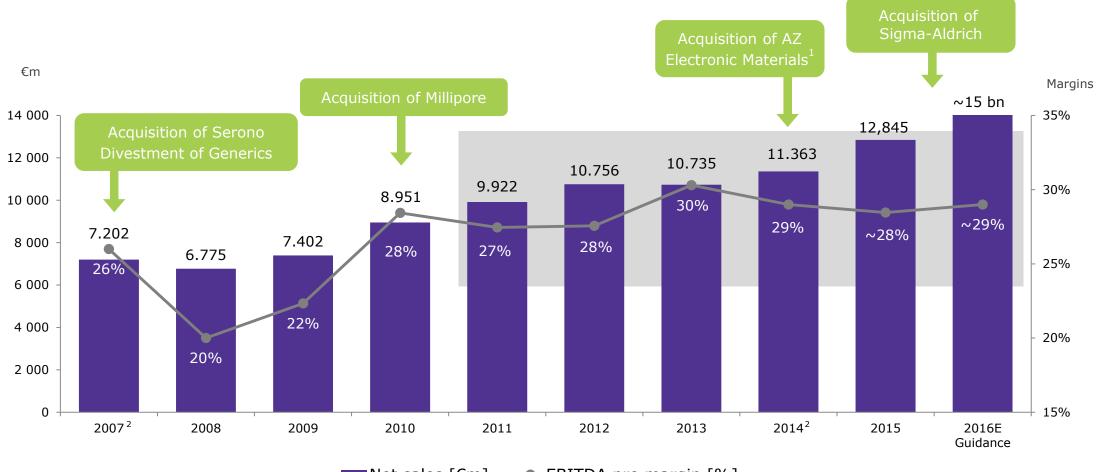
#### 2015 dividend and policy

- Dividend of €1.05 per share proposed<sup>2</sup> for 2015
- Last year's dividend constitutes the minimum level<sup>3</sup>
- Development of dividends in line with business performance and earnings progression
- Aiming for a corridor of 20%-25% of EPS pre

# Group Strategic agenda 2018 – milestones achieved



# Group Profitability improved fundamentally



<sup>1</sup>Included since 2 May 2014; <sup>2</sup>2007 and 2014 EBITDA pre margin adjusted for comparability





# Portfolio management: Differentiating across diverse business models

#### General Medicine portfolio



- •Limited risk with high cash generation
- Sustainable steady growth fueled by Emerging Markets

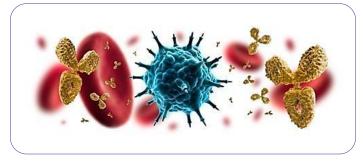
## **Biologicals portfolio**



- Moderate risk and reward profile
- Economies of scale due to stateof-the-art production capabilities
- Emerging Markets gain importance



### Oncology & Immunology innovation portfolio



- •High reward at high risk
- Innovation key success factor high R&D spend
- Promising pipeline projects



Mid-term, all parts of the portfolio need to earn their cost of capital



# The road to maximizing existing franchises is clear



Continue to drive front-line mCRC share by increasing patient testing and expanding head and neck coverage



Capitalize on strong efficacy and new smart devices to maximize differentiation and defend franchise



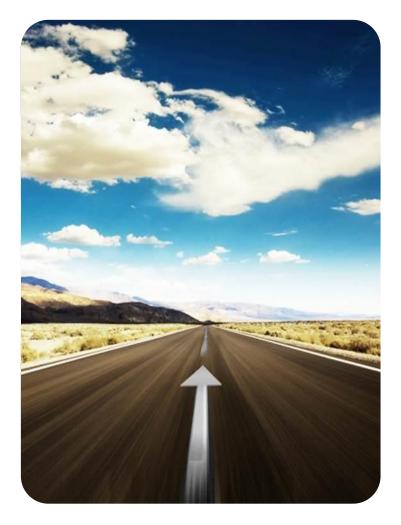
Build on No.1 position and ART<sup>1</sup> channel access with embryo diagnostics and other innovative technologies



Harness strengths of existing business and build a new focus area driven by innovative devices and services for patients



Build on existing track record in Emerging Markets, drive brand and life-cycle management and expand business including asset repatriation



Merck KGaA Darmstadt, Germany

# **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 Anti-PD-L1 mAb Solid tumors

Avelumab Anti-PD-L1 mAb Hematological malignancies

M9241 (NHS-IL12)<sup>1</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 Anti-PD-L1 mAb Merkel cell carcinoma

Sprifermin Fibroblast growth factor 18 Osteoarthritis Atacicept Anti-Blys/anti-APRIL fusion protein Systemic lupus erythematosus M2951 BTK inhibitor Rheumatoid arthritis

#### Phase III

Avelumab – Anti-PD-L1 mAb Non-small cell lung cancer 1L<sup>2</sup> Avelumab – Anti-PD-L1 mAb Non-small cell lung cancer 2L<sup>3</sup> Avelumab – Anti-PD-L1 mAb Gastric cancer 1L<sup>2</sup> Avelumab – Anti-PD-L1 mAb Gastric cancer 3L<sup>4</sup> Avelumab – Anti-PD-L1 mAb Bladder cancer 1L<sup>2</sup> Avelumab – Anti-PD-L1 mAb Ovarian cancer platinum resistant/refractory Avelumab – Anti-PD-L1 mAb Ovarian cancer 11<sup>2</sup> Avelumab - Anti-PD-L1 mAb Renal cell cancer 1L<sup>2</sup>

MSB11022 Proposed biosimilar of Adalimumab Chronic plaque psoriasis

Pipeline as of July 28th, 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.

#### Registration

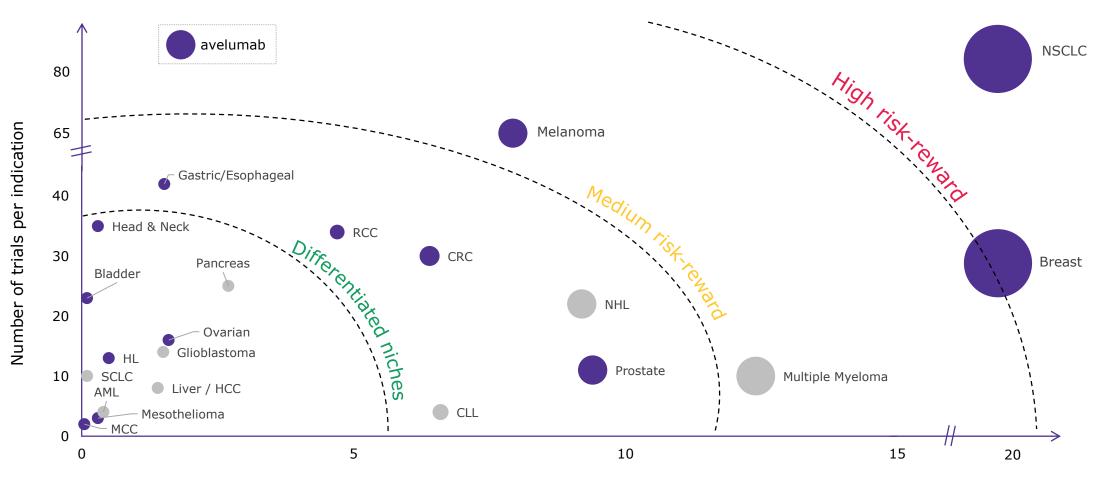
**Cladribine Tablets**<sup>5</sup> – **Lymphocyte targeting agent** Relapsing-remitting multiple sclerosis

