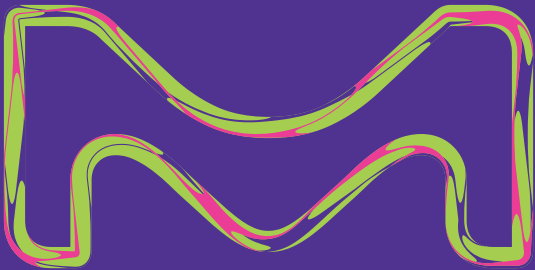




# **MERCK KGAA, DARMSTADT, GERMANY – Q3 2019 ROADSHOW**

Investor Relations

November 2019





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# Agenda

- 01 Business overview**
- 02 Transforming the company**
- 03 Healthcare – Funding for success**
- 04 Life Science – Focusing on profitable growth**
- 05 Performance Materials – Maintaining leadership and innovation**
- 06 Executive summary and guidance**



01

## **BUSINESS OVERVIEW**

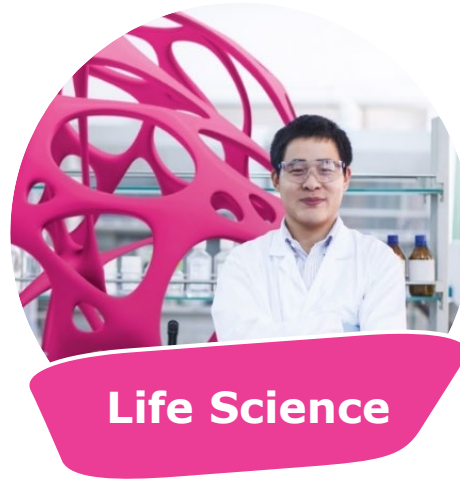
Group

## Three high-tech businesses competing in attractive markets



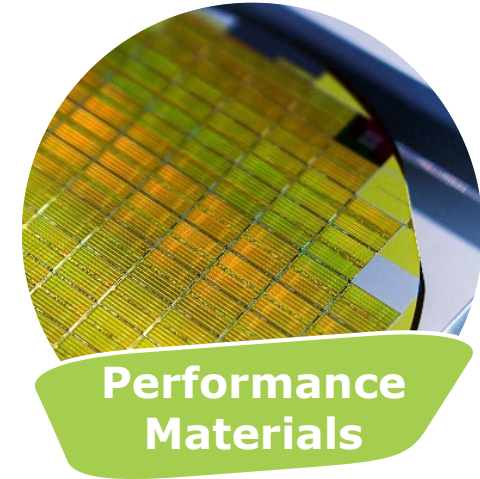
Leading in specialty  
pharma markets

- Biologics and small-molecule **prescription medicines** against cancer, multiple sclerosis, infertility
- **Research** focus: Oncology, Immunology & Immuno-Oncology
- **Successful portfolio management:** e.g. divestment of Consumer Health business



Leading life science  
company

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

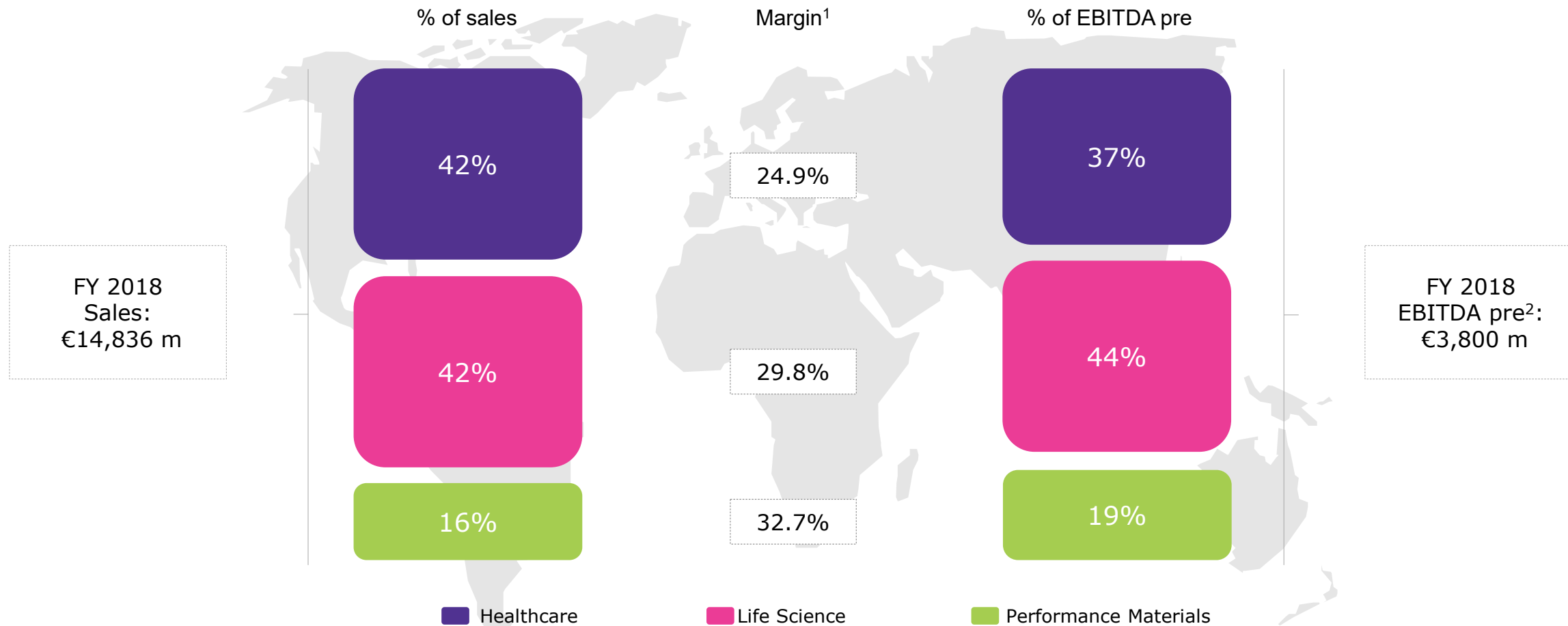


Leading company in  
high-tech solutions

- High-tech solutions and materials for **electronics**
- Broad portfolio of **decorative and functional solutions**

# Group

## Strong businesses with attractive margins



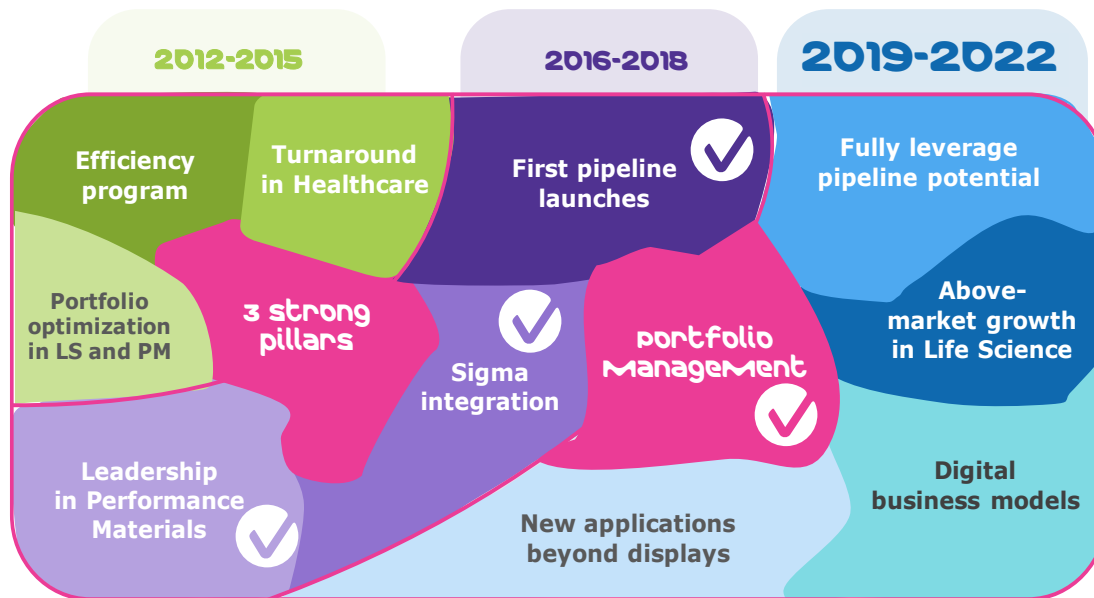
<sup>1</sup>EBITDA pre margin in % of net sales; <sup>2</sup>Including Corporate/Others (-€382 m)



## **02** TRANSFORMING THE COMPANY



# Group Strategic roadmap 2016-2022



## Group:

Sustainable profitable growth and regular portfolio evaluation



## Healthcare:

Fully leveraging pipeline potential



## Life science:

Sustaining above-market growth



## Performance Materials:

On track towards a Bright Future

**On track to deliver on the growth phase of the 2016-2022 strategic agenda**

# Group Executive Summary



## Group:

Entering the **profitable growth and expansion phase** of our 2016 – 2022 strategic agenda



## Healthcare:

Reaping the **fruit of the investment phase**, while keeping the base business at least stable, driving growth and managing costs



## Life science:

Sustaining **profitable above-market growth** strategy through portfolio focus, customer-centric services and innovation



## Performance Materials:

Transitioning from trough-year to **mid-term growth trajectory** supported by roll-out of Bright Future program

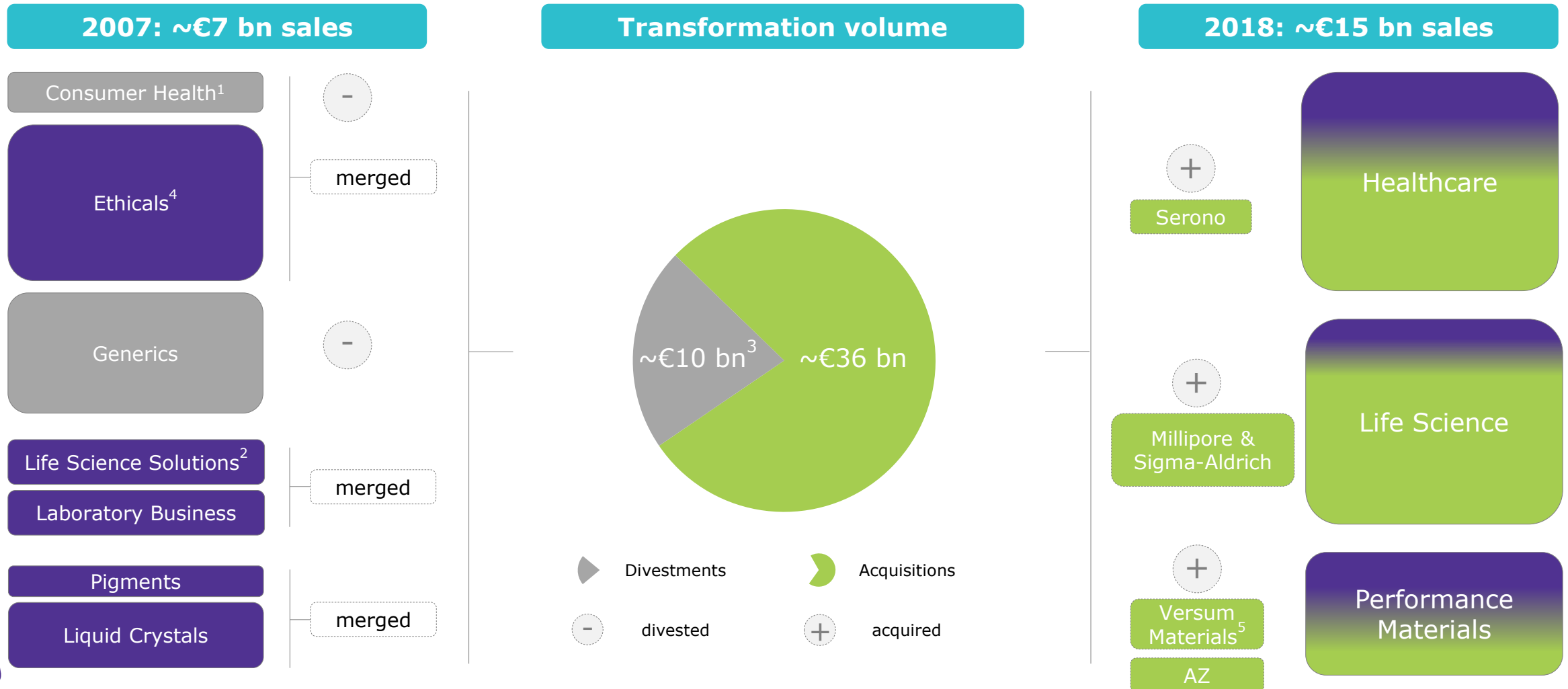


**MERCK KGAA, DARMSTADT, GERMANY –**  
**steady earnings growth at high**  
**margins and a low risk profile**



## Group

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

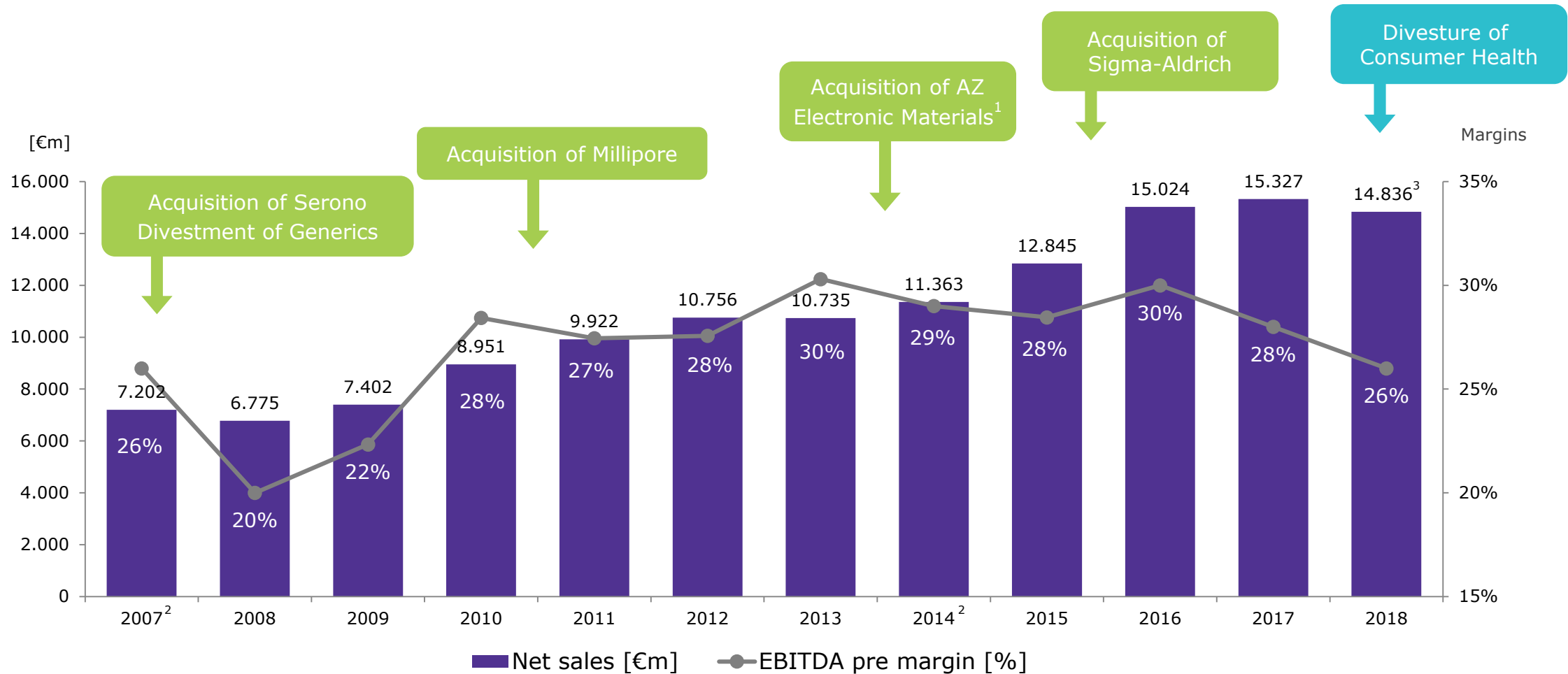


<sup>1</sup>Closing of sale of Consumer Health at a cash purchase price of €3.4 bn completed as of December 1 2018; <sup>2</sup>Excluding "Crop Bioscience", which was divested;

<sup>3</sup>Profroma divestment volume includes cash proceeds for Consumer Health; <sup>4</sup>Excluding "Theramex", which was divested; <sup>5</sup>Closing of acquisition of Versum Materials at a purchase price of €5.8 bn completed as of October 7 2019

## Group

# Continue to transform to a science and technology focused company



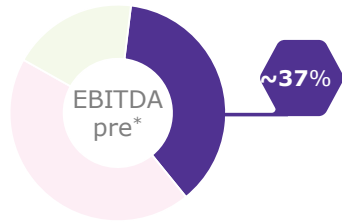
<sup>1</sup>Included since 2 May 2014; <sup>2</sup>2007 and 2014 EBITDA pre margin adjusted for comparability; <sup>3</sup>2018 net sales reflect Consumer Health divestiture (reduction of ~ €1 bn net sales p.a.)

# Group

## Clear set of priority goals



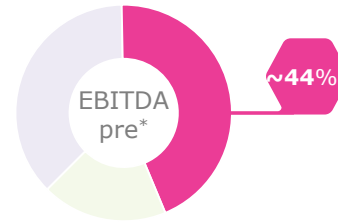
### Healthcare



- Deliver on ambition to keep core business at least stable until 2022
- Transition from investment to earnings phase by 2019
- Foster successful Bavencio<sup>®</sup> and Mavenclad<sup>®</sup> ramp up
- Stringent pipeline execution



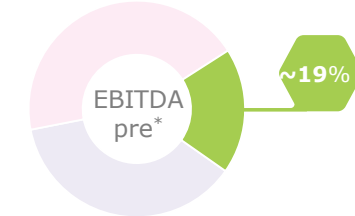
### Life science



- Strengthen position as differentiated player in a highly attractive market
- Maintain consistent above-market growth trajectory and superior profitability
- Implement dynamic strategy for future profitable growth



### Performance Materials



- Deliver on growth ambition of 2-3% CAGR
- Implement 5-year transformation program and focus on seamless integration
- Ensure efficient resource allocation to reach financial ambition of 30% margin
- Maintain strong cash generation and cash conversion

\*based on FY 2018 reported EBITDA pre, excluding Corporate & Other

## Group

# Strategic capital allocation until 2022 newly defined

### portfolio guardrails

- Three balanced pillars with no business marginalized
- Leading market positions in attractive markets
- Clear portfolio roles assigned

### Defining portfolio criteria

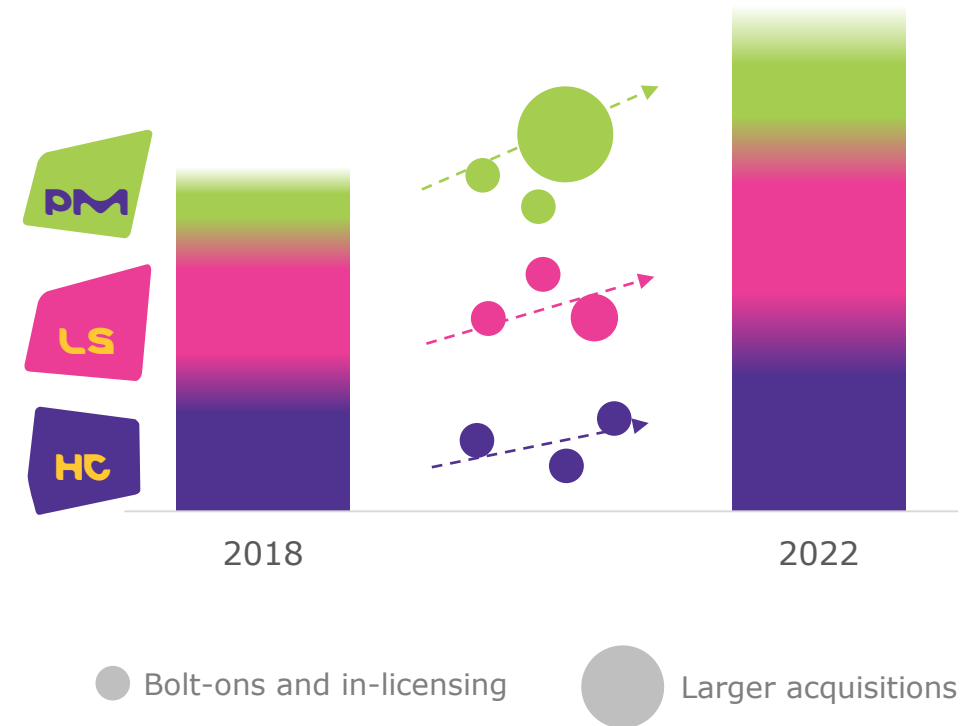
- Market attractiveness & capabilities
- Best strategic owner
- Risk profile