- Neurodegenerative Diseases
   Oncology
   Immunology
   Immuno-Oncology
- Biosimilars

<sup>1</sup>Sponsored by the National Cancer Institute (USA); <sup>2</sup>1st line treatment; <sup>3</sup>2nd line treatment; <sup>4</sup>3rd line treatment <sup>5</sup>As announced on July 18<sup>th</sup>, 2016 the European Medicines Agency accepted Merck's KGaA, Darmstadt, Germany Marketing Authorization Application

Merck KGaA Darmstadt, Germany

# Avelumab plays predominantly in attractive and differentiated niches



Market size in 2020 per indication [€bn]

# **Avelumab – Differentiation strategy varies according to chosen target indication and market**

#### Ambition: Smart leader

- Indications (Merkel cell) or markets (Asia for gastric)
  - Quick to market strategy, e.g. BTD for MCC in November 2015
  - Small, but less crowded markets and sales potential with notable impact for us
  - Strategic strength of Healthcare in niche markets

#### Ambition: Smart follower

- Indications such as NSCLC or Bladder
- Learn from experience of incumbents/early movers
- Potential for combinations given breadth of combined development pipelines, e.g. lung
- Differentiate in trial design and explore application of further biomarkers



Merck KGaA Darmstadt, Germany

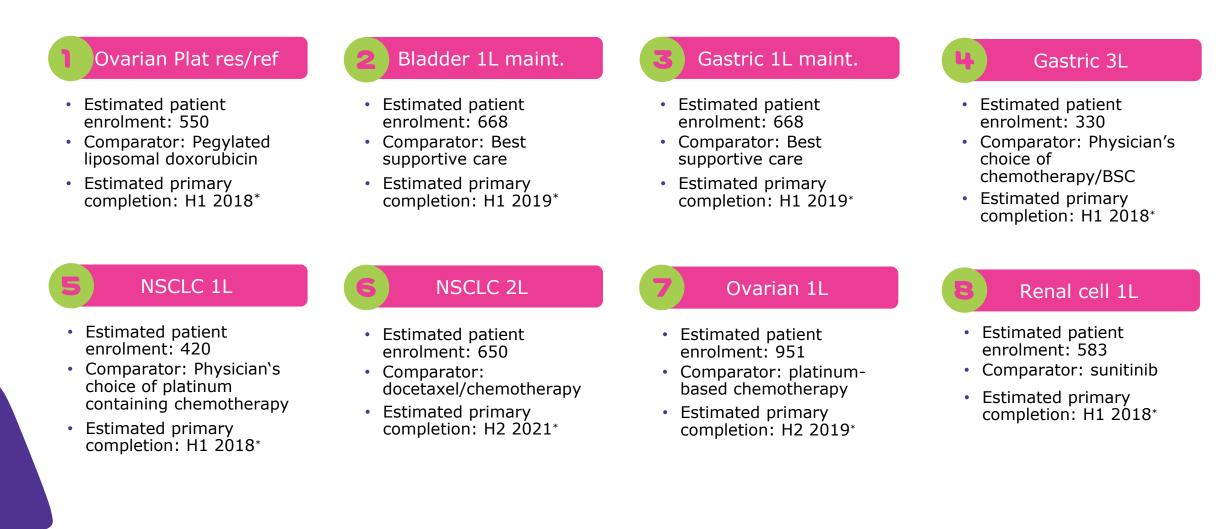
Saturated and / or major indications

Unsaturated

and / or niche

indications

# The alliance initiated 8 Phase III studies



# MCC 2L: Clinical results support avelumab as potential therapeutic option – planned to apply for marketing authorization in H2 2016

## Encouraging response rates<sup>1</sup>

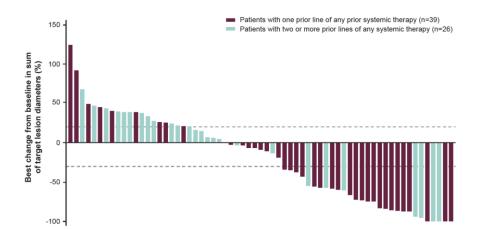
- ORR: 31.8%
  - 9.1% complete response
  - 22.7% partial response
  - Rapid (78.6% responding within 7 weeks of treatment)
  - Durable (82.1% still responding at time of analysis)
- 6-mo OS: 69% (median OS: 11.3 months)
- 6-mo PFS rate: 40%
- Manageable safety profile; no unexpected safety signals





#### Potential for differentiation

- Largest international multicenter, open-label study of anti-PD-L1/PD-1 reported in this patient population (88 patients) – Responses observed in large number of patients
- Improved response rates observed when used earlier, i.e. fewer lines of prior chemotherapy appeared to be associated with better response to avelumab in MCC 2L and beyond
  - ORR of 40.4% for patients with one prior systematic treatment
  - ORR of 19.4% for patients with two and more prior treatments



# Going forward, avelumab combinations will drive differentiation strategy



- Phase II 2L MCC (BTD, ODD and FTD)
- Phase III 1L and 2L Plat res/ref ovarian
- Phase III 1L MN and 3L gastric
- Phase III 1L and 2L NSCLC
- Phase III 1L MN bladder
- Phase I Hodgkins Lymphoma
- Multiple other tumor types



- Phase III, RCC 1L
- Phase Ib/II, NSCLC 1L ALK+
- Phase I/II
- Phase Ib/II, ovarian
- Phase I/Ib, ovarian

- (avelumab + Inlyta) (avelumab + Xalkori/lorlatinib) (avelumab + 4-1BB) (avelumab + Entinostat; Syndax collaboration) (avelumab + VS-6063; Verastem collaboration)
- Further combination trials under consideration

# Cladribine tablets – MAA submission accepted by EMA in July 2016

#### Background

- Targets lymphocytes (both B and T cells), integral to MS pathogenesis
- Two Phase III and one Phase IIIb extension studies conducted in RRMS and early MS<sup>1,2,3</sup>; Phase II study in patients failing IFN beta therapy<sup>5</sup>
- Substantial new efficacy & safety characterization including data from long-term follow up (>10,000 patient-years)
- Most recent analyses provide relevant information on benefit/risk profile of cladribine tablets in RRMS:
  - ARR reduction (58%)
  - Risk of disability progression (33% reduction)
  - Relative reduction in mean number of lesion (86% reduction in T1 gadolinium-enhanced lesions)
  - 47% of patients experience NEDA over 2 years<sup>4</sup>

#### Potential for differentiation

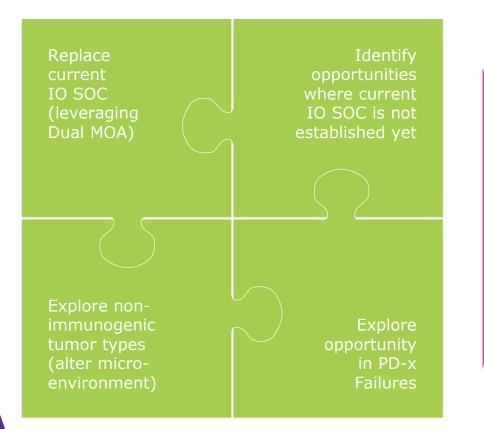
- We aim to address significant unmet needs for agents delivering high efficacy with favorable safety profile in a convenient dosing regimen
- Administered orally (tablet formulation)
- Extremely short treatment courses (8–10 days per year) leading to long-term efficacy<sup>1</sup>

#### Note: timelines are event-driven and may change

EMA = European Medicines Agency; ARR = Annualized Relapse Rate; MAA = Marketing Authorization Application; MS = multiple sclerosis; NEDA = no evidence of disease activity; RRMS = relapsing-remitting multiple sclerosis. <sup>1</sup> Giovannoni G et al. New Engl J Med 2010;362:416–26; <sup>2</sup> Giovannoni G et al. 65th annual meeting of the American Academy of Neurology 2013. P07.119. <sup>3</sup> Leist TP et al. Lancet Neurol 2014;13:257–67. <sup>4</sup> Giovannoni G et al. Lancet Neurol. 2011;10:329–37. <sup>5</sup> Montalban X et al. 65th annual meeting of the American Academy of Neurology 2013. P07.099.

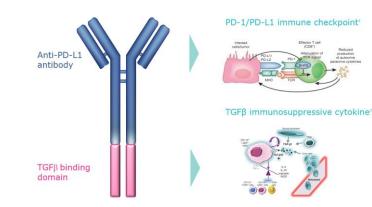
# **PD-L1–TGF-beta indicates potential to move beyond checkpoint inhibitors**

#### Four focus areas for exploration

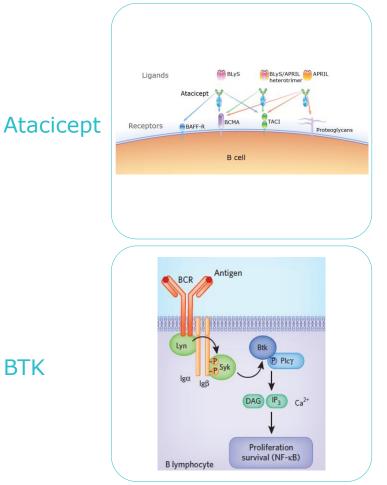


#### Status and next steps

- Novel, first-in-class bifunctional immunotherapy
- Bifunctional mode should result in broader application vs. respective mono-functional agents
- Great potential when combined with Standard of Care, immunotherapy and internal pipeline drug candidates
- Dose level finding of Phase I completed
- Expansion into Ib cohorts expected for Q3 2016



# Update on selected assets (1/2)

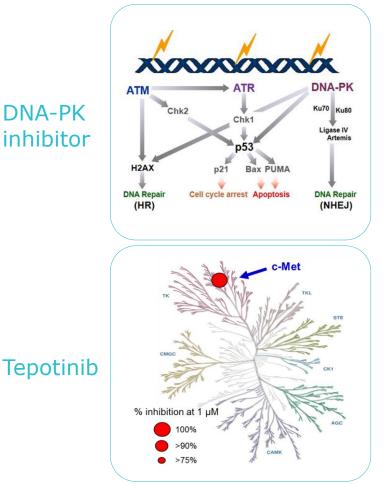


- Binds to receptors of two cytokines regulating maturation, function, and survival of B cells (B-lymphocyte stimulator (BLyS) & a proliferation-inducing ligand (APRIL))
- ADDRESS II (Ph IIb) in SLE patients aiming to show reduction in disease activity – 279 patients enrolled
- 24-week, randomized, double-blind, placebo-controlled Subcutaneous injection, once-a-week dosing
- Primary outcome: Percentage of patients with SLE responder index (SRI) response at week 24 compared to screening
- Suppress autoantibody-producing cells
- Preclinical research suggests therapeutic use in certain autoimmune diseases
- High and differentiated efficacy in preclinical models; promising kinase selectivity profile
- Aim to achieve best in class through minimization of off-target effects
- 2<sup>nd</sup> dose level of Phase I completed
- Partnering opportunities under consideration

Phase III decision expected in H2 2016

Three phase II trials expected to be started until end of 2016 (e.g. RA, SLE)

# Update on selected assets (2/2)



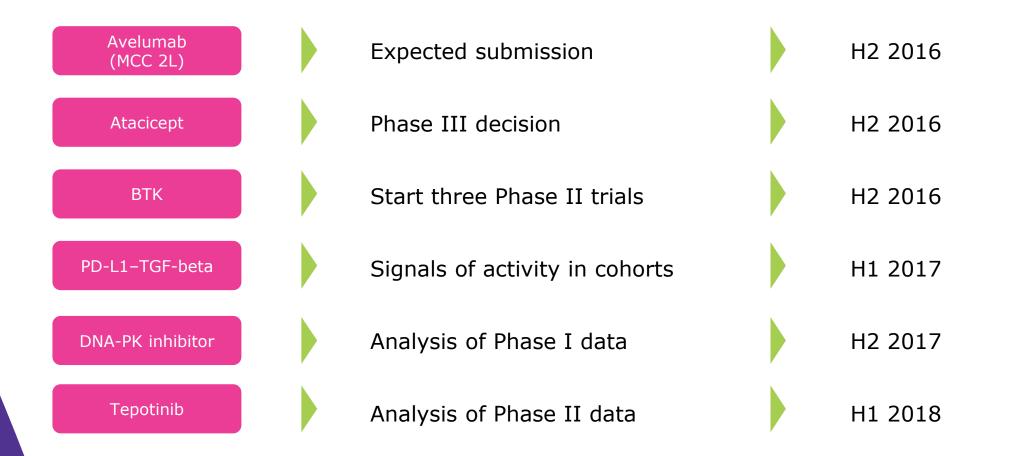
- M3814 is a selective and potent inhibitor of DNA-PK, a kinase mediating DNA double strand break repair<sup>1</sup>
- Preclinical PoC showing complete responses and/or increased PFS in combination with radiotherapy in several xenograft models (SCCHN, NSCLC, CRC, PaCa) and strong pre-clinical combination data with SoC chemotherapies
- Two Phase Ia trials ongoing: FIM (monotherapy): 5<sup>th</sup> dose level completed, MTD not yet reached; RT combination: recruitment ongoing