### clear financial M&A criteria

- $IRR > WACC$
- EPS pre accretive
- Maintain investment-grade credit rating

**Regular portfolio review and disciplined capital allocation will continue to ensure sufficiently diversified and value-creating structure of three strong pillars**

Illustration Merck KGaA, Darmstadt, Germany's sales and earnings drivers





## HEALTHCARE

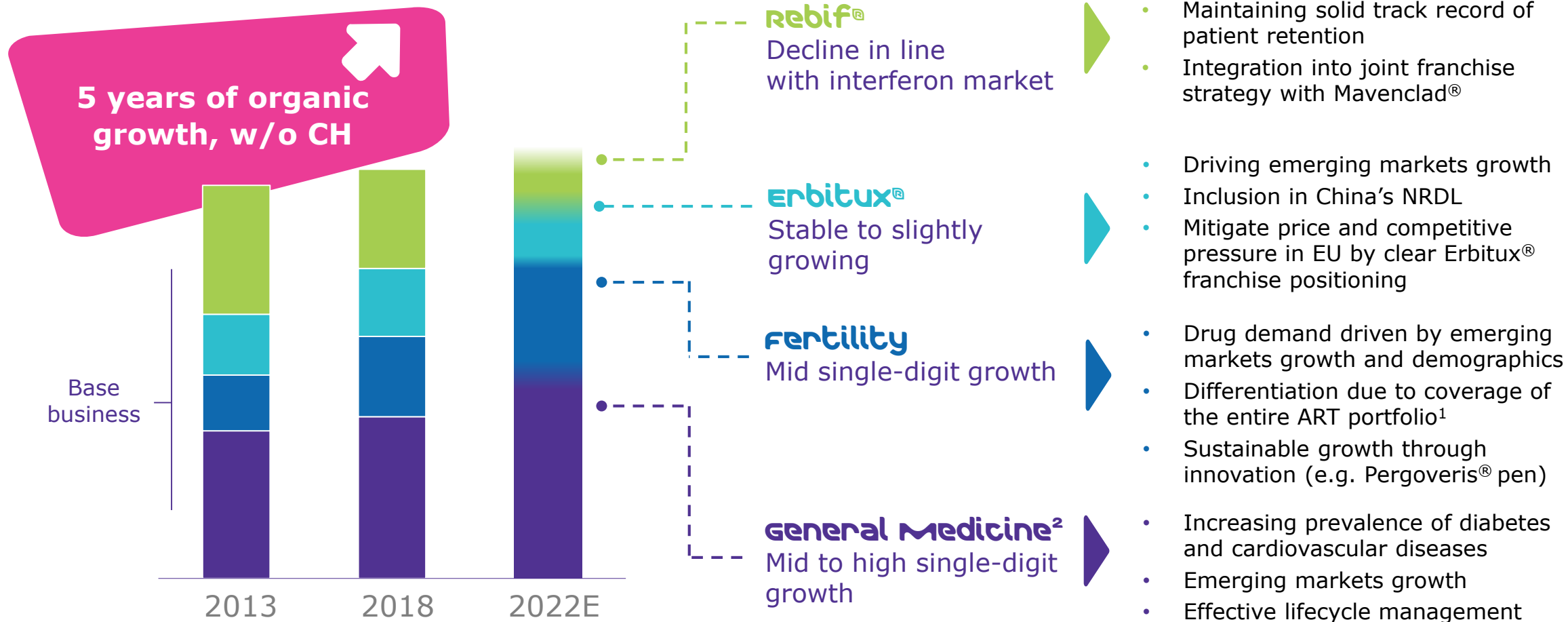
Fully leveraging pipeline potential



# Healthcare

## Ambition to keep core business sales organically stable until 2022

### Healthcare core business net sales until 2022



<sup>1</sup>ART: Assisted Reproductive Technology; <sup>2</sup>includes General Medicine, CardioMetabolic Care (CMC), Endocrinology & Allergopharma



## Mavenclad® and Bavencio® launches on track for €2 bn pipeline sales ambition

Sales from Pipeline:  
€2 bn in 2022



### Tepotinib

- Filing in Japan and USA in 2020 (Sakigake designation in JP, BTB in USA)

### Bavencio®

- FY 2019E: ~ €100 m (Jan - Sep 2019: €74 m)
- Approved for aRCC (FDA & EMA), mMCC (50 countries incl. USA and EU), and UC 2L (USA, Canada, Israel)
- Several Phase III trial read outs remaining

### Mavenclad®

- Approved in 70 countries, including USA, EU, Canada and Australia
- FY2019E: ~ €300 m (Jan - Sep 2019 : €194 m)
- Global peak sales: €1–1.4 bn

# Healthcare

## Mavenclad® continuing to make launch progress



### Ex-USA

- **Approved in 69 countries** (reimbursed in ~50%)
- **Continuous improvement of clinical perception**<sup>1</sup>
- **Continuous increase in share of high-efficacy dynamic patients** (new + switch) in major launch markets, e.g. Germany: from 14% to 17% (Q2 vs Q1 19)<sup>2</sup>
- **Increasing use in earlier lines of therapy**



### USA

Approved on March 29, 2019

- **Positive, early payer acceptance:**

~200 M lives with no  
NDC block

100% = total  
USA population

- **Leading share of voice**<sup>3</sup>, ~ 86% of neurologists willing to prescribe<sup>4</sup>
- **Broad adoption** from academic and community centers
- **Positive trend in efficacy and safety/tolerability** parameter perceptions<sup>5</sup>
- **x4 increase in high efficacy dynamic market share** (Oct 19: 4%) over past 3 months<sup>6</sup>



**On track for ~ €300 m sales in 2019**

<sup>1</sup>Global MAVENCLAD ATU; <sup>2</sup>IQVIA LRx data, consolidated retail + hospital data; <sup>3</sup>IQVIA/BrandImpactRx Report, rolling 3 months end July 2019; <sup>4</sup>Spherix Global Insights RealTime Dynamix – MS Q2/19; <sup>5</sup>RealTime Dynamix Multiple Sclerosis Q3 19 Spherix report; <sup>6</sup>Source: IQVIA projected national claims, rolling 3 weeks, October 2019; Acronyms: HE = High Efficacy, NDC = National Drug Code, RRMS = Relapsing-Remitting Multiple Sclerosis, SPMS = Secondary Progressive MS

# Bavencio® recently approved for advanced Renal Cell Carcinoma



## Regulatory Achievements



Approved by **US FDA** for 1L treatment of advanced Renal Cell Carcinoma (RCC) on May 15, 2019



Submitted to **Japanese authorities** in January 2019

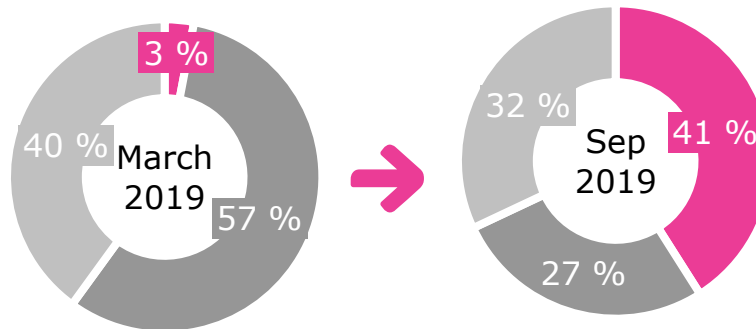


Approved by **European Commission** on October 28, 2019



## USA – Commercial Update<sup>1</sup>

### 1L New Patient Share<sup>1</sup>:



- **Leveraging Pfizer's heritage and commercial strength** in advanced RCC
- **IO-TKI established as the leading class** in 1L mRCC, with all other classes declining<sup>1</sup>
- **Bavencio®-Inlyta®** establishing itself with **~10% share** of growing IO-TKI class

■ IO-TKI ■ Others ■ IO-IO



## Remaining Phase III Trials<sup>2</sup>

**Mid-2020**

**Urothelial 1L  
NSCLC 1L**

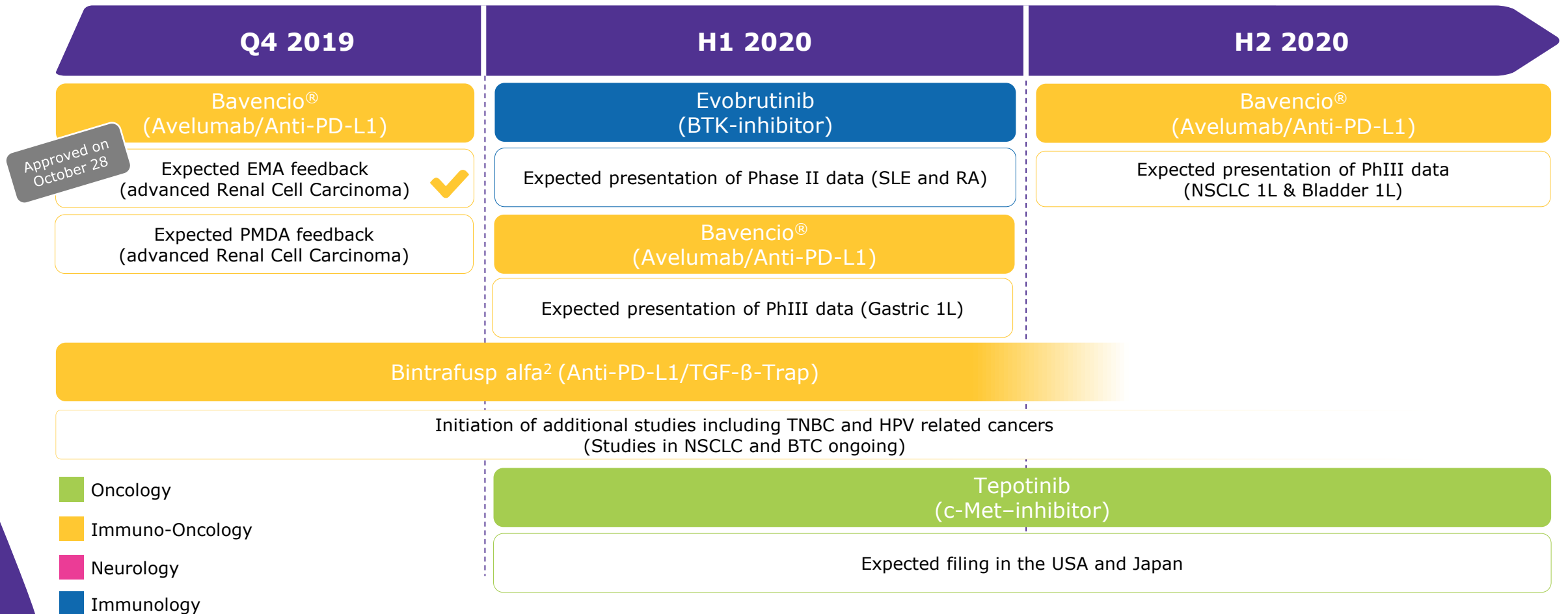
**2021**

**Locally advanced  
head & neck**

<sup>1</sup>BrandImpact Rx - 1L New Patient Start Share, Rolling 3 Months Ending September 2019, decline since Q1 2019 (VEGF mono, IO-IO); <sup>2</sup>Dates shown refer to estimated primary completion date as per [www.clinicaltrials.gov](http://www.clinicaltrials.gov);  
Acronyms: EMA = European Medicines Agency, FDA = Food and Drug Administration; IO = Immuno-Oncology, mRCC = Metastatic Renal Cell Carcinoma, TKI = Tyrosine Kinase Inhibitor, VEGF = Vascular Endothelial Growth Factor

# Healthcare

## Upcoming pipeline catalysts mark progress of the Oncology and IO portfolio<sup>1</sup>



<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 Inhibitor, EMA = European Medicines Agency, NSCLC = Non-small Cell Lung Cancer, RA = Rheumatoid Arthritis, SLE = Systemic Lupus Erythematosus, TNBC = Triple-Negative Breast Cancer, PMDA = Pharmaceuticals and Medical Devices Agency Japan



## **LIFE SCIENCE**

Focus on profitable growth

# The Life Science tools market is attractive and dynamic

## Attractive market...

€170 Bn

4-6%<sup>10</sup>  
CAGR

23-25%

average margin

## ...with robust trends



### Research

~€45-50 bn  
~2-3% CAGR<sup>9</sup>



- Increase in **NIH Funding and Pharma R&D**<sup>1,2</sup>
- Increase in **novel technologies**<sup>3</sup>
- Increase in **research outsourcing**<sup>4</sup>



### Process

~€55-60 bn  
~8% CAGR<sup>9</sup>



- Increase in **biologics pipeline**<sup>5</sup>
- More **novel modalities** (>30% CAGR)
- Greater **production outsourcing**<sup>6</sup>



### Applied

~€60-65 bn  
~4-5% CAGR<sup>9</sup>



- Higher **Drug standards** (e.g. in China)<sup>7</sup>
- Tighter **F&B regulations** (e.g. US FSMA<sup>8</sup>)
- More **novel assays/diagnostics**

<sup>1</sup>CAGR 2015-2019; <sup>2</sup>PhRMA members, CAGR 2013-2017; <sup>3</sup>CAGR 2014-2018 VC investment into platform technologies; <sup>4</sup>CAGR 2015-2022. Discovery outsourcing market;

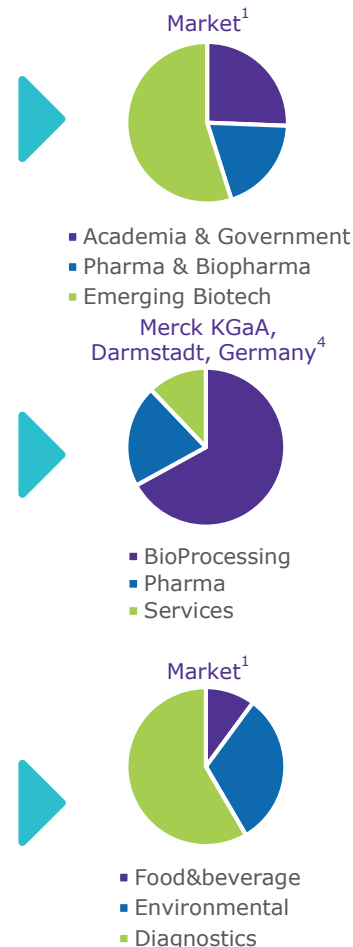
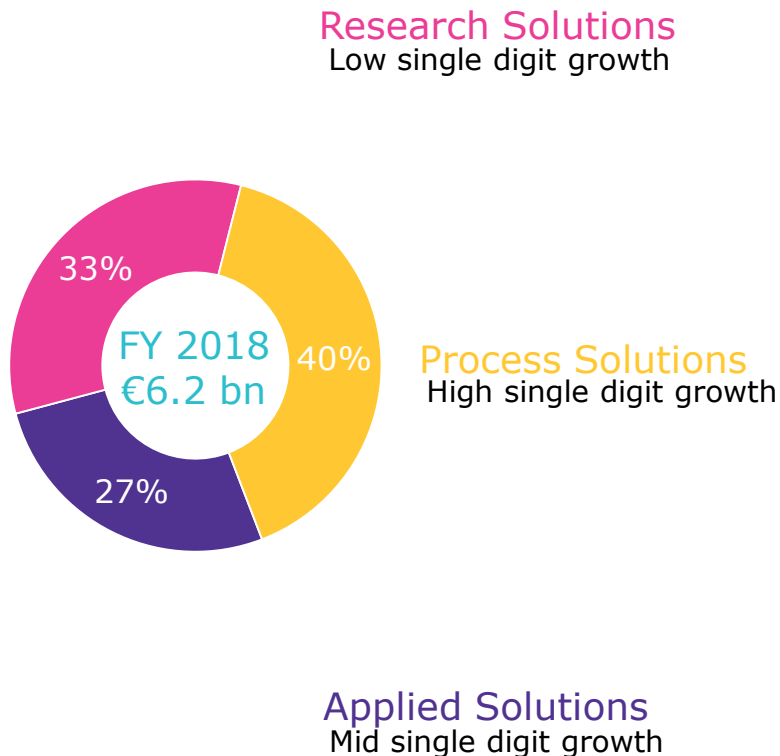
<sup>5</sup>CAGR through 2020; <sup>6</sup>CAGR 2016-2020; <sup>7</sup>International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use; <sup>8</sup>Food Safety Modernization Act implementation through 2024; <sup>9</sup>Total market CAGR; <sup>10</sup>Company estimate based on industry forecast over 5 year horizon;

Acronyms: NIH = National Institutes of Health, US FSMA = FDA Food Safety Modernization Act

# Life Science

## Business is on track to deliver above-market organic growth

### Life Science

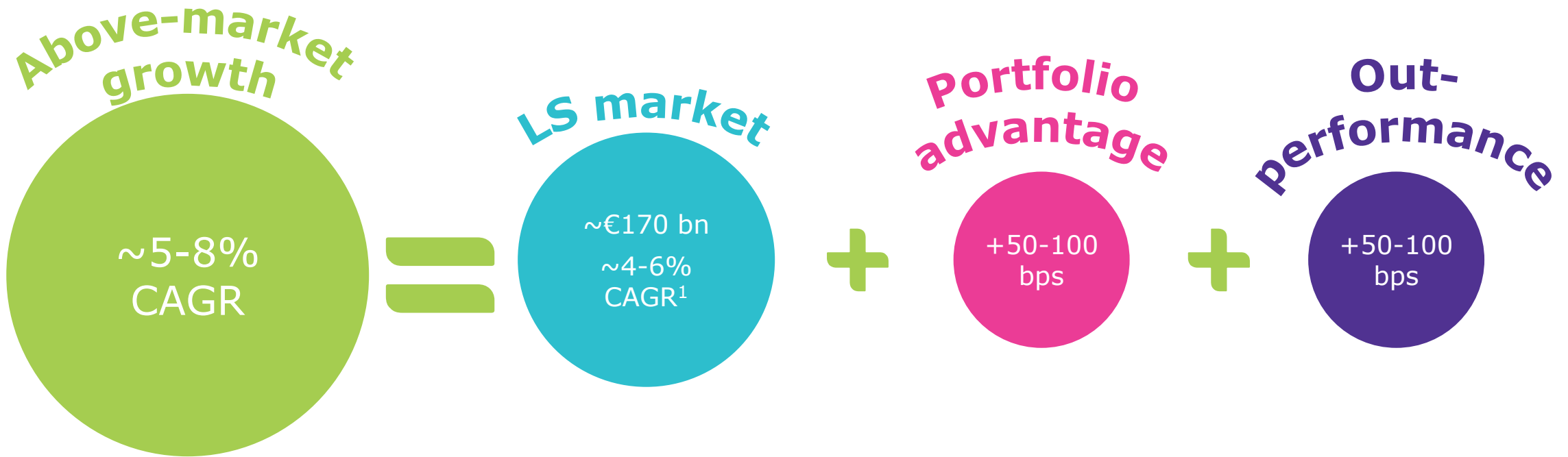


### Long-term growth drivers

- **Research activity:** >3,000 projects in research pipelines<sup>2</sup>, rising number of experiments and newly emerging therapies/technologies backs healthy growth in biotech and CROs<sup>3</sup>
  - **Public and private funding:** availability, access and predictability drive demand from academia and emerging biotech customers
  - **Regulation:** rising requirements foster long-term customer partnerships
- 
- **Biologics:** mAbs production<sup>5</sup> growing by ~11-15% p.a. for 2018-2024 driven by new molecules and biosimilars
  - **Diversification:** contribution by top 10 molecules will decline to ~20% until 2024 from 60% today<sup>6</sup>
  - **Noval modalities:** innovation in complex-to-deliver therapies, e.g. gene and cell therapy, will drive demand for single-use, end-to-end and new technology solutions
- 
- **Regulation:** testing volumes overall are rising globally rise in quality standards and increased demand for testing across customer segments
  - **Population and economic growth:** demand for access to more sophisticated products and services rises, e.g. in emerging markets
  - **Speed:** need for fast testing results raises requirements for Applied customers, esp. in clinical testing and food & beverage testing

<sup>1</sup>Source: Merck KGaA, Darmstadt, Germany Factbook; <sup>2</sup>Source: PhRMA; <sup>3</sup>CRO = Contract Research Organization; <sup>4</sup>Indicative only; <sup>5</sup>mAbs = monoclonal antibodies; <sup>6</sup>Source: EvaluatePharma September 2018