Analysis of Phase I data for RT combination expected in H2 2017

- Highly selective small molecule c-Met inhibitor
- Active in ligand-dependent and ligand-independent tumor models
- Biomarker-driven approach for patient selection
- Preliminary data show encouraging signs of anti-tumor activity in c-Met positive patients in NSCLC and HCC<sup>2,3</sup>
- Phase II trials in progress in NSCLC and HCC

Analysis of Phase II data for HCC and NSCLC expected in H1 2018

# **Outlook – MCC submission planned in H2 2016**



# Healthcare Investments in future growth

 Immuno-Oncology: avelumab and ramp-up of earlier pipeline projects +€150-200m cost increase in 2016

- Oncology/Immunology, e.g. tepotinib, BTK inhibitor: mid to high double-digit €m cost increase in 2016
- Launch readiness to be ensured for avelumab and cladribine
- Costs for launch preparation in the mid to high double-digit €m range in 2016



- Stringent pipeline assessments continue
- Investments based on sound business cases and robust clinical data

## Long-term growth investments partly mitigated by strict cost management

\*For scenario that pipeline catalysts materialize

Merck KGaA Darmstadt, Germany

R&D\*

Marketing & Selling<sup>\*</sup>

# Healthcare is well set for future growth

Stable existing business

Business and market specific initiatives in place to maximize existing business franchises

Strong R&D pipeline Diversified but focused pipeline with high quality assets in the areas Immuno-Oncology, Oncology and Immunology healthily spread across all clinical phases

Successful collaborations

Proven success in partnering through joint investments and collaborations – maximizing potential of assets in competitive space

Promising late stage progress Two expected submissions in 2016 may potentially result in product launches in 2017

Disciplined execution

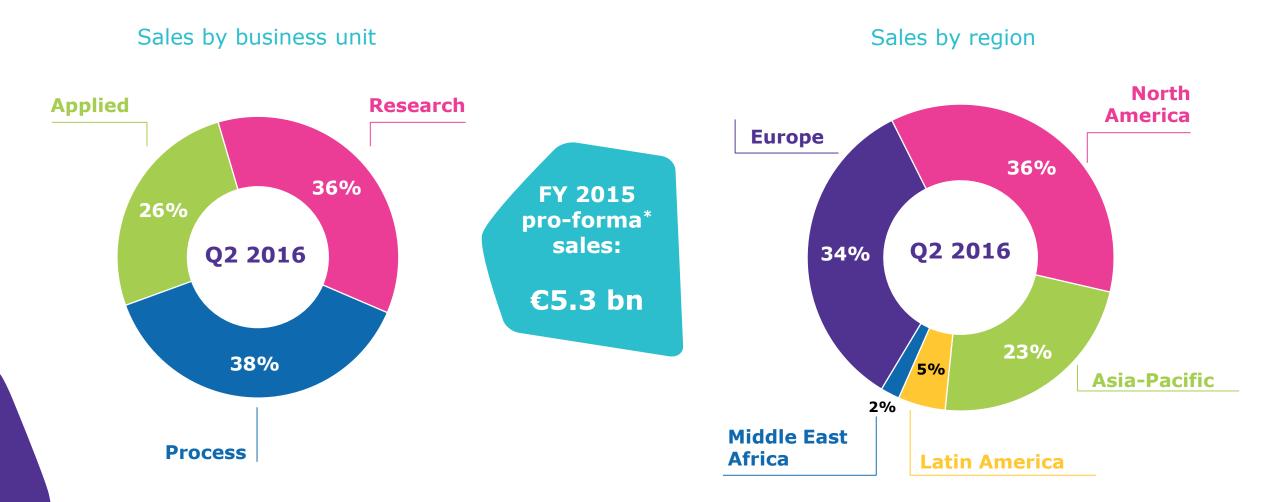
Systematic pipeline review and timely decision making allow efficient resource and budget allocation







# A balanced portfolio and geographic presence



Merck KGaA Darmstadt, Germany

# Life Science is an attractive market



- Growth in volume of experiments
- Mild growth in academic funding
- Investment in industry R&D

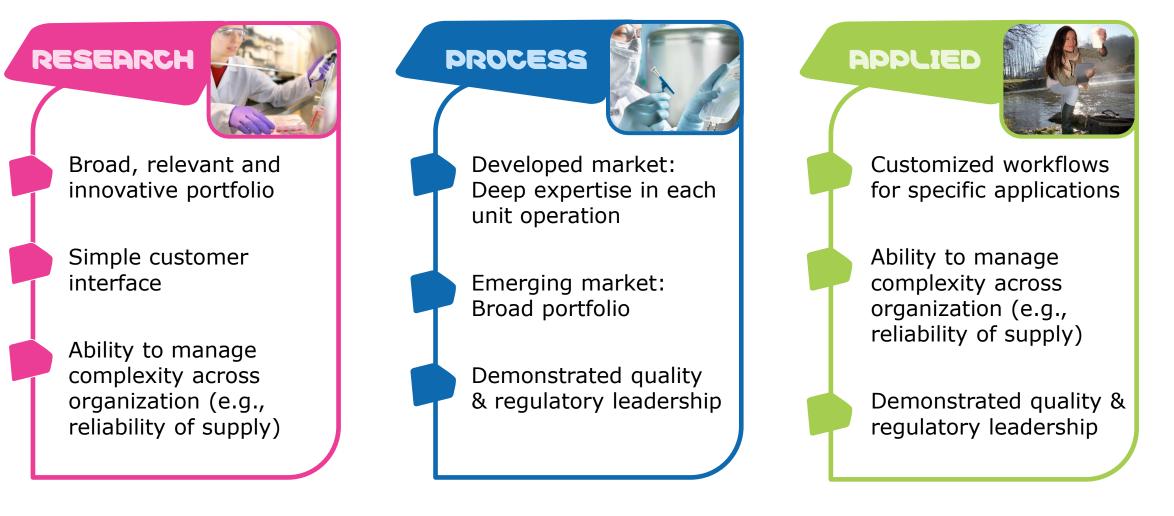


- Drug volume growth
  - from biologics
  - from emerging modalities
- Continued shift to single-use



- Volume growth from
  - Population growth
  - Increased testing needs

# Success driven by portfolio breadth and differentiation, a customer-centric approach and world-class capabilities



Merck KGaA Darmstadt, Germany

# Process Solutions **Our end-to-end portfolio for manufacturing mAbs**



MAKE Produce antibodies



Advanced<sup>™</sup> CHO Fed-batch Medium *Cell culture media to enhance cell growth* 

2000L CellReady bioreactor **Tank for** cultivating cells

Clarisolve ® clarification



Provantage <sup>®</sup>

**PURIFY** Remove cell debris, virus, etc.



FlexReady <sup>®</sup> chromatography **Purifying mAbs** 



Viresolve<sup>®</sup> Pro solution *Removing viruses from protein solutions* 

EMP<u>ROV</u>E<sup>®</sup>

Pellicon<sup>®</sup> cassette filters *Washing and removing cells, lipids, particles* 



**FORMULATE** Final drug product

> Opticap<sup>®</sup> capsules Sterile filtration

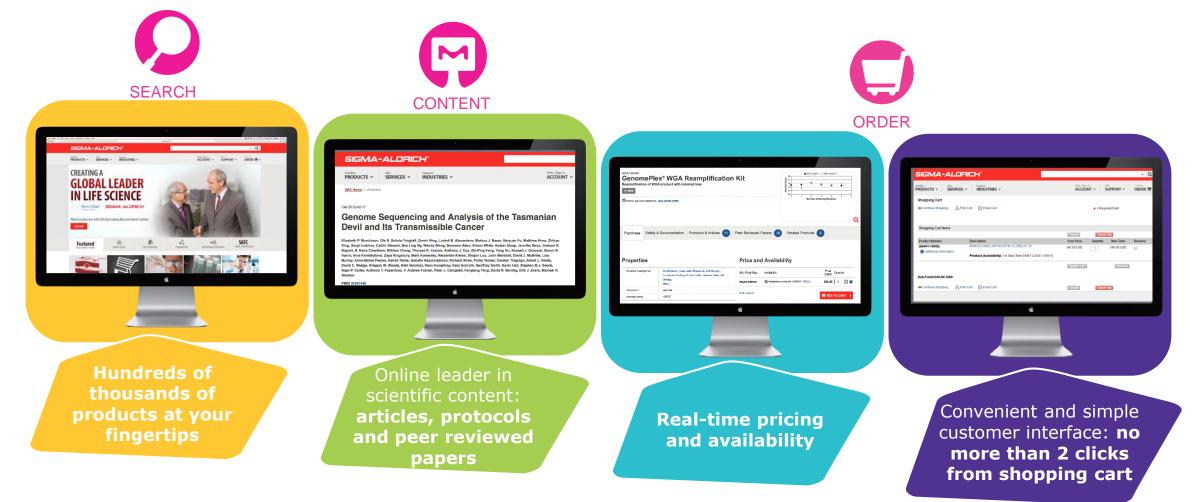
**cGMP SOLUTIONS & SERVICES** 

BioReliance ®

Merck KGaA Darmstadt, Germany

# **#1** website in research life science industry

Industry leading e-commerce platform and supply chain capability

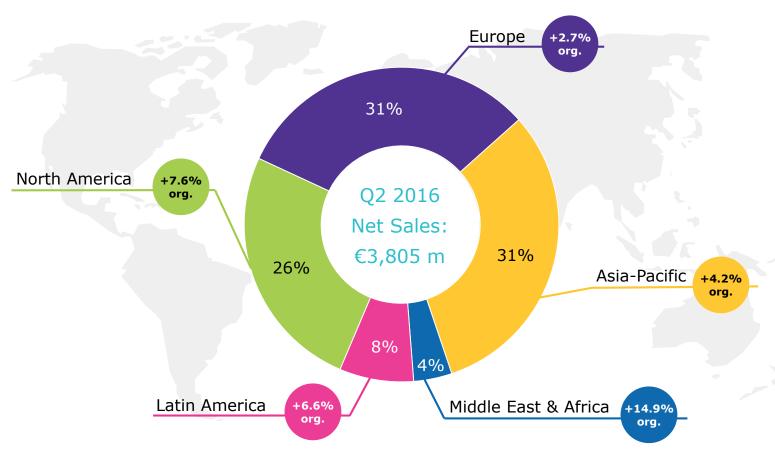






# **Organic growth in all regions**

### Regional breakdown of net sales [€ m]



#### Regional development

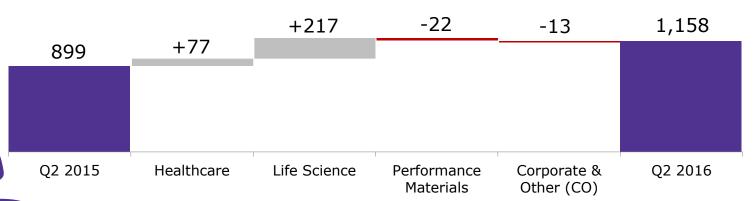
- Organic growth in Europe driven by robust demand in Process Solutions
- North America benefits from strong Fertility business, Rebif pricing and demand for Process Solutions products
- Asia-Pacific shows solid organic growth driven by Fertility, GM and Life Science partially offset by display destocking
- Solid organic growth in LatAm driven by GM and CH as well as increasing demand for analytical testing (Applied Solutions)

# Life Science and Healthcare drive increase in EBITDA pre

## Q2 2016 YoY net sales

	Organic	Currency	Portfolio	Total
Healthcare	7.3%	-9.0%	-1.0%	-2.7%
Life Science	8.1%	-2.8%	79.7%	85.0%
Performance Materials	-4.7%	-2.0%	3.1%	-3.5%
Group	5.1%	-6.1%	19.2%	18.2%

## Q2 YoY EBITDA pre contributors [€ m]



- •Growth in Healthcare driven by strong Fertility, GM\* as well as Xalkori commissions
- Process Solutions continues to drive strong organic growth in Life Science
- Organic decline in Performance Materials reflects display supply chain destocking
- Portfolio is Sigma and Kuvan
- •HC benefits from strong organic growth, end of Rebif commission expenses and ~€30 m disposal gain
- Life Science driven by Sigma, strong organic growth and synergies
- Performance Materials only slightly lower despite LC sales decline
- •CO contains corporate initiatives & hedging