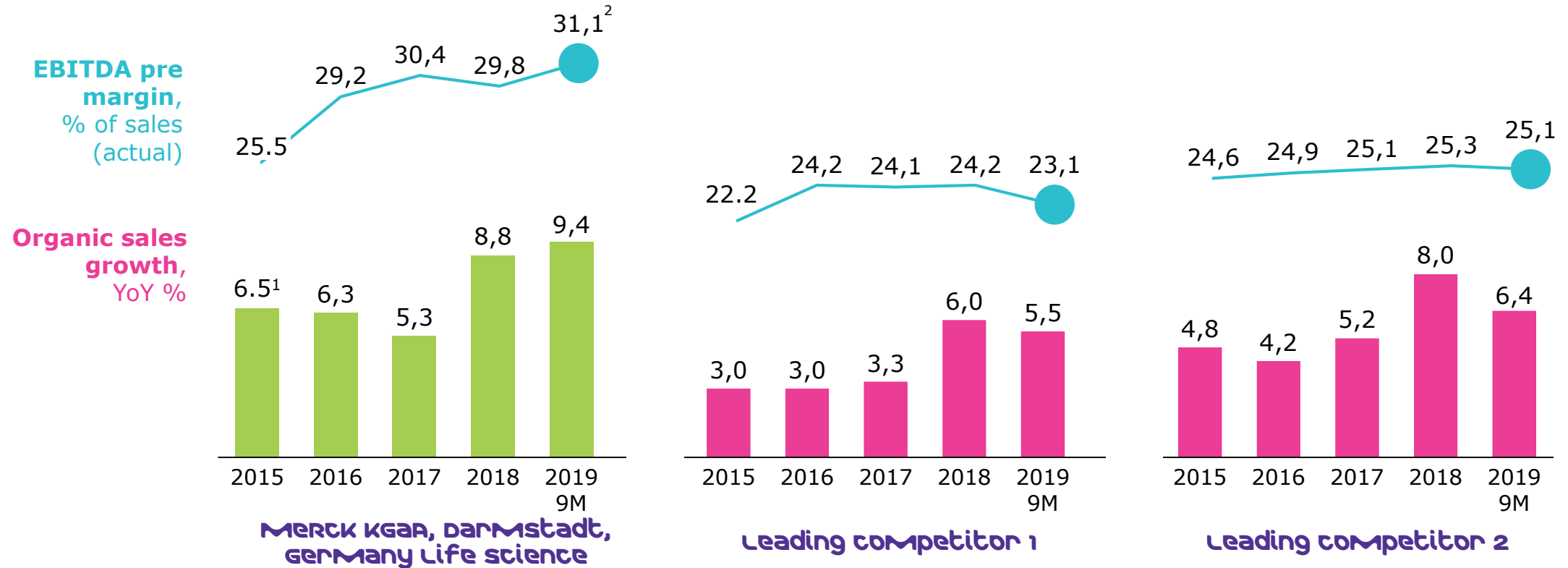
## Above-market growth continues to be driven by portfolio focus



<sup>1</sup>Company estimate based on industry forecast over 5 year horizon



# We continue to set the benchmark for industry performance



## Objective

- ➔ Grow **above market**
- ➔ Maintain **industry-leading profitability** with 20-30 bps underlying margin progression
- ➔ Sustain **leading market position**

<sup>1</sup>6.5% for EMD Millipore; 6.0% for SIAL calculated from first 9 months of 2015; <sup>2</sup>excl. CO

## Investing into innovation for future profitable growth

**New product sales** doubled in the past 5 years



<sup>1</sup>Launches from last 4+1 years excluding sales of year of launch



### External recognition



**2018:** Excellence in innovation Parateck® MXP Excipient & modified amino acid



**2019:** Exhibitor Award for Best New Product (Pellicon® Capsule with Ultracel® Membrane)

**2018:** Exhibitor Award for Best Technological Innovation (Millistak+® HC Pro portfolio)



**2018:** BioReliance® Viral & Gene Therapy Assay Portfolio & Proxy-CRISPR Technology

**2018:** Corporate Social Responsibility

**2017:** Sanger Arrayed Lentiviral CRISPR Libraries

## Leveraging both organic and inorganic levers for growth

### Organic – Global capacity expansion

**Asia:** e.g. manufacturing and distribution centers in South Korea, China and India (2018)

**North America:** e.g. BioReliance® End-to-End Biodevelopment Center in Burlington, USA (2018)

**Europe:** e.g. M Lab™ Collaboration Center in Molsheim, France (2019)



### Inorganic – Transformative M&As and bolt-ons for strategic growth

2010: **Millipore** (US\$7 bn)

2015: **Sigma-Aldrich** (US\$17 bn)

2017: **BioControl** – Food Safety Testing

...

### Strategic alliances – Exploring novel growth opportunities

- **Broad Institute (MIT and Harvard)** (2019) – accelerating access to CRISPR intellectual property for research
- **TRANSVAC2 (part of EU's Horizon 2020)** (2019) – advancing vaccine development and manufacturing
- **GenScript** (2019) – accelerating Cell and Gene Therapy industrialization in China





# Life Science

## Strengthening the #1 eCommerce site in Life Science through increased agility and greater customer-centricity

**Best-in-class eCommerce** 

**Leading Life Science website** 

### Continued enhancements driven by focus on ...

-  **Content** – Informative content with easy access
-  **Geographic fit** – Tailored to local preferences
-  **Scalability** – Best-in-class site
-  **Connectivity** – Enabling dialogue within the scientific community

- >€1.5 bn sales
- >420 million annual page views
- Rated **#1 website for traffic**<sup>1</sup>





05

## **PERFORMANCE MATERIALS**

Maintaining leadership and innovation

# Performance Materials

## A leading player in the electronic materials market

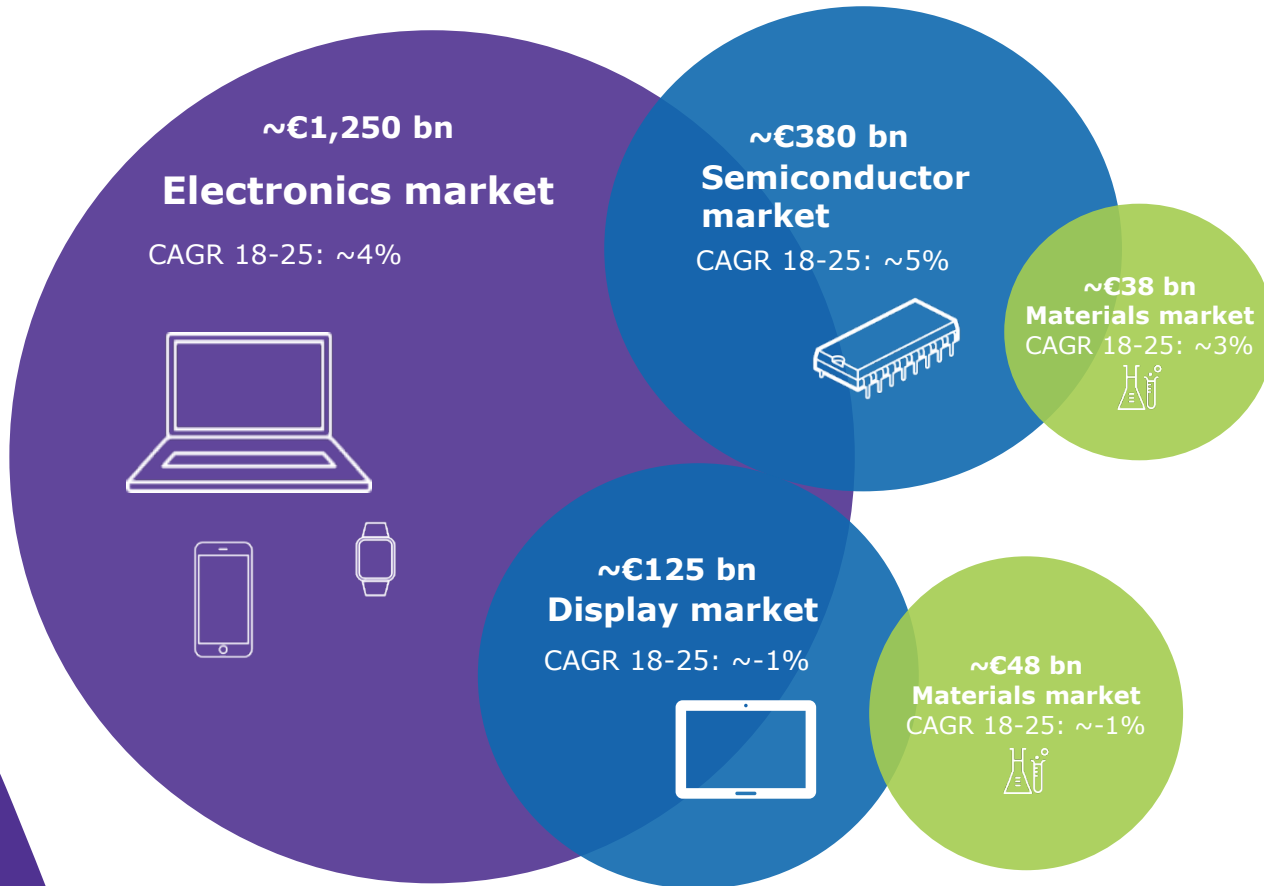
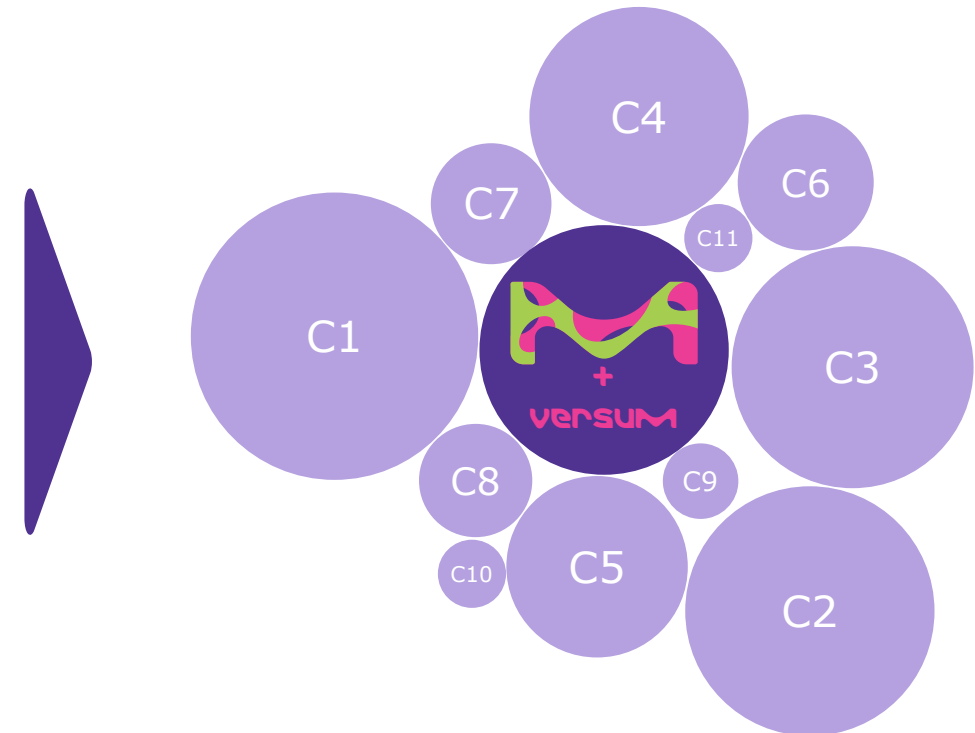


Illustration of the electronics market and thereof its selected sub markets

### Electronic materials competitor landscape<sup>1</sup>



<sup>2</sup>Bubble size in competitive landscape illustrates share of electronics material sales of indicated competitors (C1 – C11)

<sup>1</sup>Source: Linx 2018, Research & Markets 2017, Semi 2015, McClean/IC Insights 2018, IC insights, Gartner 2017, Prismark 2018, FujiChimera, IHS, Market size as of 2017

# Performance Materials targets attractive markets – especially in the electronics space



<sup>1</sup>Pro forma net sales: PM net sales LTM Q3 2018-Q2 2019 + Versum Materials sales LTM Q4 2018-Q3 2019; Source: McClean 2018/IC Insights 2017, Gartner 2017, Prismark 2018, Statista 2016; Abbreviation: CAGR = Compound annual growth rate; GDP = Gross domestic product

# Performance Materials

## Three high-tech pillars serving a diverse customer base

### Business allocation within Performance Materials

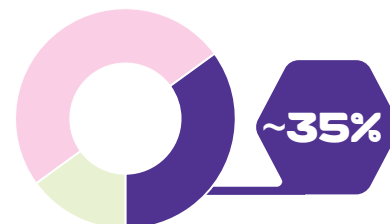


% of sales<sup>1</sup>



### Products

- Dielectrics, colloidal silica, lithography materials, yield enhancers, edge-bead removers
- Polyimide raw materials, printing materials and specialty gases
- Delivery equipment for gas, chemicals and CMP slurries, installation services and parts & support



- Liquid crystals (LC) and photoresists for TVs, smartphones and tablet computers
- Other display and non-display applications (e.g. LC Windows)
- Organic and inorganic light emitting diodes



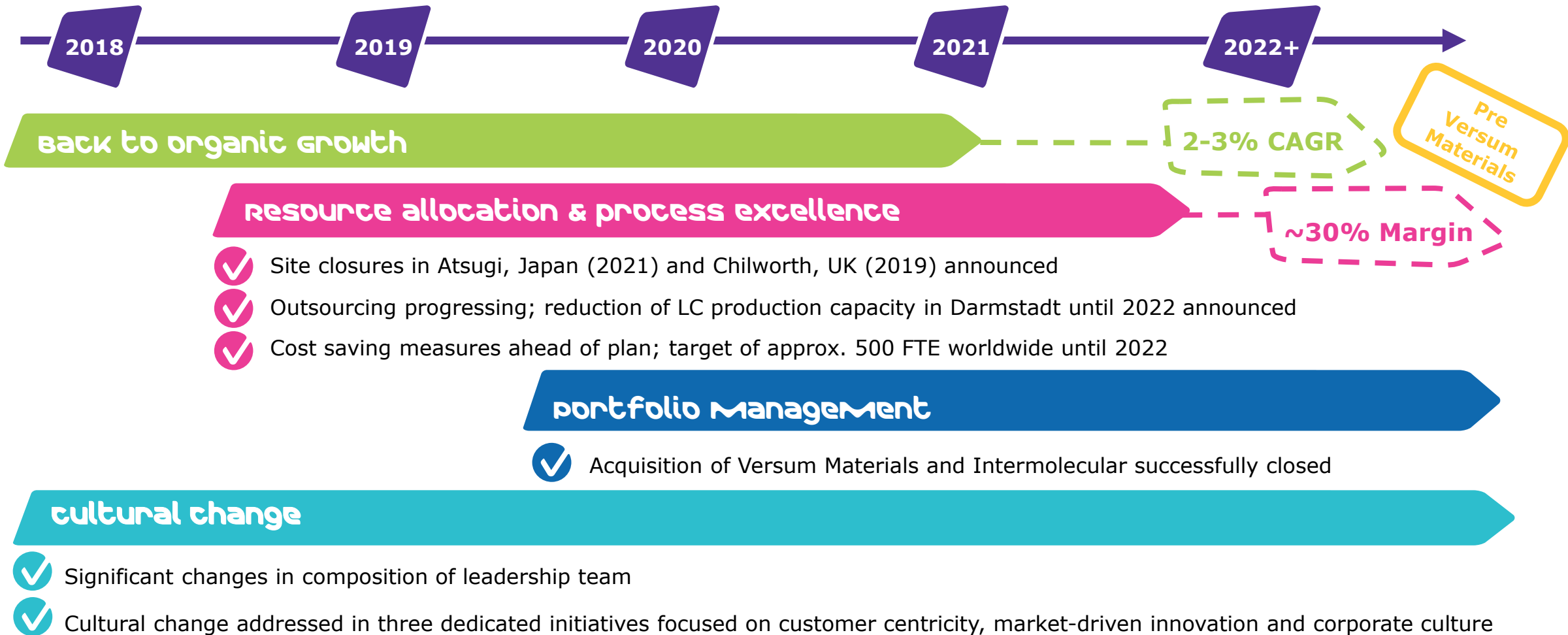
- Effect pigments and functional materials for coatings, plastics, printing and cosmetics
- Functional materials for cosmetics & special applications
- Functional materials for electronics and energy solutions

<sup>1</sup>Pro forma net sales: PM net sales LTM Q3 2018-Q2 2019 + Versum Materials sales LTM Q4 2018-Q3 2019



## Performance Materials

### 5-year transformation program Bright Future is well on track



# Performance Materials

## Strategic roadmap starting to materialize...

### Measures for a bright future



#### Darmstadt

- The focus in Darmstadt will be on R&D and production
- Immediate bottom line contribution from 2019 onwards
- Reduce the number of FTEs by ~15%  
= ~400 FTEs



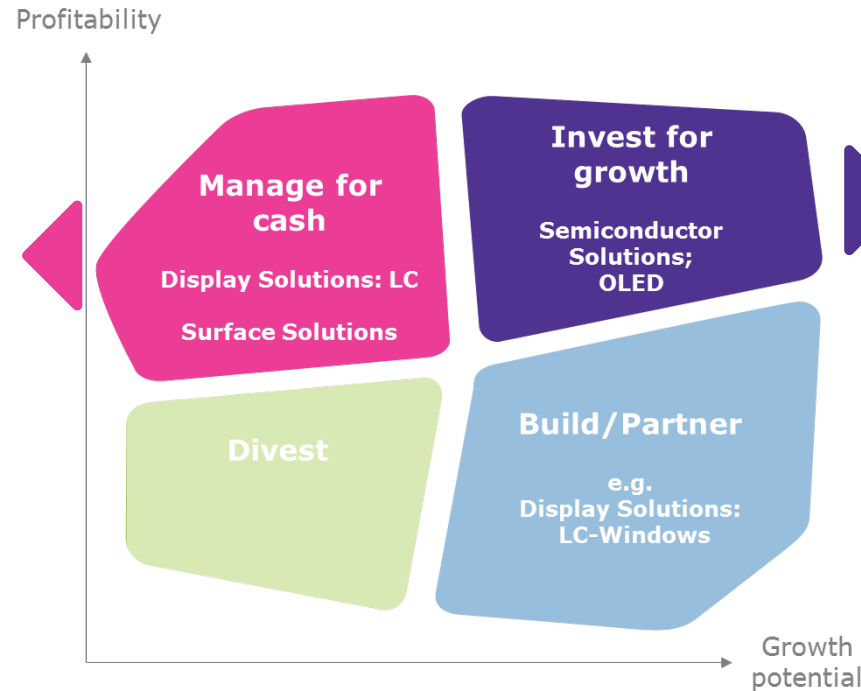
#### Chilworth

- Chilworth site during September 2019 successfully closed



#### Atsugi

- Shut down of Performance Materials activities at Atsugi site started (to be completed during 2021)
- R&D and production activities in Atsugi transferred and consolidated in other PM locations in Asia
- Consolidation of site structure in Japan



- Leading supplier of high-purity process chemicals, gases and equipment serving semiconductor manufacturers
- Track record of accelerated growth and industry leading profitability
- Creating a **leading electronic materials player** with **attractive long-term prospect**



- Leading in advanced materials innovation
- Acquisition to strengthen semiconductor technology offering
- Application specific **materials expertise** with that **perfectly complement** Group's business and technology portfolio