Merck KGaA

Darmstadt, Germany

# Q2 2016: Overview

### Key figures

[€m]	Q2 2015	Q2 2016	Δ
Net sales	3,219	3,805	18.2%
EBITDA pre Margin (in % of net sales)	889 <i>27.9%</i>	<b>1,158</b> 30.4%	28.8%
EPS pre	1.30	1.55	19.2%
Operating cash flow	326	311	-4.7%
[€m]	Dec. 31, 2015	June 30, 2016	Δ
Net financial debt	12,654	12,510	-1.1%
Working capital	3,448	3,813	10.6%
Employees	49,613	50,456	1.7%

#### Comments

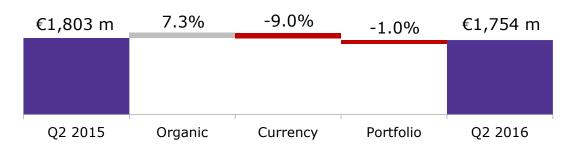
- EBITDA pre & margin increase driven by Sigma, organic performance and end of Rebif commission expenses
- EPS pre up due to EBITDA pre increase, but higher LTIP\* charges burden financial result
- Healthy operating cash flow due to strong business performance amid higher tax payments
- Net financial debt reflects operating cash flow and dividend payments
- Working capital shows increase in business activity – further room for improvement

# Healthcare: Strong organic growth, EBITDA pre and profitability

### Healthcare P&L

[€m]	Q2 2015	Q2 2016
Net sales	1,803	1,754
Marketing and selling	-730	-643
Administration	-69	-66
Research and development	-358	-378
EBIT	267	298
EBITDA	461	558
EBITDA pre	480	557
Margin (in % of net sales)	26.6%	31.8%

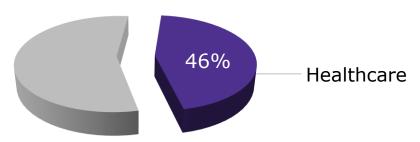
## Net sales bridge



## Comments

- Rebif organically stable; ramp-up of competition in Europe partially offset by tender in Russia; in U.S. pricing offsets declining volumes
- Solid organic growth of Erbitux across all regions, especially strong volume growth in China, but also low comparables
- Fertility shows strong growth across portfolio especially in China; Gonal-f benefiting from competitive situation in U.S. and low base
- Marketing & selling reflects end of commission expenses for Rebif (U.S.) partially offset by reinvestments in sales force & launch preparations
- R&D spend increases as pipeline development progresses
- Higher EBITDA pre due to strong organic growth, end of Rebif commissions and ~€30 m disposal gain from Merck KGaA, Darmstadt, Germany Ventures minority

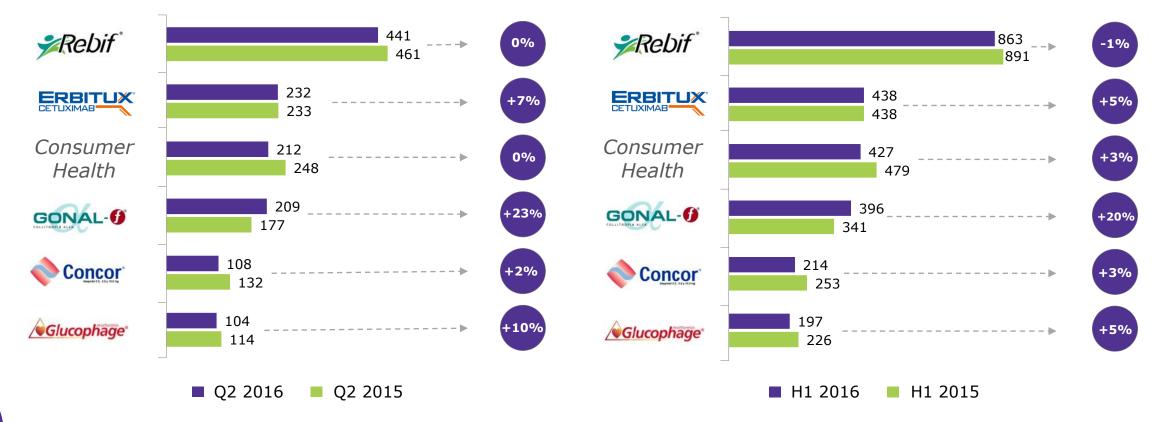
## Q2 2016 share of group net sales



Merck KGaA Darmstadt, Germany

# Healthcare organic growth by franchise/product

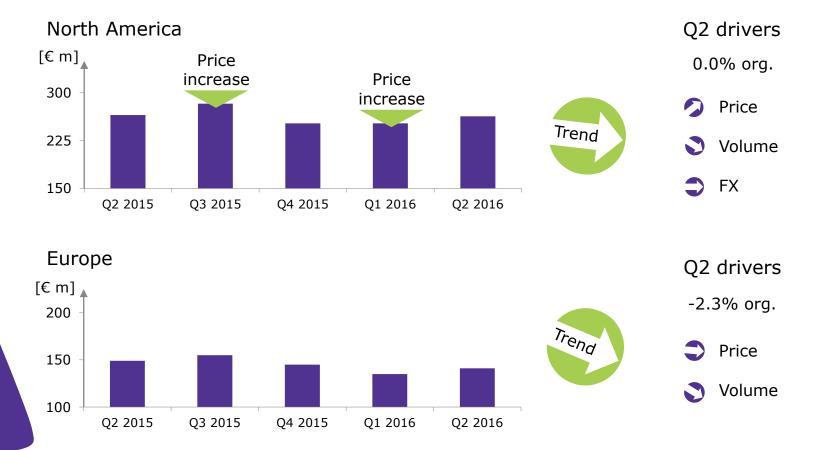
Q2 2016 organic sales growth [%] by key product [€ m]



H1 2016 organic sales growth [%] by key product [ $\in$  m]