**Bottom-line management to support margin ambition of 30% in the long-term**



**Both transactions successfully closed**

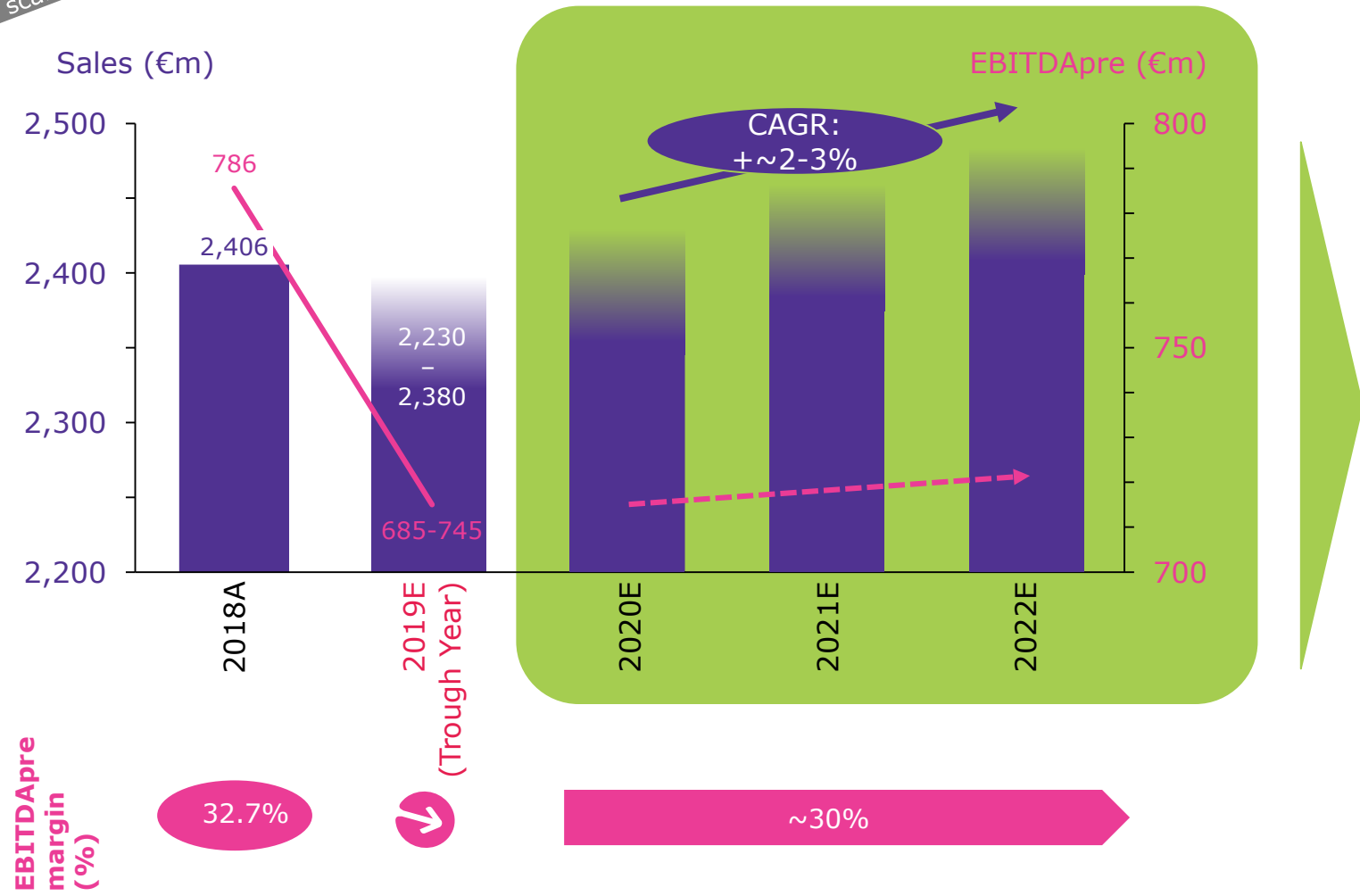
**Merck KGaA**  
Darmstadt, Germany

# Performance Materials

The business is expected to return to organic growth as of 2020

Pre  
Versum  
Materials

ILLUSTRATIVE  
Not to scale



## Contribution by business

- Semiconductor Solutions**  
Mid- to high-single digit growth
- Surface Solutions**  
Low single digit growth
- Display Solutions**  
Low single digit decline
  - OLED ↗
  - LC ↘



## 06 EXECUTIVE SUMMARY AND GUIDANCE

# Group

## Key earnings drivers to remember for 2019



### EBITDA<sup>1</sup>-supporting factors

- Strong sales contribution from Mavenclad® ramp-up and Bavencio®

new

Ongoing strength in Life Science with 8% to 9% 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 in Q2 to Q4 2019

- Income from milestones and management of pipeline (part of operating business in Healthcare) materializing in Q2 and Q4 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

new

Positive FX impact: Emerging market currencies remain weak but offset by favorable EUR/USD development (range 2019: 1.11-1.15)

new

86 days of Versum contribution

new

About stable R&D costs budgeted for Healthcare and decrease as % of sales (actual development will be subject to clinical data outcome of priority projects and prioritization decisions)



### EBITDA<sup>1</sup>-reducing factors

- Healthcare underlying margins negatively impacted by product mix

- Performance Materials sales and earnings reaching trough due to expected decline in Liquid Crystals in H2; economic environment may lead to moderate decline in Semiconductors, returning to growth in 2020

<sup>1</sup>EBITDA pre; <sup>2</sup>~€130m contribution from IFRS 16 (Healthcare ~40%, Life Science ~40%, PM ~10%, CO ~10%)

# Group

## Full-year 2019 guidance

Merck KGaA, Darmstadt, Germany guidance for 2019, including Versum for 86 days

### Net sales:

Organic +3% to +5% YoY

FX +1% to +2% YoY

~ **€15.7 – 16.3 bn**

thereof Versum: ~ €270 m

### EBITDA pre:

Organic +10% to +13% YoY<sup>1</sup>

FX 0% to +2% YoY

~ **€4,230 – 4,430 m**

thereof Versum: ~ €80 – 90 m

### EPS pre:

~ **€5.30-5.65**

thereof Versum: ~ €0.11 – 0.14

<sup>1</sup>Incl. ~€130m YoY contribution from adoption of IFRS 16 (Healthcare ~40%, Life Science ~40%, PM ~10%, CO ~10%);



# Group 2019 business sector guidance<sup>1</sup> without Versum

## Healthcare



### Net Sales

- Solid organic growth +4% to +6%
- Base business at least stable organically
- Strong contributions from launches including Mavenclad

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

- Organic +19% to +23% YoY
- FX 0% to +2% YoY
- ~ €1,830 – 1,940 m

## Life Science



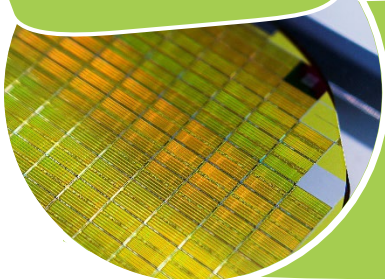
### Net Sales

- Organic growth +8% to +9%, above expected market growth
- Main growth driver Process Solutions but all businesses contributing

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

- Organic +12% to +14% YoY
- FX +0% to +2% YoY
- ~ €2,040 – 2,140 m with 20-30 bps<sup>3</sup> underlying margin progression

## Performance Materials



### Net Sales

- Organic decline -4% to -7%
- LC resuming decline, following temporary capacity ramp-up in China
- Economic environment may lead to moderate decline in Semicon, return to growth in 2020

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

- Organic -9% to -13% YoY
- FX +3% to +5% YoY
- ~ €695 – 755 m

<sup>1</sup>Divisional guidances are only support to the group guidance and do not have to add up; <sup>2</sup>Incl. ~€130 m YoY contribution from adoption of IFRS 16 (Healthcare ~40%, Life Science ~40%, PM ~10%, CO ~10%); <sup>3</sup>bps = basis points; <sup>4</sup>Merck KGaA, Darmstadt, Germany stand-alone, i.e. without acquisition of Versum Materials and Intermolecular Inc.



# Additional financial guidance 2019

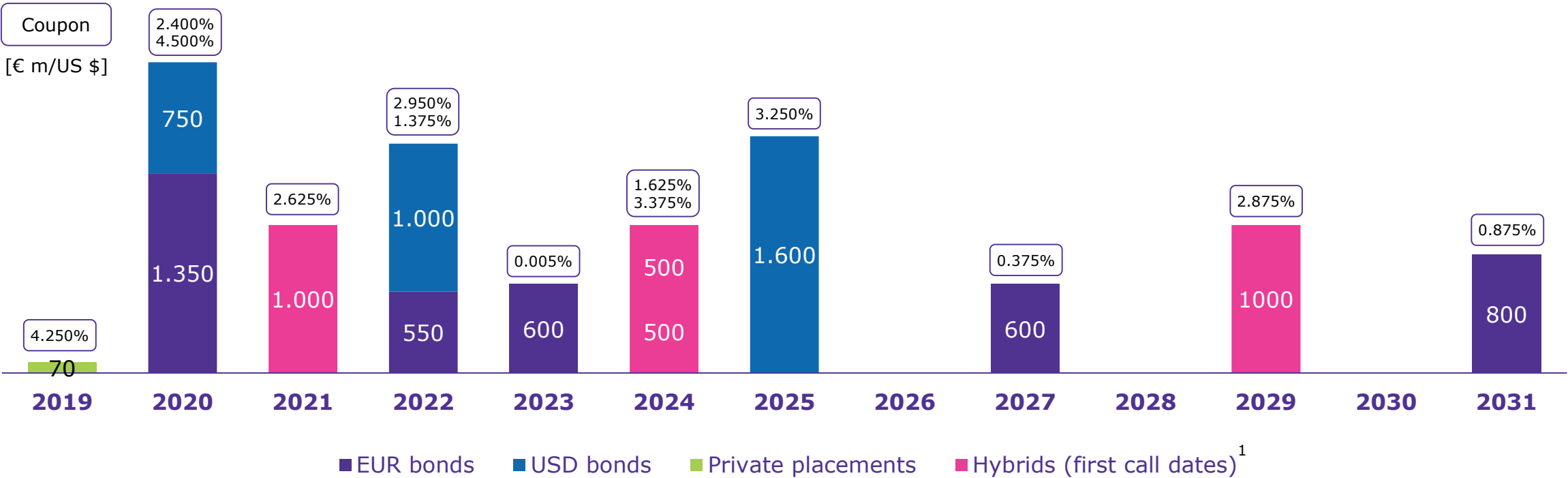
## Further financial details

Corporate & Other EBITDA pre*	~ <b>-€460 – -490 m</b>
Interest result	~ <b>-€260 – -280 m</b>
Effective tax rate	~ <b>24% to 26%</b>
Capex on PPE	~ <b>€1.0 bn – 1.1 bn</b>
Hedging/USD assumption	<b>FY 2019 hedge ratio ~60% at EUR/USD ~1.20</b>
2019 Ø EUR/USD assumption	~ <b>1.11 – 1.15</b>

\*CO guidance 2019: -€460 m to -€490 m (assuming FX adjusted CO costs -€390 m to -€400 m)

# Maturity profile reflects Sigma-Aldrich and Versum financing transactions

Maturity profile as of Sept. 30, 2019

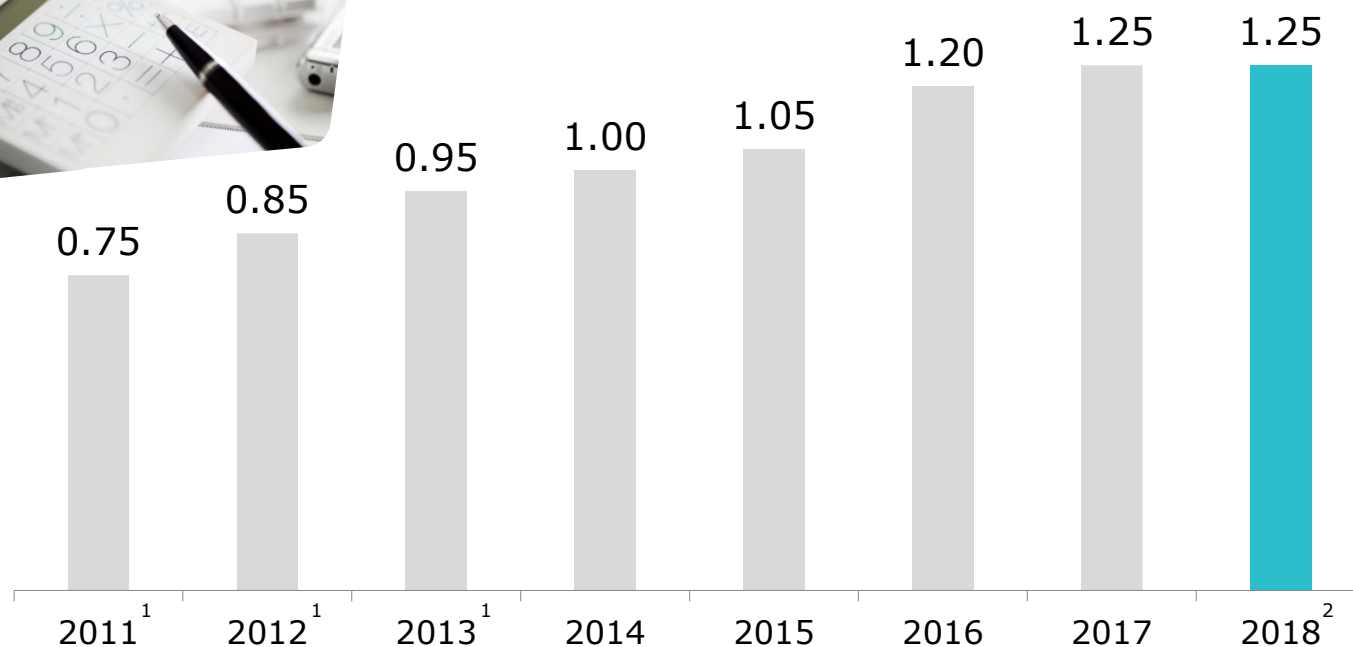


Balanced maturity profile in upcoming years avoids refinancing risks; Merck KGaA, Darmstadt, Germany will become a more frequent issuer

<sup>1</sup>No decision on call rights taken yet

# Stable dividend amid lower EPS pre

## Dividend<sup>1</sup> development 2011-2018



## 2018 dividend

- Dividend of €1.25 per share for 2018
- Increase in payout ratio to 24.5% of EPS pre in 2018 vs. 20.3% in 2017<sup>2</sup>
- Dividend yield<sup>3</sup> of 1.4%

<sup>1</sup>Adjusted for share split, which has been effective since June 30, 2014; <sup>2</sup>Calculated with 2017 EPS pre of €6.16, while ex CH EPS pre €5.92 posts 21.1% payout ratio; <sup>3</sup>Calculated with 2018 year-end share price of €89.98 per share

# Clinical Pipeline

November 8, 2019

## Phase I

**M3258**  
**LMP7 inhibitor**  
Multiple myeloma

**M3541**  
**ATM inhibitor**  
Solid tumors

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

**M4344**  
**ATR inhibitor**  
Solid tumors

**M6620**  
**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

**abrituzumab**<sup>2</sup>  
**pan-αv integrin inhibiting mAb**  
Colorectal cancer 1L

**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 1L

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

**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>

**atacept**  
**anti-BlyS/APRIL fusion protein**  
Systemic lupus erythematosus

**atacept**  
**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**  
Urothelial cancer 1L-M

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

**evobrutinib**  
**BTK inhibitor**  
Multiple sclerosis

## 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.

<sup>1</sup> Includes studies in combination with avelumab.

<sup>2</sup> As announced on May 2 2018, in an agreement with SFJ Pharmaceuticals Group, abrituzumab will be developed by SFJ for colorectal cancer through Phase II/III clinical trials.

<sup>3</sup> Avelumab combination studies with talazoparib, axitinib, ALK inhibitors, cetuximab, chemotherapy, or novel immunotherapies.

<sup>4</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.

<sup>5</sup> As announced on October 28 2019, the European Commission (EC) approved avelumab in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma.

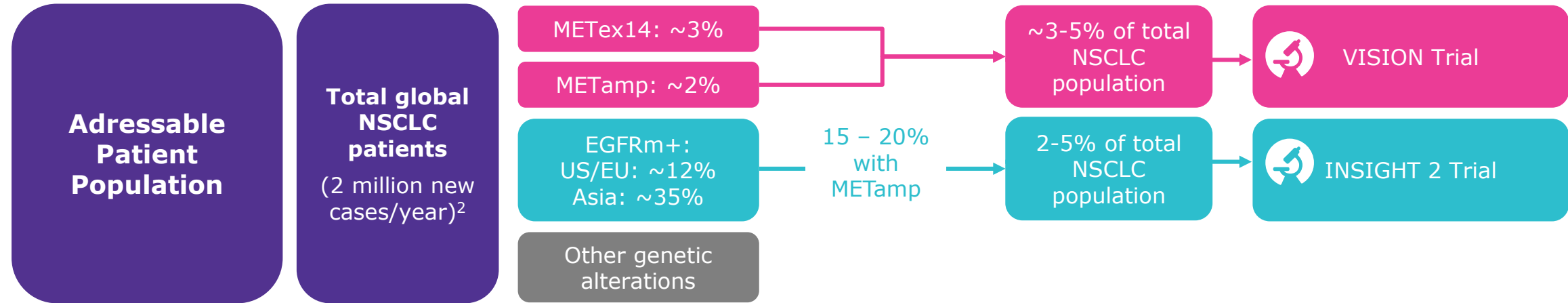
Pipeline products are under clinical investigation and have not been proven to be safe and effective. There is no guarantee any product will be approved in the sought-after indication.

Tepotinib: Significant unmet need

## Tepotinib is a highly selective oral, once daily, MET TKI that blocks MET-mediated signaling pathways



- Preclinical and clinical evidence support MET activation as a **primary oncogenic driver in lung cancer subsets** and as a **secondary driver** of acquired resistance to targeted therapy in other lung cancer subsets<sup>1</sup>
- Higher **prevalence of MET alterations amongst elderly patients in Lung** (median age of patients with METex14: 72.5 years)
- Evidence exists to support the **role of MET in cancers and resistance settings other than lung cancer**



### Key Achievements

- **SAKIGAKE designation** awarded in Japan, **Breakthrough designation** awarded by US FDA
- **Validated liquid biopsy and/or tissue biopsy test** used to prospectively recruit in both trials
- **METex14**: On track for filing in 2020 in US and Japan
- **EGFRm+/METamp**: INSIGHT 2 program recently started

<sup>1</sup>Drilon A et al., J Thoracic Oncol. 2016; <sup>2</sup>Bray F, et al. CA Cancer J Clin. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. 2018;68(6):394–424. <https://doi.org/10.3322/caac.21492> PMID:30207593



# Data presented at ASCO 2019

## Promising data from VISION (NSCLC, MET Exon 14 cohort) study

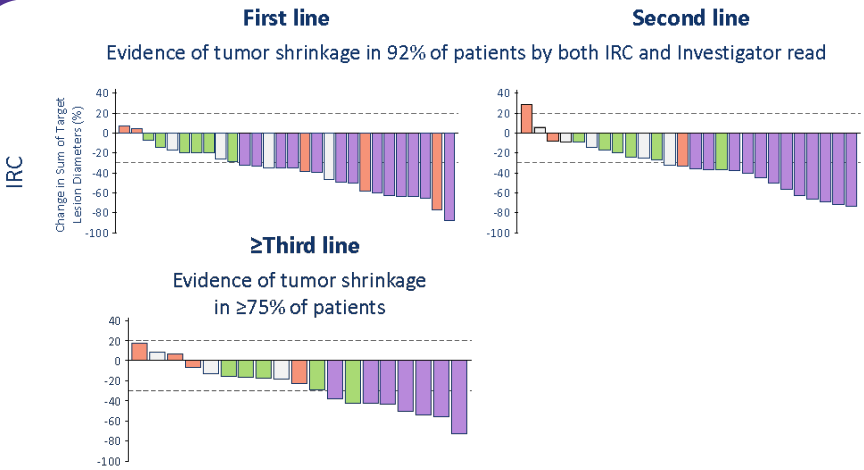
### Durable clinical activity across treatment lines<sup>2</sup>

Cut off date	Other leading MET inhibitor <sup>1</sup>	VISION (tepotinib) <sup>2</sup>	
		Liquid biopsy analysis set (L+)	Tissue biopsy analysis set (T+)
	Oral	Oral	Oral
	(15 Apr 2019)	(18 Feb 2019)	(18 Feb 2019)
	<b>IRC</b>	<b>IRC</b>	<b>IRC</b>
<b>Overall</b>	<b>N=97</b>	<b>n=48</b>	<b>n=51</b>
<b>ORR, %</b>	48.5%*	50.0%	45.1%
[95% CI]	Not reported	[35.2, 64.8]	[31.1, 59.7]
<b>mDOR, months</b>	Not reported	<b>12.4</b>	<b>15.7</b>
[95% CI]		[5.8, ne]	[9.0, ne]
<b>1L</b>	<b>N=28</b>	<b>n=17</b>	<b>n=18</b>
<b>ORR, %</b>	67.9%	58.8%	44.4%
[95% CI]	[47.6, 84.1]	[32.9, 81.6]	[21.5, 69.2]
<b>≥2L</b>	<b>N=69</b>	<b>n=31</b>	<b>n=33</b>
<b>ORR, %</b>	40.6%	45.2%	45.5%
[95% CI]	[28.9, 53.1]	[27.3, 64.0]	[28.1, 63.6]
<b>mDOR, months</b>	9.7	<b>12.4</b>	<b>12.4</b>
[95% CI]	[5.6, 13.0]	[5.6, ne]	[3.7, ne]
<b>PFS</b>	<b>1L</b> <b>n=28</b>	<b>n=57</b>	
	<b>2L/3L</b> <b>n=69</b>	<b>n=58</b>	
<b>mPFS, months</b>	9.7	<b>9.5</b>	<b>10.8</b>
[95% CI]	[5.5, 13.9]	[6.7, ne]	[6.9, ne]

### Favorable safety profile<sup>2</sup>

- Grade 3 TRAEs reported in **19% of patients**
- No grade 4 or grade 5** TRAEs
- Discontinuations** due to treatment-related adverse events in **only 4.6% of patients**

### Consistent tumor shrinkage across lines<sup>2</sup>



<sup>1</sup>J. Wolf et al., Capmatinib (INC280) in METΔex14-mutated advanced non-small cell lung cancer (NSCLC): Efficacy data from the phase II GEOMETRY mono-1 study, presented at ASCO 2019; <sup>2</sup>P. Paik et al., Phase II study of tepotinib in NSCLC patients with METex14 mutations, presented at ASCO 2019; \*Data not reported in the oral presentation. Manually calculated from 1 CR, 18 PRs in Cohort 5b (1st line) and 28 PRs in Cohort 4 (+2nd line).

# Clinical Efficacy in Met-amp EGFR-mutant Population

## INSIGHT 2 study follows from encouraging INSIGHT 1 data

UPDATED

Data from INSIGHT 1 study  
(18-months follow-up presented at WCLC 2019)<sup>1</sup>

• **MET-amp population:**

Endpoint	Tepotinib + gefitinib	Chemotherapy
Primary - PFS (HR 0.13 [90% CI 0.04, 0.43])	16.6 m	4.2 m
Secondary - ORR (OR 2.67 [90% CI 0.37, 19.56])	66.7%	42.9%
Secondary - OS (HR 0.09 [CI 0.01, 0.54])	37.3 m	13.1 m

- **METamplification** can be considered a **suitable biomarker for treatment with tepotinib**
- **Safety:** generally well-tolerated, most AEs mild to moderate
- Enrollment halted due to low recruitment

Open for enrollment

Recently posted INSIGHT 2 study

**Study Design:**

- Locally advanced/metastatic EGFR + NSCLC
- MET amplification
- Acquired resistance to prior EGFR TKI therapy
- N = 90

**Dose:**

- Tepotinib 500mg QD + Osimertinib 80mg QD (21-day cycles until PD)

**Primary endpoints:**

- Objective response rate by independent review
- Dose limiting toxicity (safety run-in only)

<sup>1</sup>Yi Long Wu et al., Long term outcomes to tepotinib plus gefitinib in patients with EGFR mutant NSCLC and MET dysregulation: 18 month follow up, presented at WCLC 2019



## Biomarker focused development program in NSCLC with potential beyond NSCLC **MET exon-14; Met-amp; and EGFR-mutant populations**

### NSCLC MET exon-14 alterations (VISION study)

- **SAKIGAKE designation** awarded by Japanese Ministry of Health, Labour and Welfare in March 2018
- **Promising ORR, durable responses and long PFS** reported across treatment lines presented at ASCO 2019
- **Favourable safety profile** with 19% treatment-related grade 3 events, no grade 4 events and **only 4.6% treatment related discontinuations**

### NSCLC harboring EGFR-mutations (INSIGHT study)

- Encouraging data seen in INSIGHT 1 trial, triggering **recent initiation of INSIGHT 2** (Tepotinib + Osimertinib)
- **Liquid biopsy testing (LBx)** integrated into INSIGHT 2 to help mitigate the limited availability of tissue in this tumor indication and treatment setting

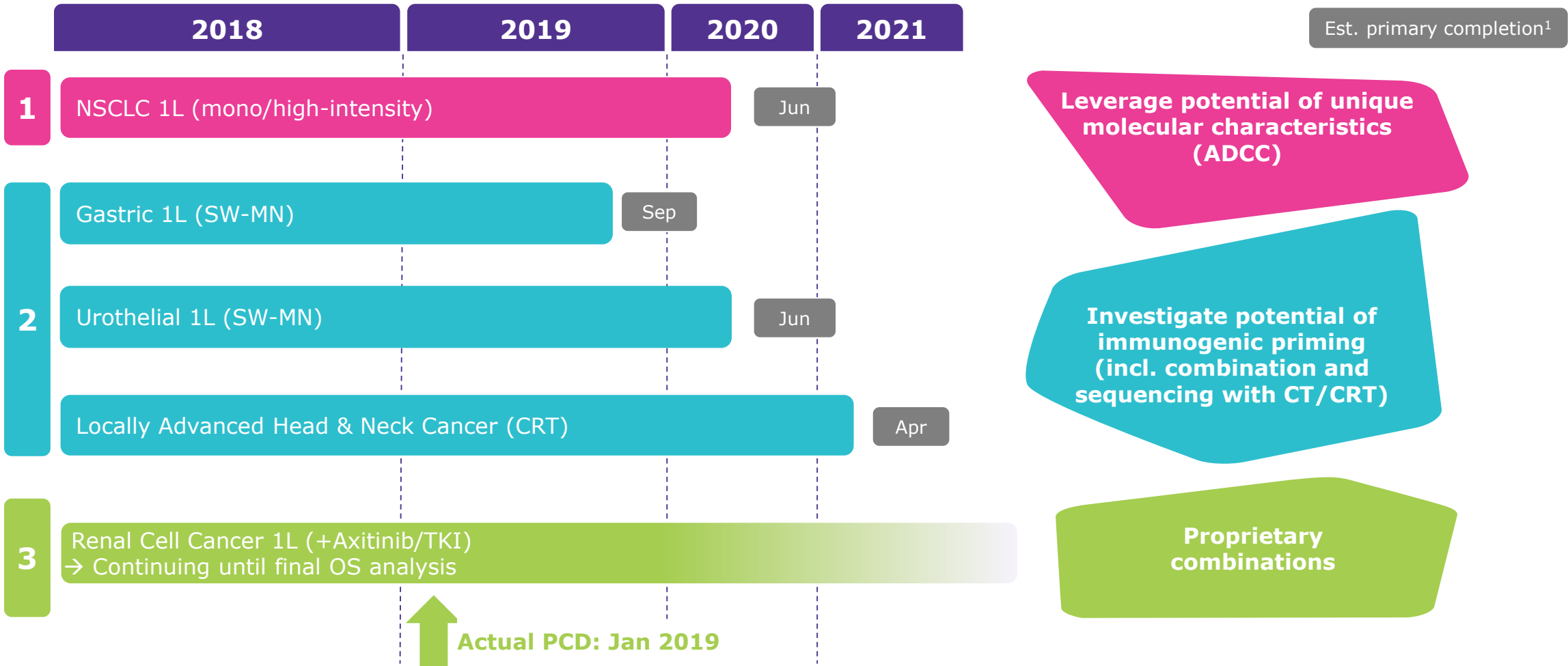


### Patients prospectively recruited with validated liquid biopsy (LBx) test in VISION

1. **Less invasive** (i.e. than tissue based testing) → appropriate for **elderly patients, rapid study recruitment**
2. **Increased selectivity/identification** → improved recruitment numbers/**greater identification**

# Avelumab: Program overview

## Ongoing studies – Five Phase III trials

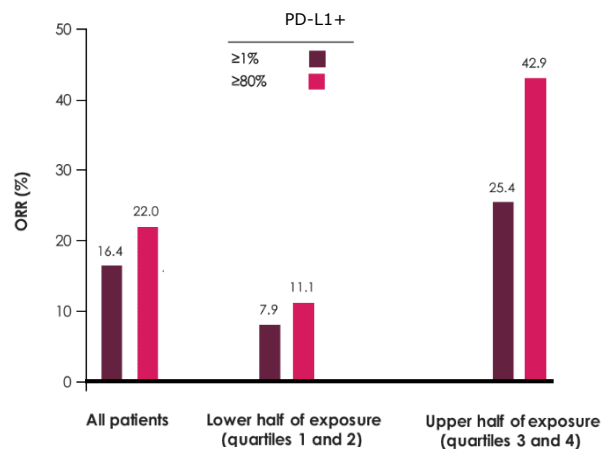
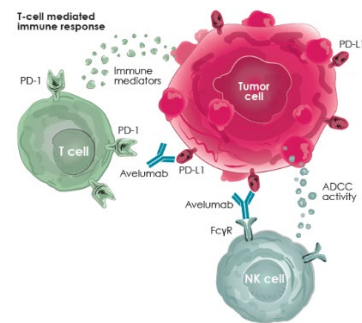


<sup>1</sup>Estimated primary completion date according to clinicaltrials.gov as of July 24, 2019, timelines are event-driven and may be subject to change;  
 Acronyms: NSCLC = Non-small Cell Lung Cancer, CT = Chemotherapy, CRT = Chemoradiotherapy, MN = Maintenance, SW = Switch, TKi = Tyrosine Kinase inhibitor

# Avelumab: NSCLC 1L

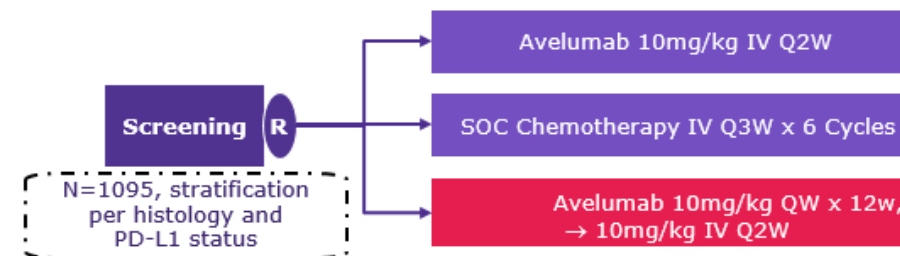
## Assessing potential efficacy upside in mono-therapy<sup>1</sup>

### NSCLC 2L+: exposure response



### NSCLC 1L: testing hypothesis of higher efficacy/intensity correlation

- **Hypothesis:** higher drug intensity may result in greater efficacy (potentially driven by ADCC)
- Potential association between **higher ORR** and **higher avelumab exposure**
- ORR highest in patients with both higher avelumab **exposure** and tumors with higher levels of **PD-L1 expression**
- **NSCLC 1L phase III trial amended** to leverage high-intensity hypothesis (est. primary completion Jul 2019)



- **Primary endpoints:** PFS & OS @ high PD-L1-expression
- **Secondary endpoints:** PFS & OS @ moderate and low PD-L1-expression (BOR, DOR, Safety, QoL)
- **Hierarchical ordered hypothesis**

<sup>1</sup>Abstract No. 9086. Presented at the 53rd ASCO Annual Meeting; June 2-6, 2017; Chicago, IL, USA: Exposure-response and PD-L1 expression analysis of second-line avelumab in patients with advanced NSCLC: data from the JAVELIN Solid Tumor trial; Acronyms: ORR = Overall Response Rate

# Avelumab: Renal Cell Carcinoma (RCC) 1L

## Extensive biomarker data set released at ASCO 2019 from Javelin Renal 101

### Core data presented at ESMO 2018 and ASCO GU 2019<sup>1</sup>

HR < 1 = favors Avelumab-Axitinib or competitor combo HR > 1 = favours sunitinib	mPFS (Hazard Ratio, Risk groups per IMDC) <sup>2,4</sup>		
	Favorable	Intermediate	Poor
Competitor A	2.18 (1.29-3.68)	0.82 (0.64-1.05)	
Competitor B	0.81 (0.53-1.24)	0.70 (0.54-0.91)	0.58 (0.35-0.94)
<b>Avelumab – Axitinib (JAVELIN)</b>	<b>0.54 (0.32-0.91)</b>	<b>0.74 (0.57-0.95)</b>	<b>0.57 (0.38-0.88)</b>

#### Safety (% patients, Gr 3-5 TRAEs)<sup>3,4</sup>

- Avelumab-Axitinib: 57% / 55% (Sunitinib)
- Competitor B: 63% / 58% (Sunitinib)

#### Discontinuation (% patients)<sup>3,4</sup>:

- Avelumab-Axitinib: 4%
- Competitor B: 8.2%

- **Approved for 1L treatment of advanced RCC by US FDA on May 15, 2019**
- **Filing validated by EMA and submitted to Japanese health authorities**

### Significant contribution to understanding of biomarkers presented at ASCO 2019<sup>5</sup>

- **Sunitinib patients with PD-L1+ tumors showed reduced PFS**
- Patients whose tumors contained **greater number of CD8+ cells had extended PFS in the avelumab + axitinib arm** and reduced PFS in the sunitinib arm
- **Novel signature comprised of immune-related genes associated with PFS in the avelumab + axitinib arm**
- Elevated **expression of the published angiogenesis gene signature** and other related genes was **associated with improved PFS in the sunitinib arm**, but did not differentiate PFS in the avelumab + axitinib arm
- Significant **treatment-arm specific differences in PFS were observed relative to wild type when mutations** in genes such as CD163L1, DNTM1 or PTEN were present

**“Findings may inform personalized strategies for patients with advanced RCC”**

<sup>1</sup>Choueiri et al., „Subgroup analysis from JAVELIN Renal 101: outcomes for avelumab + axitinib vs sunitinib in advanced renal cell carcinoma“, presented at ASCO GU 2019;

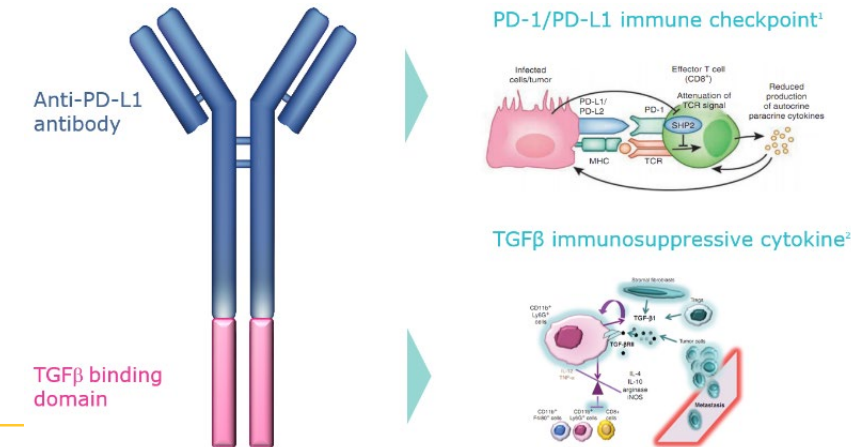
<sup>2</sup>Table adapted from slides of discussant Dr. Lori Wood, presented at ASCO GU2019; <sup>3</sup>Motzer et al., „Avelumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma“, New England Journal of Medicine, February 16, 2019; Brian et al., „Pembrolizumab plus Axitinib versus Sunitinib for Advanced Renal-Cell Carcinoma“, New England Journal of Medicine, February 16, 2019; <sup>4</sup>Note that this is not a head-to-head trial comparisons; <sup>5</sup>Choueiri et al., „Biomarker analyses from JAVELIN Renal 101: Avelumab + axitinib (A+Ax) versus sunitinib (S) in advanced renal cell carcinoma (aRCC)“, presented at ASCO 2019

# Bintrafusp alfa<sup>1</sup> (M7824)

## An innovative first-in-class bifunctional fusion protein leading the TGF- $\beta$ immuno-oncology field

### Mode of action

- Innovative **first-in-class bifunctional fusion protein** designed to simultaneously target two immune suppressive pathways (blocking PD-L1 and reducing TGF- $\beta$  signaling)
- Demonstrated **superior anti-tumor activity in pre-clinical study** compared to anti-PD-L1 alone, and anti-PD-L1 and TGF- $\beta$  given in combination as separate agents
- **Great excitement in IO community** about M7824 uniquely addressing TGF- $\beta$  biology widely accepted as key resistance factor for anti-PDx therapies



### Clinical development achievements

- Tested in **14 Phase Ib expansion cohorts** across >700 patients in more than 10 tumor types
- Shown clinical anti-tumor activity across multiple hard-to-treat cancers including **advanced NSCLC, biliary tract cancer, HPV-associated cancers, and gastric cancer**
- PhII study **M7824 monotherapy versus pembrolizumab 1L**, advanced NSCLC high PD-L1-tumor expressers started in October 2018
- **Two additional studies started** in April 2019

### Clinical development plans

- **Eight high priority immuno-oncology clinical development studies** ongoing or expected to commence in 2019, including **studies in non-small cell lung and biliary tract cancers with registrational intent**
- Further plans to be communicated at a later stage

<sup>1</sup>proposed International Nonproprietary Name (INN)  
Acronyms: NSCLC = Non-small Cell Lung Cancer, IO = Immuno-Oncology

## Strategic Alliance with GlaxoSmithKline (GSK)

### Attractive payment terms rewarding developmental success

Effective as of  
March 27, 2019



#### upfront & Milestone payment structure

**Total deal volume: €3.7 bn**

**Upfront  
payment:**  
€300 m

**Milestone payments:** €3.4 bn

Development  
(up to €500 m)

Approval

Commercial

**Development milestones:** Up to €500 m triggered by data from the M7824 lung cancer program

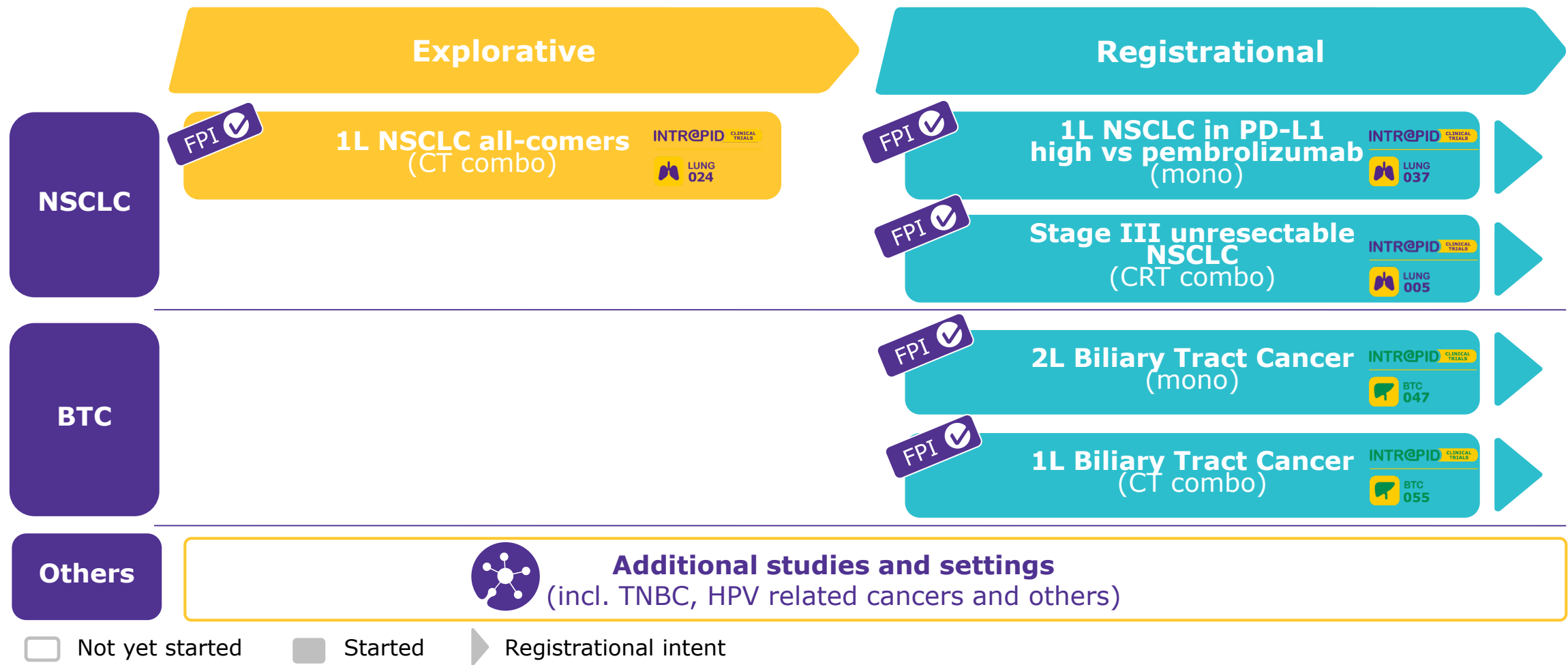


#### profit & cost sharing

- **Profits & Costs:** Shared equally on a global basis
- **Sales:** Merck KGaA, Darmstadt, Germany to recognize sales in the United States, GSK to recognize sales ex-US