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

## Rebif sales evolution

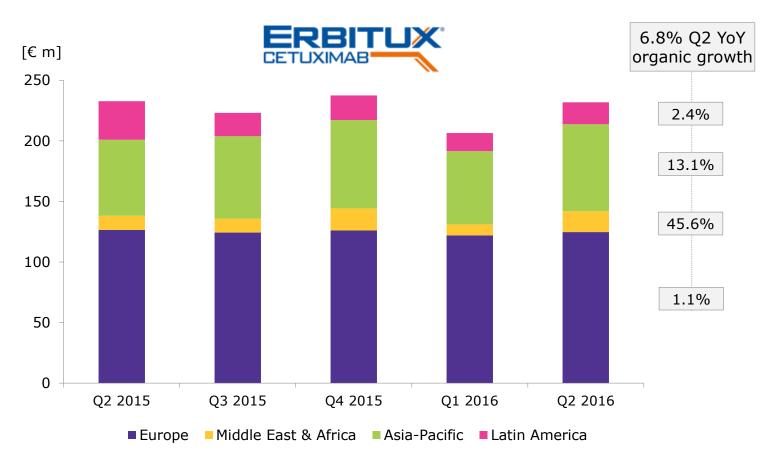


## Rebif performance

- Rebif sales of €441 m in Q2 2016 reflect flat organic performance amid negative FX effects from LatAm & EU
- Market shares within interferons stable due to high retention rates and longterm safety track record
- •U.S. pricing & market share stabilization offset decline of interferon class
- 5% U.S. price increases in July will support performance going forward
- Phased market entry of orals in Europe causes ongoing volume decline;
   Q2 2016 contains tender in Russia

# **Erbitux: A challenging market environment**

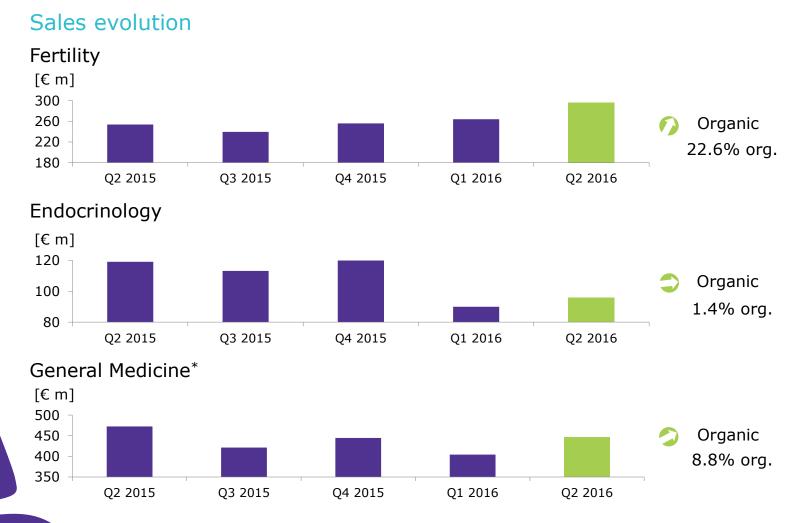
## Erbitux sales by region



## Erbitux performance

- Sales increase to €232 m due to solid volume development especially in growth markets
- Europe stable in ongoing tough environment (price and competition)
- Asia-Pacific shows strong growth led by China
- Organic jump in MEA reflects growing demand but also beneficial tender phasing

## Strong organic growth in Fertility, General Medicine and Endocrinology



#### Q2 drivers

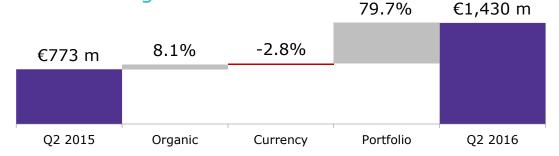
- •Gonal-f continues to benefit from competitive situation in U.S. and strong demand in China
- Sales drop in Endocrinology reflects Kuvan divestment; remaining portfolio (Saizen, Serostim) growing organically
- General Medicine sales burdened by FX headwinds from LatAM, organic performance sustainably healthy
- Euthyrox posts strong growth fueled by all regions, China remains key organic contributor of organic growth
- Glucophage growing in all regions especially benefiting from high demand in Middle East

## Life Science: Another strong quarter while integration on track

#### Life Science P&L

[€m]	Q2 2015	Q2 2016
Net sales	773	1,430
Marketing and selling	-244	-413
Administration	-28	-58
Research and development	-49	-65
EBIT	87	166
EBITDA	170	343
EBITDA pre	200	417
Margin (in % of net sales)	25.9%	29.1%

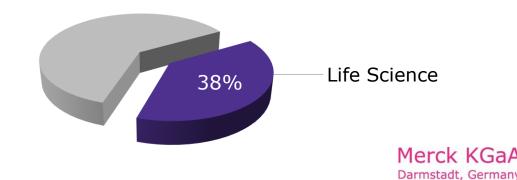
## Net sales bridge



### Comments

- Double-digit growth of Process Solutions driven by increasing production of large molecules across global and regional accounts
- Applied Solutions shows moderate organic growth, driven by biomonitoring products for pharma & demand for analytical testing
- Research Solutions benefits from strong demand in Emerging Markets, and for chemical analytics and molecular biology products
- Absolute costs higher due to Sigma, but improve in relation to sales
- Profitability reflects Sigma, business mix and synergies



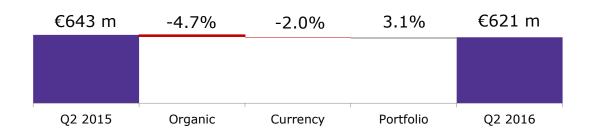


# Performance Materials: Strong profitability amid ongoing destocking

## Performance Materials P&L

[€m]	Q2 2015	Q2 2016
Net sales	643	621
Marketing and selling	-53	-59
Administration	-14	-14
Research and development	-49	-53
EBIT	238	193
EBITDA	299	267
EBITDA pre	295	273
Margin (in % of net sales)	45.9%	44.1%

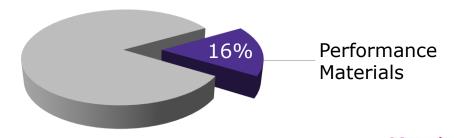
## Net sales bridge



## Comments

- LC declining as ongoing supply chain destocking & volume declines of mature TN-TFT outweighs volume increase in PS-VA and IPS
- Destocking is expected to continue into H2 2016
- OLED continues to grow on industry capacity expansion & investments
- Integrated Circuit Materials (ICM) shows above market growth mainly driven by dielectric and lithography materials for chip production
- Strong growth of Pigments & Functionals due to strong Xirallic for automotive coatings and cosmetic functionals, but on low comparables
- High profitability reflects leading market position, positive product mix within ICM and Pigments as well as active cost management