# Development Strategy

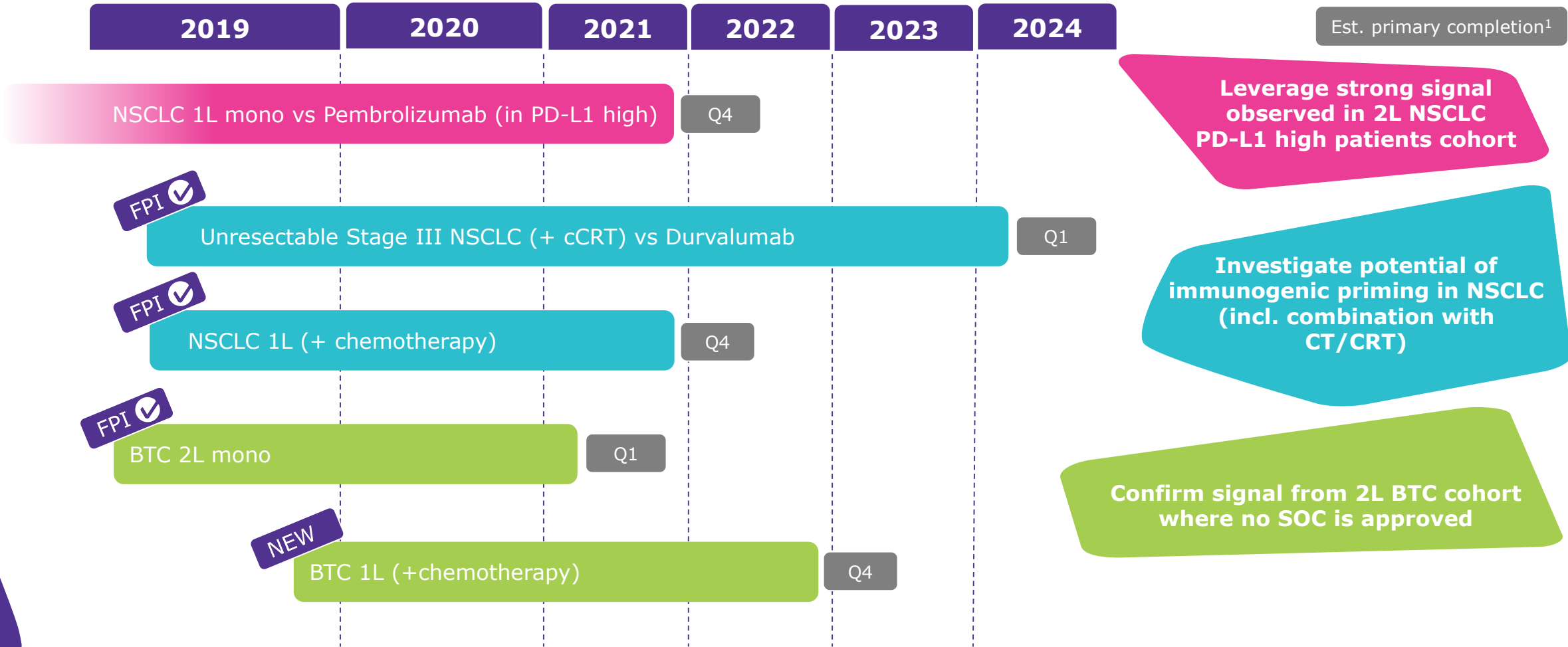
Several studies ongoing with additional studies expected to commence in the upcoming months



Acronyms: FPI = First Patient In, TNBC = Triple Negative Breast Cancer

# Development Strategy

## Program overview: Two additional studies recently started



<sup>1</sup>Estimated primary completion date according to clinicaltrials.gov as of July 24, 2019 and internal estimates for upcoming studies; timelines are event-driven and may be subject to change;  
 Acronyms: NSCLC = Non-small Cell Lung Cancer, BTC = Biliary Tract Cancer, CT = Chemotherapy, cCRT = Chemoradiation therapy, FPI = First Patient In



## Developmental Progress

### 2L Biliary Tract Cancer (BTC) monotherapy trial recently initiated

#### M7824 BTC data presented at ESMO 2018

- **Need:** Few available treatment options (no 2L standard of care)<sup>1</sup>
- **Results: Encouraging activity<sup>2</sup>** in 30 Asian patients with pretreated biliary tract cancer
- **ORR<sup>2</sup>:** 20% (IRC assessment). Median DoR was NR (range, 8.3–13.9 months) with confirmed responses ongoing in all patients
- **Overall Survival by IRC: mOS:** 12.7 months (6.7 – NR), comparing favorably with historical data in pretreated patients receiving second- or later line treatment (<7 months mOS in 2L<sup>1</sup>)
- Responses observed **irrespective of PD-L1 expression levels<sup>2</sup>**
- **Orphan Drug Designation** granted by FDA in December 2018

#### Leading PDx data presented at ASCO 2019<sup>3</sup>

- **ORR:** 5.8% (PhII, 2L); 13.0% (PhI)
- **OS:** 7.4 months (PhII, 2L); 6.2 months (PhI)

#### INTR@PID BTC 047

INTR@PID CLINICAL TRIALS

BTC  
047

Locally  
advanced or  
metastatic  
BTC 2L  
N = 141

M7824 1200 mg IV,  
Q2W, up to 24  
months

#### Endpoints

##### Primary endpoint: ORR

Secondary endpoints: DOR, DRR, PFS, OS, Safety

Biomarker endpoints: PDL1 expression MSI status, comprehensive genomic profiles

<sup>1</sup>Lamarca A, et al. Ann Oncol. 2014;25(12):2328–2338; <sup>2</sup>Yoo et al., Poster presented at the 43rd European Society for Medical Oncology Annual Meeting, Munich, October 19–23, 2018; <sup>3</sup>Bang et al., "Pembrolizumab (pembro) for advanced biliary adenocarcinoma: Results from the KEYNOTE-028 (KN028) and KEYNOTE-158 (KN158) basket studies", presented at ASCO 2019; Acronyms: DoR = Duration of Response, NSCLC = Non-small Cell Lung Cancer, NR = Not Relevant, MSI = Microsatellite Instability Status, OS = Overall Survival, PFS = Progression-Free Survival

# Developmental Progress

## NSCLC Stage III cCRT Combo trial recently initiated

### NSCLC 2L data presented at ESMO 2018

- **Need:** NSCLC accounts for 80-85% of all cases of lung cancer<sup>1</sup>
- **Results: Encouraging efficacy comparing favorably** to established PDx-inhibitor monotherapy (IRC)<sup>2,3</sup>:
  - **ORR (all-comers):** 25.0%
  - **ORR (PD-L1-positive):** 37.0%
  - **ORR (PD-L1-high):** 85.7%
- **Progression free survival by IRC (PD-L1 ≥ 1%):**
  - M7824: **mPFS = 9.5 months**, competitor: 4.0 months<sup>2,3</sup>
- **Overall Survival by IRC (PD-L1 ≥ 1%):**
  - M7824: **mOS not reached**, competitor: 12.7 months<sup>2,3</sup>

### Pre-clinical data on M7824 + RT combo<sup>5</sup>

- M7824 and RT combination therapy **enhances antitumor activity relative to mono-therapies** in mouse models
- EMT, VEGF, and RT-induced fibrosis gene signatures are decreased with M7824 and combination therapy, and **M7824 reduces RT-induced fibrosis**
- Results **support evaluation of M7824 + RT in the clinic**

### INTR@PID LUNG 005

INTR@PID CLINICAL TRIALS



Stage III  
unresectable  
NSCLC  
n=350

Experimental Arm:  
M7824 Q2W  
1200mg + cCRT<sup>4</sup>

M7824 (up to 1 year  
after cCRT until  
acceptable toxicity)

Active Comparator  
Arm: Placebo Q2W  
+ cCRT<sup>4</sup>

Durvalumab (up to 1  
year after cCRT until  
acceptable toxicity)

### Endpoints

#### Primary endpoint: PFS

Main secondary endpoints: OS, Safety, Pulmonary function, Association of PD-L1 expression at base line and efficacy

<sup>1</sup>Jemal A et al., Cancer statistics, 2007, CA Cancer J Clin 2007;57:43-66; <sup>2</sup>Paz-Ares et al., Poster presented at the 43rd European Society for Medical Oncology Annual Meeting, Munich, October 19–23, 2018, data shown for 1200mg Q2W dose; <sup>3</sup>Herbst et al.; Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial (www.thelancet.com Published online December 19, 2015 [http://dx.doi.org/10.1016/S0140-6736\(15\)01281-7](http://dx.doi.org/10.1016/S0140-6736(15)01281-7)); <sup>4</sup>Cisplatin/Etoposide or Carboplatin/Paclitaxel or Cisplatin/Pemetrexed concomitant with Intensity Modulated Radiation Therapy (IMRT); <sup>5</sup>Lan et al., Combination of M7824 and radiation therapy enhances antitumor activity, increases immune response, and modulates radiation-induced fibrosis in cancer models, 2018

## Developmental Progress

### Data shown at AACR 2019 highlights opportunity in HPV-related cancers

Efficacy variable	HPV-associated cancer (n=43)	HPV+* (n=36)
<b>Confirmed BOR, n (%)</b>		
CR	2 (4.7%)	2 (5.6%)
PR	10 (23.3%)	9 (25%)
SD	6 (14.0%)	5 (13.9%)
PD	20 (46.5%)	17 (47.2%)
Not evaluable	5 (11.6%)	3 (8.3%)
Delayed PR <sup>†</sup>	3 (7.0%)	3 (8.3%)
<b>ORR per RECIST v1.1, n (%)</b> [95% CI]	<b>12 (27.9%)</b> [15.3–43.7]	<b>11 (30.6%)</b> [16.3–48.1]
<b>Total clinical response rate<sup>†</sup>, n (%)</b>	<b>15 (34.9%)</b>	<b>14 (38.9%)</b>
DCR, n (%)	18 (41.9%)	44.4%

**Prevalence:** >630,000 new cases of HPV-related cancer are reported worldwide annually<sup>1</sup>

#### Response Rates:

- Bintrafusp alfa response rates **compared favorably to those with anti-PD-1 inhibitors** (ORRs of 13%–24%)<sup>1-7</sup>
- **ORR was 27.9% and 30.6% in HPV-associated and HPV+ cancers, respectively**
- Including three additional patients with delayed PRs after initial PD: **Total response rate was 34.9% and 38.9% in HPV-associated and HPV+ cancers, respectively**

#### Long-term Benefit:

- **Most responses durable** with 4 responses having DoR >18 months and 11/15 responses ongoing at the data cutoff
- Responses to bintrafusp alfa occurred **irrespective of tumor type** or PD-L1 expression
- **Safety profile was similar to anti-PD-(L)1 therapy<sup>1,5</sup>** except for SCC/KAs and low grade mucosal bleeding which are anticipated AEs with TGF- $\beta$  inhibition<sup>8,9</sup>

**Additional study in HPV-related cancers to commence shortly**

<sup>†</sup>Due to confirmed PD before onset of response, these patients did not meet response criteria by RECIST v1.1; \*HPV status was determined from prior documentation, or by using cobas® 4800 HPV Test (Roche) in the dose escalation phase or RNA sequencing (RNASeq) in the expansion phase. <sup>1</sup>Baumli J, et al. J Clin Oncol. 2017;35:1542–49; <sup>2</sup>Ott PA, et al. Ann Oncol. 2017;28:1036–41; <sup>3</sup>Hollebecque A, et al. J Clin Oncol. 2017;35(Suppl):Abstract 5504; <sup>4</sup>Chung HC, et al. J Clin Oncol. 2018;36(Suppl):Abstract 5522; <sup>5</sup>Ferris RL, et al. N Engl J Med. 2016;375:1856–67; <sup>6</sup>Mehra R, et al. Br J Cancer. 2018;119:153–59; <sup>7</sup>Morris VK, et al. Lancet Oncol. 2017;18:446–53; <sup>8</sup>Lacouture ME, et al. Cancer Immunol Immunother. 2015;64:437–46; <sup>9</sup>Trachtman H, et al. Kidney Int. 2011;79:1236–43

# DNA Damage Response (DDR)

## Leadership in next generation assets beyond PARP



### DNA Damage Response

A Core Research  
Innovation Cluster

- DDR defects are an **“achilles heel” of cancer cells**
- **ATR, ATM and DNA-PK are the trinity of targets** that orchestrate cellular response DNA damage and replication stress
- **Leading clinical portfolio** with 6 assets (in Phases 1 and 2) targeting ATR, ATM and DNA-PK
- Rich pre-clinical and translational science driving **biological innovation and patient selection**
- Ideally placed to drive **novel combinations within DDR portfolio and broader immuno-oncology portfolio**
- Multiple **early signal finding studies** allow for **evidence-based decision making & focus** in future development

# DNA Damage Response (DDR)

## Development is focused on three foundations

Differentiating aspects of cancer DDR that can be targeted therapeutically<sup>1</sup>:

Loss of one or more  
DDR pathways

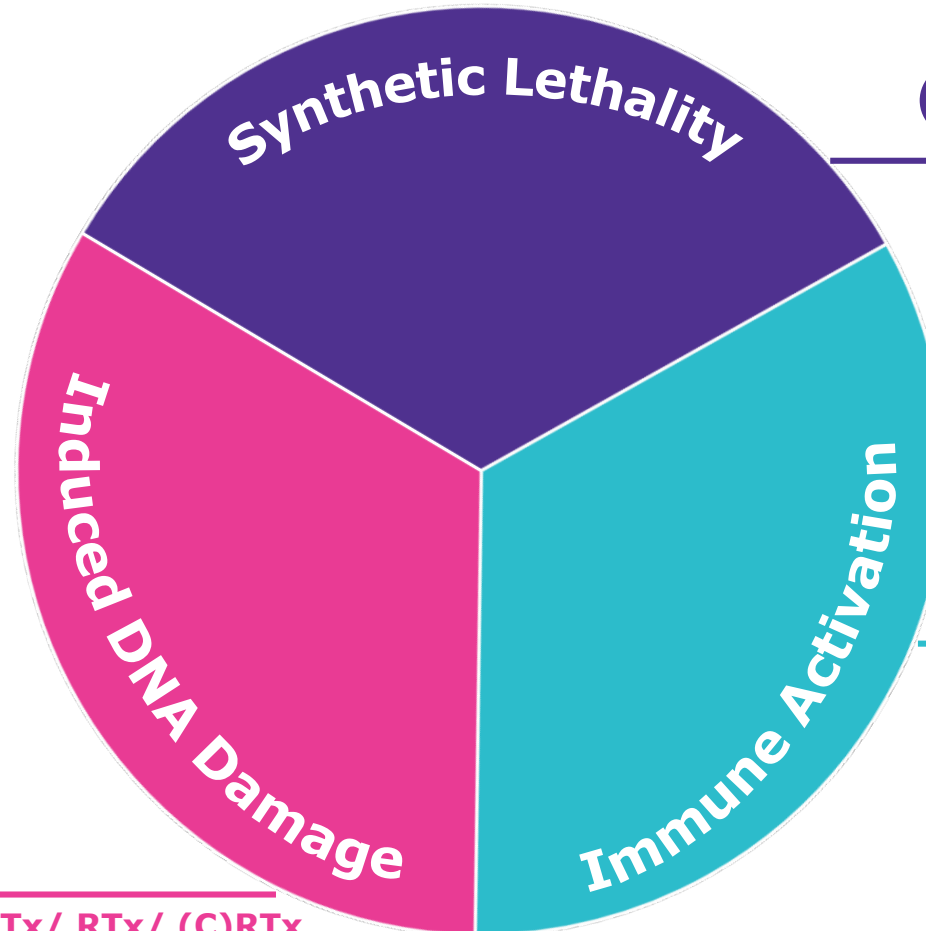
Increased levels of  
replication stress

Increased levels of  
endogenous DNA  
damage

Increased Immunogenicity

3

DDRI + CTx/ RTx/ (C)RTx  
Improve efficacy in post-IO  
landscape



1

Monotherapy  
DDRI + DDRI  
(incl. PARP)  
Grow the DDR class,  
building on PARPs

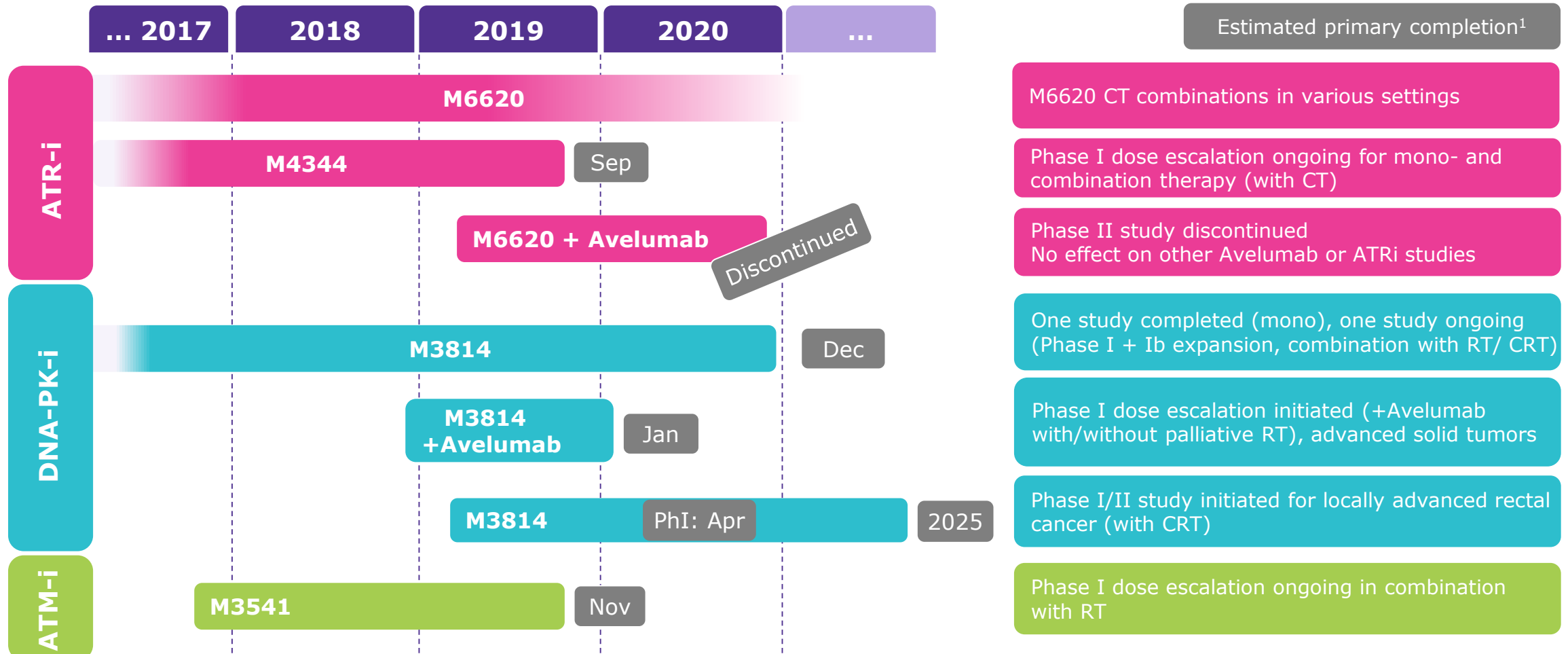
2

DDRI + IO  
Differentiate future  
IO treatments

<sup>1</sup>adapted from M. O'Connor, Targeting the DNA Damage Response in Cancer, *Molecular Cell Review*, November 2015;  
Acronyms: IO = Immuno-Oncology, CT = Chemotherapy, DDRI = DNA Damage Response inhibitor, RT = Radiotherapy, (C)RT = Chemo-radiotherapy

# DNA Damage Response (DDR)

## Clinical program targets three major DDR pathways, in mono- and combination (incl. Avelumab)



<sup>1</sup>Estimated primary completion date according to clinicaltrials.gov as of September 13, 2019, timelines are event-driven and may change;

Acronyms: ATM = Ataxia-Telangiectasia Mutated, ATR = Ataxia Telangiectasia and Rad3, DNA-PK = DNA-dependent Protein Kinase, CT = Chemotherapy, RT = Radiotherapy, CRT = chemoradiotherapy, NSCLC = Non-small Cell Lung Cancer, SCLC = Small-cell Lung Cancer, TNBC = Triple Negative Breast Cancer

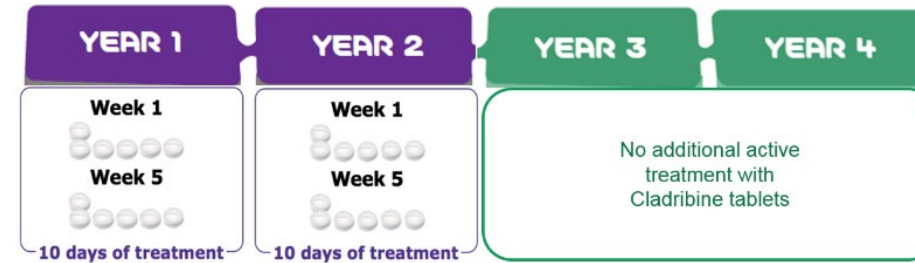
Mavenclad

# Mavenclad could change the MS treatment paradigm

**Selective immune reconstitution therapy (SIRT)<sup>1</sup>**

Selective reduction in B & T lymphocytes...

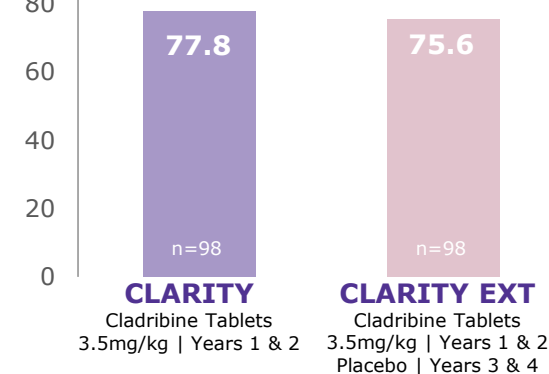
...followed by reconstitution



**Unique posology: max. 20 days of oral treatment<sup>3</sup>**

**4 years disease control with treatment over 2 years<sup>2</sup>**

**Proportion of Patients Qualifying Relapse Free (%)<sup>2</sup>**



										Key	Lymphocyte count	Treatment	MRI
	Prior to treatment initiation	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Year 1	 TB/HSV/HCV screenings*												
		5 days of treatment	5 days of treatment										
Year 2													
	TB/HSV/HCV	5 days of treatment	5 days of treatment										

**Low monitoring requirements<sup>4</sup>**

<sup>1</sup>Giovannoni G. Neurotherapeutics 2017; Nov 22 [Epub ahead of print] | Wiendl H et al. Neurology 2017;89:1098-100 | Wiendl H. Nat Rev Neurol 2017; Sept 8 [Epub ahead of print]

<sup>2</sup>Giovannoni G et al. N Engl J Med 2010;362:416-26 | Giovannoni G et al. Mult Scler Aug 1 [Epub ahead of print] <sup>3</sup>Maximum of 20 days of oral dosing over 2 years with no further treatment required in the next 2 years. For important safety information, refer to the abbreviated Prescribing Information | Oral, weight-based dosing. For an average patient weighing 67 kg. Recommended treatment over 2 years. One treatment course per year, followed by observation for another 2 years. Each treatment course consists of two treatment weeks, one at the beginning of the first month and one at the beginning of the second month of the respective year | MAVENCLAD® EU SmPC, September 2017 | Giovannoni G et al. N Engl J Med 2010;362:416-26 <sup>4</sup>MAVENCLAD® EU SmPC September 2017 | Screening must be performed prior to initiation of therapy in Year 1 and Year 2. Vaccination of antibody-negative patients is recommended prior to initiation of Cladribine Tablets. AE, adverse event; HBV, hepatitis B virus; HCV, hepatitis C virus; MRI, magnetic resonance imaging; NEDA, no evidence of disease activity; TB, tuberculosis



## Mavenclad

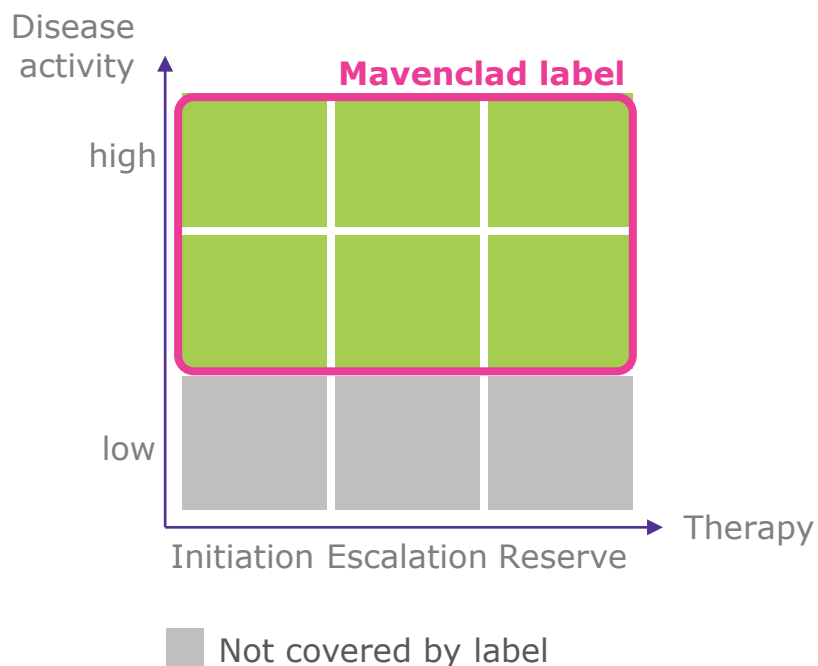
# Mavenclad's attractive label in Europe supports integrated franchise strategy

Mavenclad label covers  
60-70% of patients with RRMS<sup>1</sup>  
within the MS<sup>1</sup> patient population  
in Europe

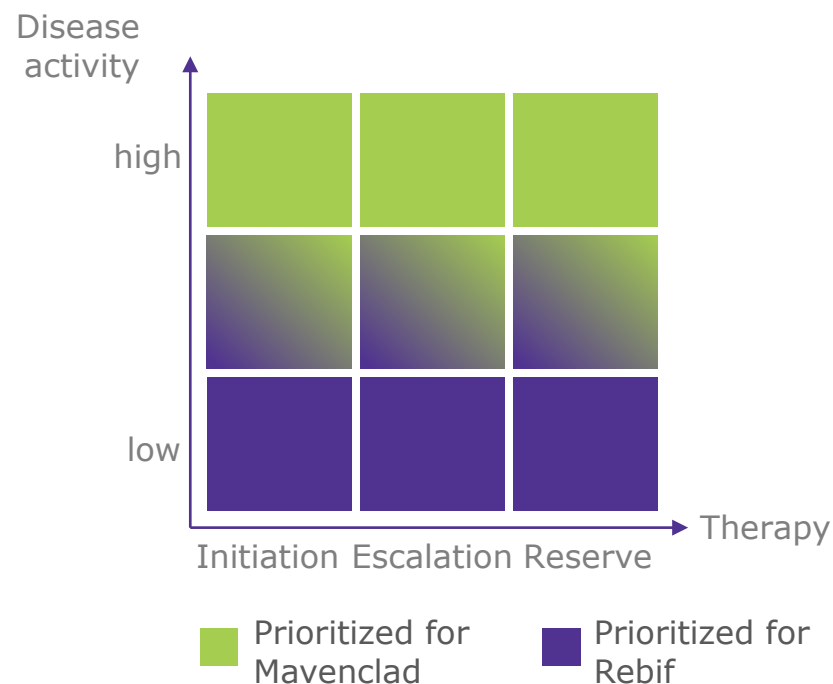
Merck KGaA, Darmstadt,  
Germany's overall NDD franchise  
will cover a broad MS patient pool

Integrated franchise  
strategy

## MS patient population<sup>2</sup>



## RRMS patients, EU-5<sup>3</sup>



- ✓ At patient level: Rebif and Mavenclad are **highly complementary**
- ✓ At physician level: High overlap
- ✓ Franchise infrastructure investment benefits both brands

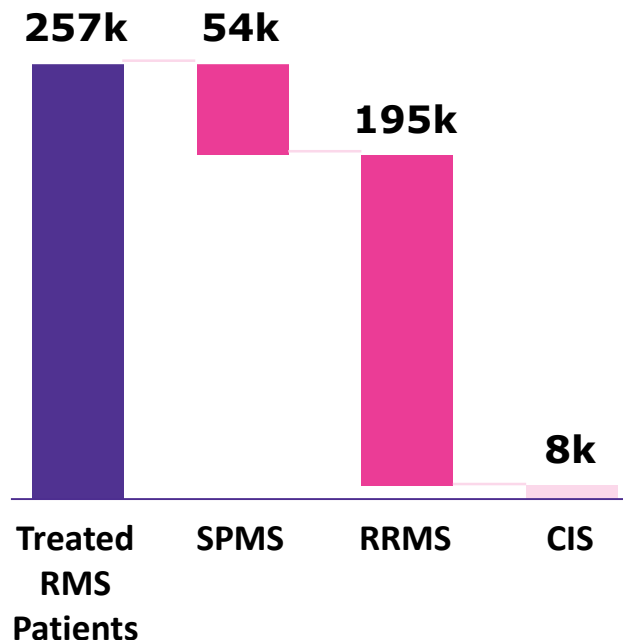
<sup>1</sup>Approved by EMA for treatment of highly active relapsing multiple sclerosis; Abbreviations: RRMS = Relapsing-Remitting Multiple Sclerosis; <sup>2</sup>Source: Merck KGaA, Darmstadt, Germany <sup>3</sup>Source: Merck KGaA, Darmstadt, Germany, Ipsos; As of May 2019, Mavenclad was approved in 55 countries globally and reimbursed in half



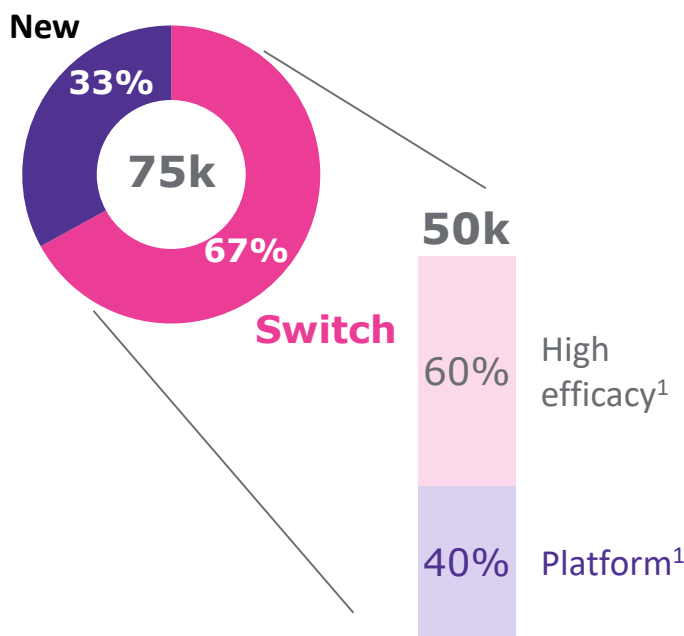
## Mavenclad

**On March 29, the FDA approved Mavenclad for the treatment of adults with relapsing-remitting (RRMS) and active secondary progressive disease (SPMS)**

## Treated RMS patients in US



## Dynamic RMS treated patients



## Mavenclad addresses clear medical needs

- **Previously treated** patients represent the vast majority of the dynamic patient pool
  - **Lack of efficacy** is the predominant driver of switching, hence observed "high-efficacy" share of switches
  - **Intolerance** also drives switching, though to a lesser degree, and results in switches between classes
- Novel mechanism and unique oral short-course regimen of **Mavenclad addresses these needs**

Source: Decision Resource Group, MS Epidemiology Overview, October 2017; <sup>1</sup>High efficacy includes Ocrevus, Tysabri, Lemtrada, Gilenya – platform includes all other approved agents

# Evobrutinib - Unmet needs remain in the treatment of RMS patients

## First BTK-inhibitor to show clinical proof-of-concept in RMS<sup>1</sup>

### Unmet needs in RMS



#### Need for new Mechanisms to control disease

- **Approx. 50% of patients with RMS continue to have ongoing disease activity** over 2 years even when treated with the most effective agents
- **Agents in phase 3** development and registration for MS are **"me-too" mechanisms**



#### Need for higher efficacy oral therapies

- 5 approved therapies considered "higher efficacy", only **2 of which are oral**
- No approved oral therapy with **efficacy on progression vs an active control**



#### Opportunity to advance on benefit-to-risk

- **Systemic side effects** of therapies limit patient acceptance and compliance
- All approved higher efficacy therapies **associated with elevated risk of infection**

### Evobrutinib in RMS

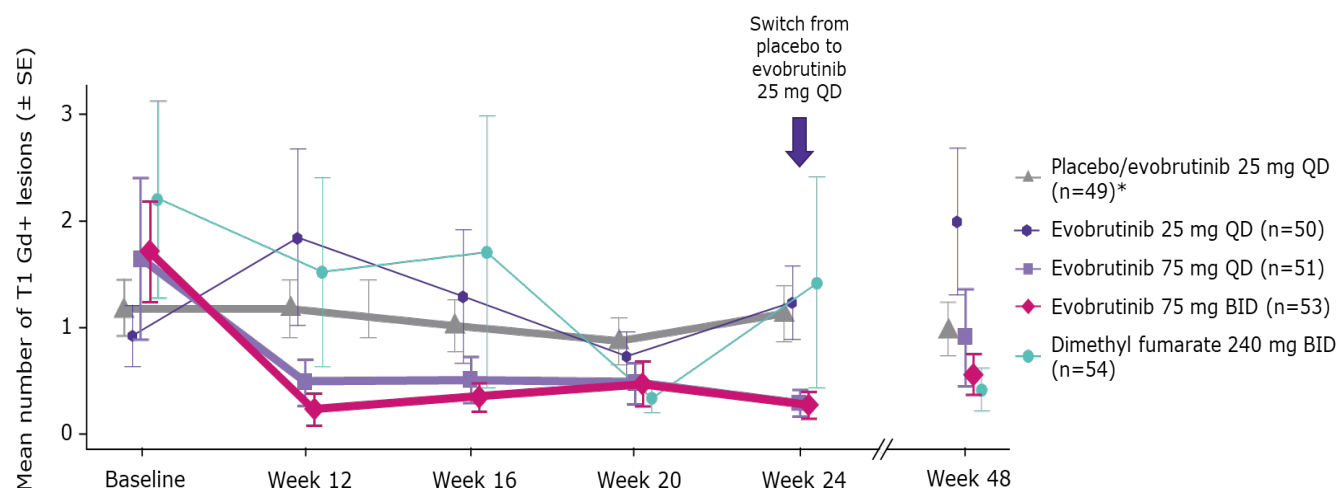
- **Novel dual Mechanism** – thought to address the **innate and adaptive immune compartments** with the prospect of both **peripheral and CNS** effects
- **Robust effect on MRI and relapses** in Phase II randomized control trial (RCT) over 48 weeks
- **No systemic side effects** (e.g. GI disturbance)
- **No elevation in infections** seen over 48 weeks in RCT Phase II
- **Rapid reversibility of inhibition on treatment discontinuation** allows for treatment sequencing and risk management
- Phase III program designed to **Maximize registrational success** and to fully elucidate **potential of evobrutinib Mechanism** through sub- and ancillary studies

<sup>1</sup>Motalban et al., "Efficacy and Safety of the Bruton's Tyrosine Kinase Inhibitor Evobrutinib (M2951) in Patients with Relapsing Multiple Sclerosis over 48 Weeks", presented at AAN 2019

## Evobrutinib

# 48 week data from Ph II randomized placebo-controlled trial robustly inform Ph III trial design<sup>1,2</sup>

## 48 week data: Primary endpoint (T1 Gd+ lesion reduction) maintained<sup>1,2</sup>



## Safety<sup>1,2</sup>

### Generally well tolerated over 52 weeks:

- **Transaminase elevations predominantly mild:** Some grade 3–4 events observed; all had their onset within the first 24 weeks of the study
- **All transaminase elevations asymptomatic** and reversible upon withdrawal of evobrutinib
- **No serious opportunistic infections or lymphopenia**

## Robust foundation for Ph III

✓ **robust effect on relapse rate** - ARR reduction maintained over 48 weeks with Evobrutinib 75mg BID (0.11 at 48 weeks)

✓ **rapid reduction in mean number of T1 Gd+ lesions** - Early onset at Week 12 and persistence to Week 48 in the evobrutinib 75 mg BID arm

✓ **no new safety signals**

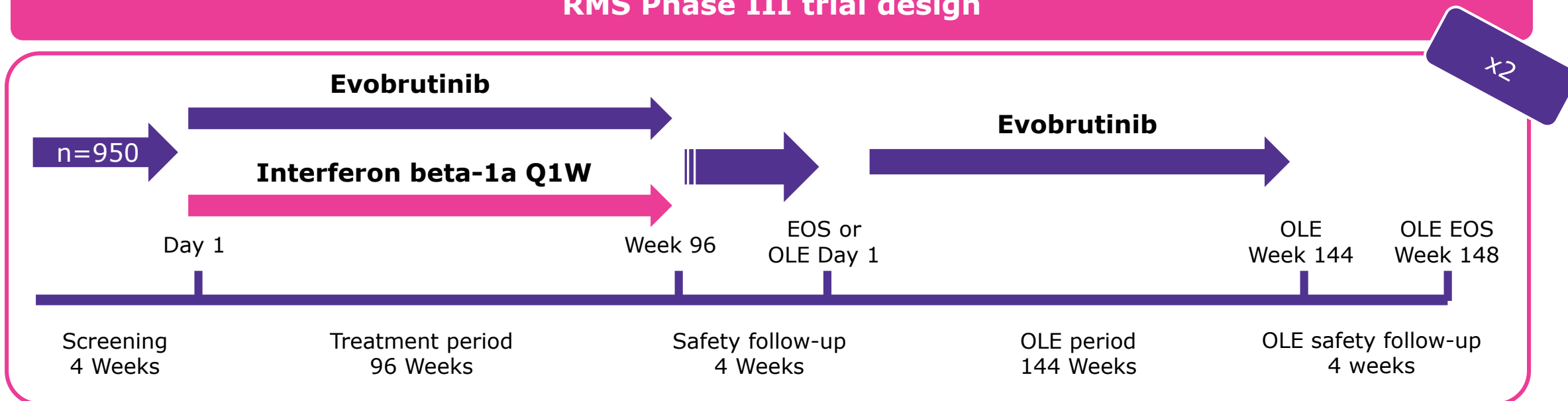
✓ **results support further clinical development of evobrutinib in RMS**

<sup>1</sup>Motalban et al., "Efficacy and Safety of the Bruton's Tyrosine Kinase Inhibitor Evobrutinib (M2951) in Patients with Relapsing Multiple Sclerosis over 48 Weeks", presented at AAN 2019; <sup>2</sup>Montalban et al., "Placebo-Controlled Trial of an Oral BTK Inhibitor in Multiple Sclerosis" published in NEJM, May 2019

# Evobrutinib

**Phase III trial recently started, with goal to rapidly advance BTKi into clinical practice**

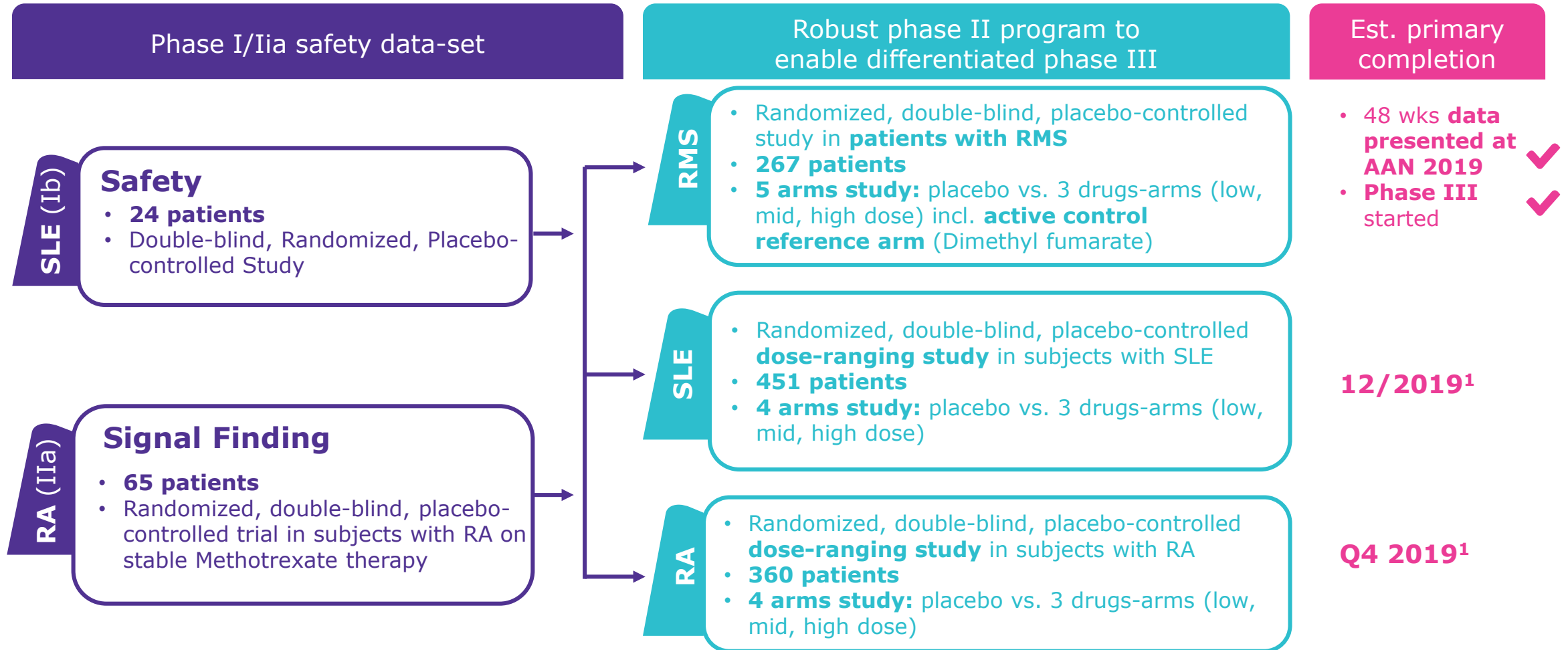
## RMS Phase III trial design



- Eligible participants will be **randomized 1:1** in Phase 3
- **Two parallel phase 3 studies** to be conducted to support registration
- Core + ancillary study program will **robustly characterize impact of Evobrutinib** on measures of RMS disease including both **novel and unique measures relevant to its presumed MOA**