## Q2 2016 share of group net sales



## **Reported figures reflect strong business performance**

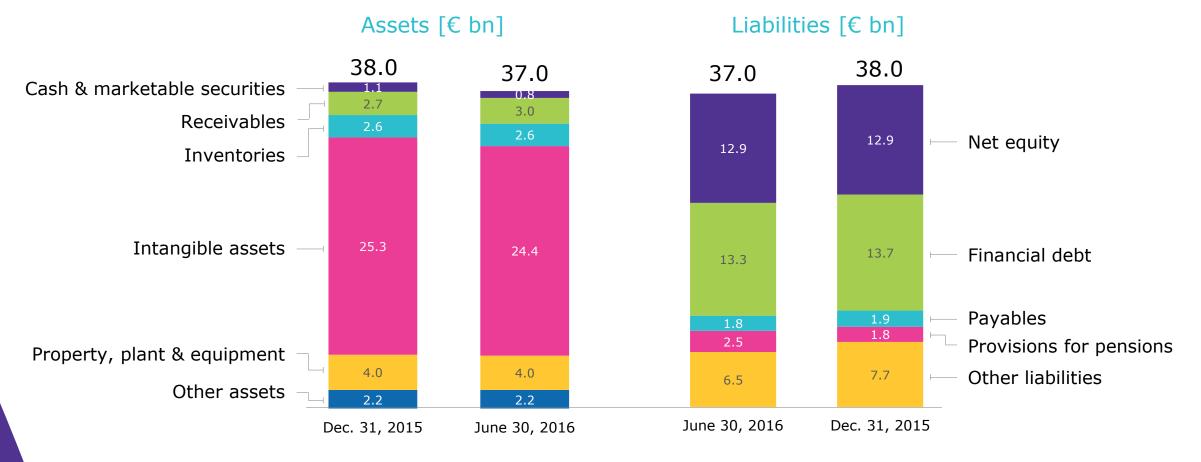
#### Reported results

[€m]	Q2 2015	Q2 2016	Δ
EBIT	501	550	9.8%
Financial result	-41	-121	>100%
Profit before tax	461	429	-6.8%
Income tax	-115	-115	0.0%
<i>Effective tax rate (%)</i>	24.9%	26.7%	
Net income	343	312	-9.1%
EPS (€)	0.79	0.72	-8.9%

#### Comments

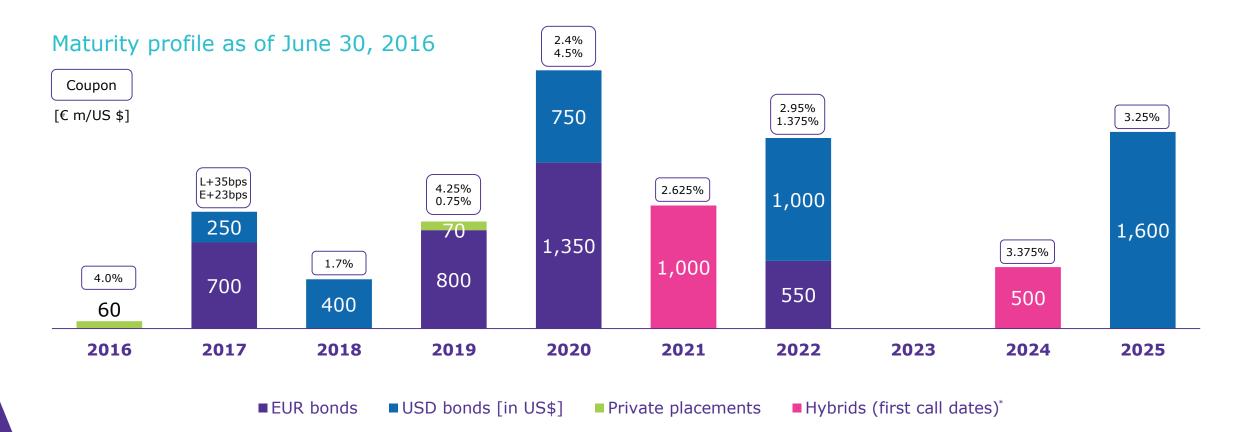
- EBIT reflects increased EBITDA pre amid integration costs, Sigma D&A and Xalkori impairment (~€70 m)
- Financial result contains Sigma financing interest expenses and significant adverse effects from LTIP
- Effective tax rate slightly above guided range of ~23% to 25% due to Xalkori impairment

## **Balance sheet – deleveraging in progress after Sigma acquisition**



- Total assets decline by 2.6%, equity ratio grows to 34.7%
- Other liabilities decrease by €1.2 bn mainly due to dividend payment to E. Merck KG, Darmstadt, Germany and lower deferred taxes
- Further decline in interest rates increases pension provisions
- Stable net equity: Profit after tax offset by dividends, FX translation and actuarial losses

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



Financing structure enables flexible and swift deleveraging

# Healthy underlying operating cash flow

## Q2 2016 – cash flow statement

[€m]	Q2 2015	Q2 2016	Δ
Profit after tax	346	314	-32
D&A	343	519	176
Changes in provisions	-70	-67	3
Changes in other assets/liabilities	-270	-397	-127
Other operating activities	3	-28	-31
Changes in working capital	-25	-30	-5
Operating cash flow	326	311	-15
Investing cash flow	1,860	-114	-1,974
thereof Capex on PPE	-93	-125	-32
Financing cash flow	-174	-357	-183

## Cash flow drivers

- •D&A increases due to Sigma and Xalkori impairment
- Higher tax payments burden changes in other assets/liabilities
- Investing cash flow LY contained cash-in from Sigma hedging
- Capex higher due to HQ & Sigma; 2016 peak expected in Q4
- Financing cash flow reflects repayment of Millipore bond and commercial paper

# **Exceptionals in Q2 2016**

## Exceptionals in EBIT

[€m]	Q2 2015		Q2 20	016
	Exceptionals	thereof D&A	Exceptionals	thereof D&A
Healthcare	21	2	70	71
Life Science	30	0	74	0
Performance Materials	-3	0	7	0
Corporate & Other	9	0	10	0
Total	56	2	160	71



# **Financial calendar**

Date	Event
October 13, 2016	Capital Market Day - 2016
November 15, 2016	Q3 2016 Earnings release
March 9, 2017	Q4 2016 Earnings release
April 28, 2017	Annual General Meeting
May 18, 2017	Q1 2017 Earnings release



#### CONSTANTIN FEST



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

#### ANNETT WEBER



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

#### EVA STERZEL



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

#### SVENJA BUNDSCHUH



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

#### NILS VON BOTH



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

#### OLLIVER LETTAU



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

#### **ALESSANDRA HEINZ**



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

## **EMAIL:** <u>investor.relations@emdgroup.com</u> **WEB:** <u>www.emdgroup.com/investors</u> **FAX:** +49 6151 72-913321