## Evobrutinib

## Comprehensive development plan across immune-mediated diseases

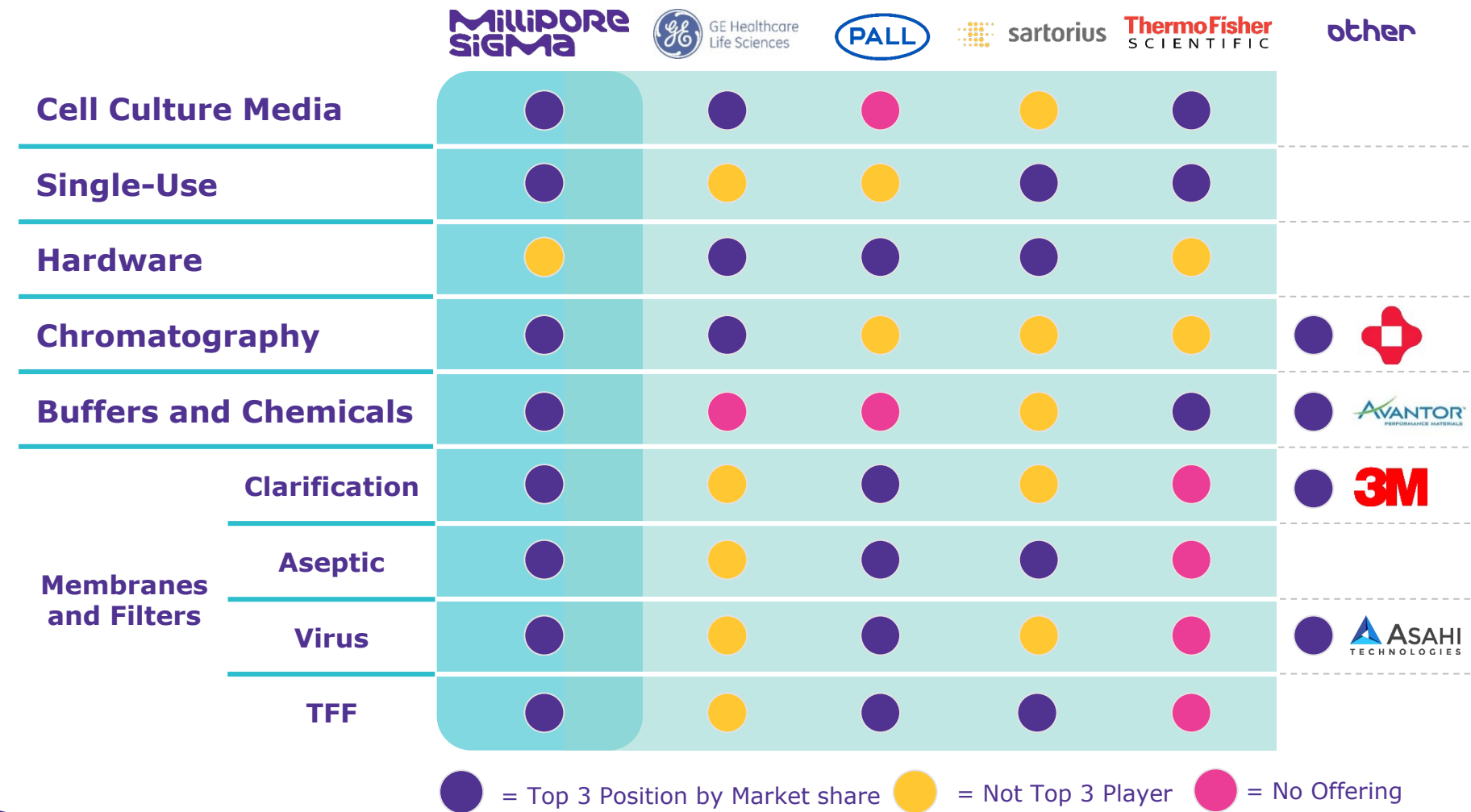


All timelines are event-driven and may be subject to change; <sup>1</sup>Data read-out expected in H1 2020

Process Solutions

We are the only company to span the entire value chain of our customers

2018 Market share position estimate<sup>1</sup>



Life science

has a leading position in 8 out of 9 critical steps

<sup>1</sup>Based on internal Life Science market research; TFF = tangential flow filtration

# Process Solutions

## Next-generation bioprocessing on the cards

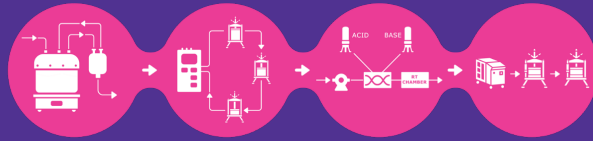
**Make**

**purify**

Today's  
process & portfolio



**mAb process intensification 2017 - 2020+**



**continuous processing >2025**



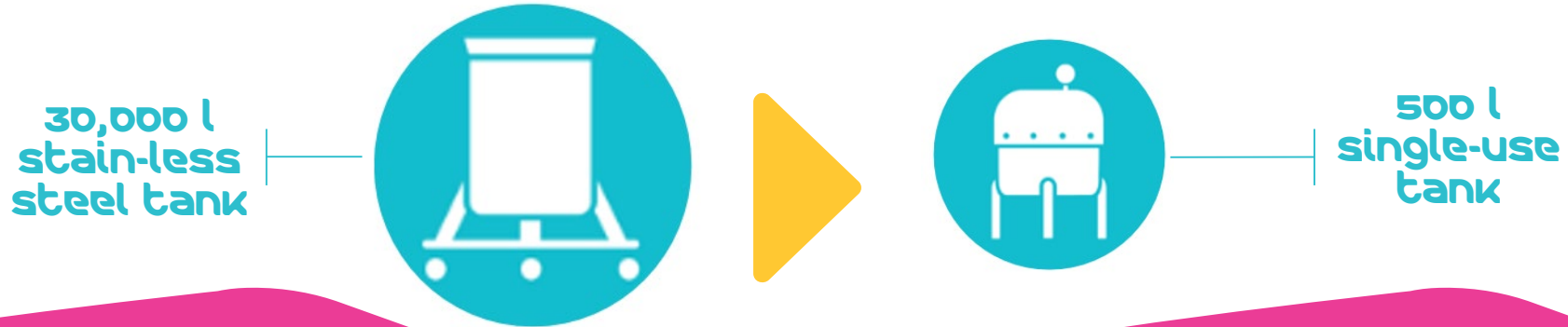
**Continuous bioprocessing will ...**

- be an evolution in mAb bioprocessing
- take time to establish
- leverage the present
- lead to hybrid solutions

Tomorrow's  
process

## Process Solutions

### Our single-use technologies drive flexibility in modern bioprocessing



#### Traditional Multi-use facility

CAPEX* required	~\$500 m to \$1 bn
Time to construct	5 to 10 years
Change over time	4 weeks
Footprint	~>70,000 m <sup>2</sup>

#### Innovative single-use facility

CAPEX required	\$20 m to \$100 m
Time to construct	1.5 years
Change over time	0.5 days
Footprint	~11,000 m <sup>2</sup>

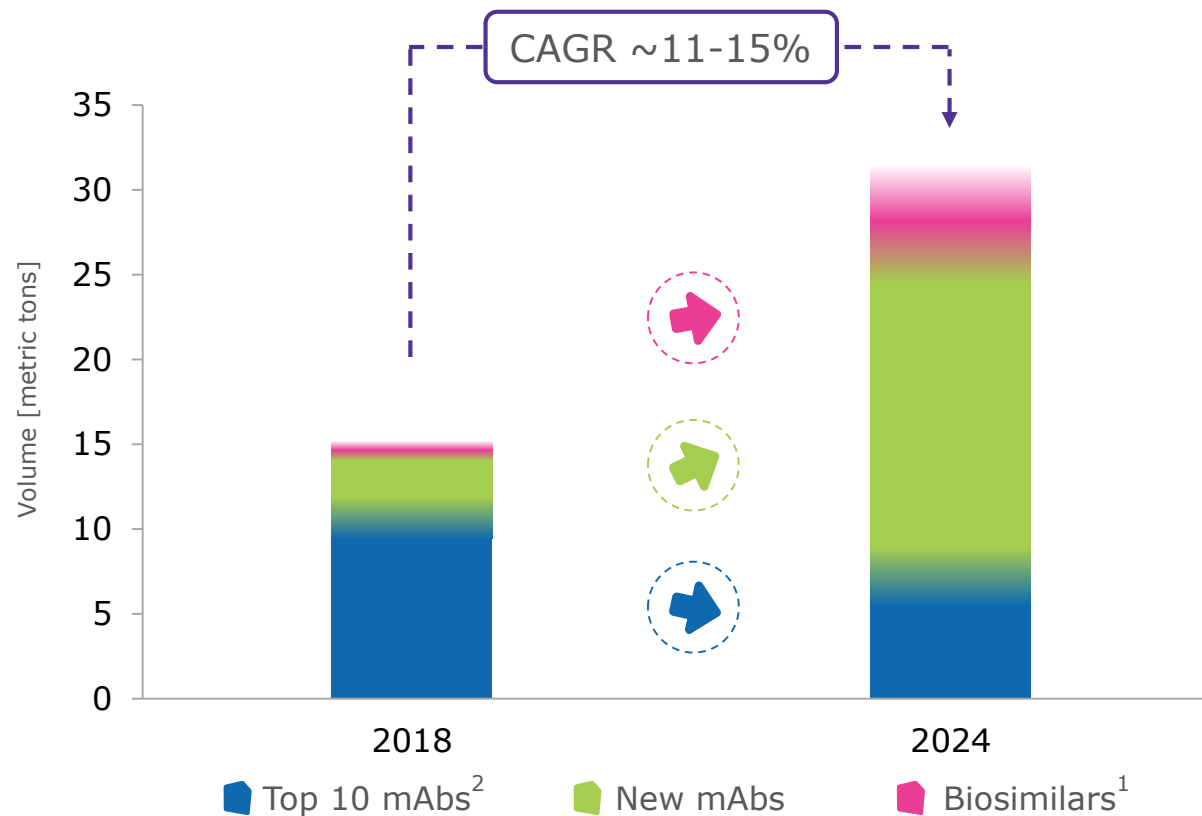
**Strong demand for single-use technologies and Process Solutions' broad offering was and will remain a key source of growth for Life Science**

\*CAPEX = Capital Expenditure



## Democratization of mAbs market will drive diversification, change, variability

### mAb volume projections 2018 to 2024



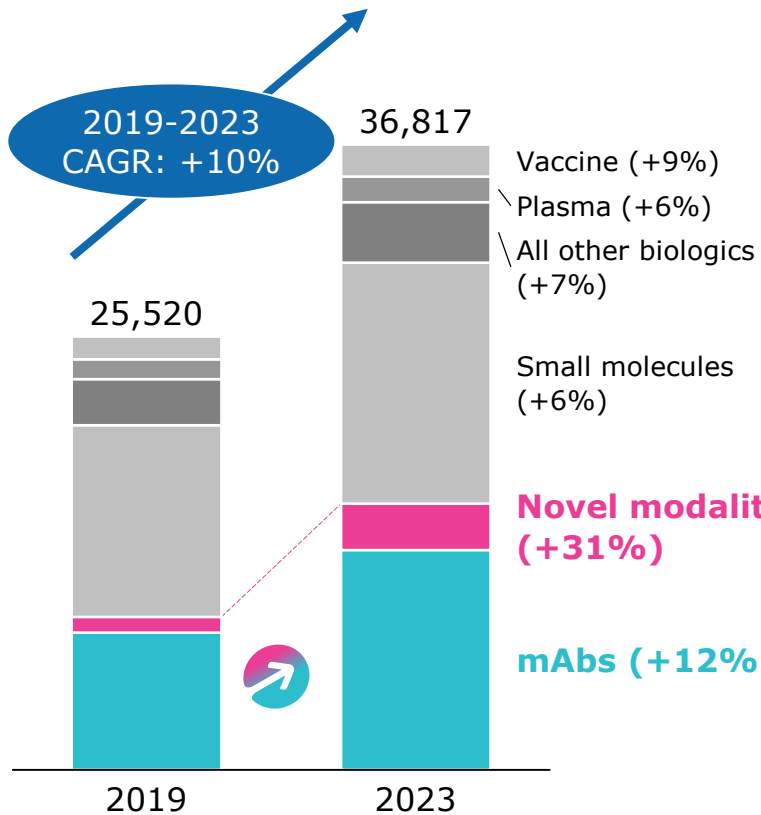
### Market development

- Overall mAbs market will grow ~11-15% CAGR
- Top 10 originator mAbs represent ~60% of market volume today and will decline to ~20% in 2024
- Biosimilars will gain share

<sup>1</sup>Biosimilars scaling factor = 2.8 based off internal estimates and McKinsey analysis; <sup>2</sup>Top 10 mAbs by 2017 volume, includes Enbrel.  
Source: EvaluatePharma | Sept 2018; mAbs = Monoclonal antibodies

## Process Solutions: Growth opportunities beyond mAbs

### Growth potential by segment Accessible market [€m], 2019-2023 CAGR<sup>1</sup>



- **Diversifying products and services** in line with the new modalities coming to the market: fusion biologics, viral and gene therapies, cellular therapies
- **Leading technologies:** investments over 15 years, 20 granted CRISPR patents
- **Services:** investments in CDMO capacity for Viral Vector Manufacturing, and HP-API
- **Leading technologies:** Single Use and BioContinuum™ for intensified and continuous bioprocessing
- **Services:** Contract manufacturing for biotechs at 3 global sites

### Growth market - China



- **Half of world-wide early stage mAb market** by 2022
- **A leading country** in clinical trials
- **Increased investments** into Nantong and Wuxi manufacturing sites
- **China's first BioReliance® End-to-End Biodevelopment Center** opened in Shanghai in 2017

<sup>1</sup>Evaluate Pharma market research; Novel modalities include VGT, Cell Therapy and Stem Therapy; Acronyms: CDMO = Contract Development and Manufacturing Organization, CRISPR = Clustered Regularly Interspaced Short Palindromic Repeats, HP-API = Highly Potent Active Pharmaceutical Ingredients  
ased on internal Life Science market research; TFF = tangential flow filtration

## Applied Solutions

### Broad offering across the dynamic cell and gene therapy value chain



#### Merck KGaA, Darmstadt, Germany offering

Develop **cutting-edge tools** for scientists to

- Uncover **foundational understanding**, e.g. CRISPR patent grants in 7 geographies
- **Modify** genetic functions, e.g. CRISPR/Cas 9 tools, library and reagents, ZFN

Create **cell lines and cell models** for testing **safety and efficacy**

- Pharmacokinetics (ADME)
- Toxicology testing
- Potency model
- Examples: primary human hepatocytes, Intestine, liver and kidney assays

- Offer cGMP clinical and commercial manufacturing, e.g. manufacture **viral vectors**
- Improve the **supply chain of cell therapy**, e.g. cell and gene therapy products and services

**Merck KGaA, Darmstadt, Germany is a supplier of novel products and services with a strong IP portfolio to meet the rapidly growing demand for novel therapies**

Abbreviations: CRISPR = Clustered Regularly Interspaced Short Palindromic Repeats; VGT = Virology and Gene Therapy, ZFN = zinc finger nuclease; ADME = absorption, distribution, metabolism, and excretion; GMP = good manufacturing practice

# Research Solutions

## Leading e-Commerce and operational excellence to serve customers

### unique customer Experience



Hundreds of thousands of products

SEARCH



Articles, protocols and peer reviewed papers



SCIENTIFIC  
CONTENT



Real-time pricing and availability

ORDER

### Highly reputable e-COMMERCE platform

**#1** in Life Science for web traffic

Ranking of websites:\*



<b>sigmaaldrich.com</b>	<b>No. 1</b>
thermofisher.com	No. 2
fishersci.com	No. 3
vwr.com	No. 4
<b>emdmillipore.com</b>	<b>No. 5</b>

**>100 M** unique visits

**>€1.5 BN** sales

**>30%** of Merck KGaA, Darmstadt, Germany eCommerce orders contain products from former Sigma AND Millipore

### Impeccable supply chain

**>300K** products

**~13 M** lines shipped per year

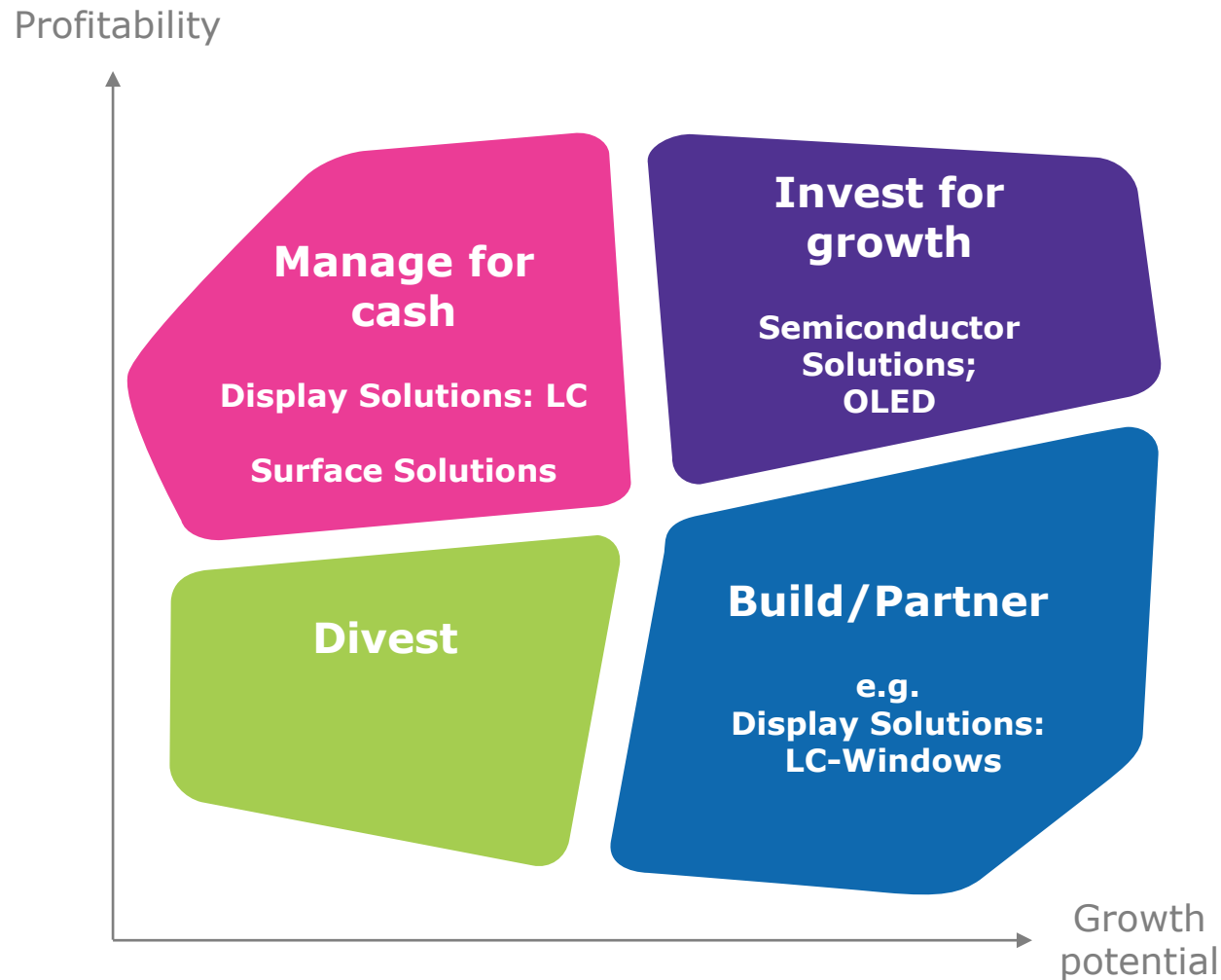
**~90%** fill rate globally

**>80%** of lines shipped within 24-48 hours in Western Europe and North America

\*Alexa report, global, all sectors – Web traffic ranking June 2018: sigmaaldrich.com = Rank 3,361, thermofisher.com = Rank 3,935, fishersci.com = Rank 17,473, vwr.com = Rank 27,061, emdmillipore.com = Rank 29,637

## Performance Materials

# Business portfolio management drives capital allocation and enables future value creation



### Invest for growth

- Strong and sustainable market growth
- Leading positions and attractive growth opportunities

### Manage for cash

- Mature and lucrative market segments
- Invest in extension, while managing for profit

### Build or Partner

- Early industry cycles with strong potential
- Strictly prioritize and diversify risk

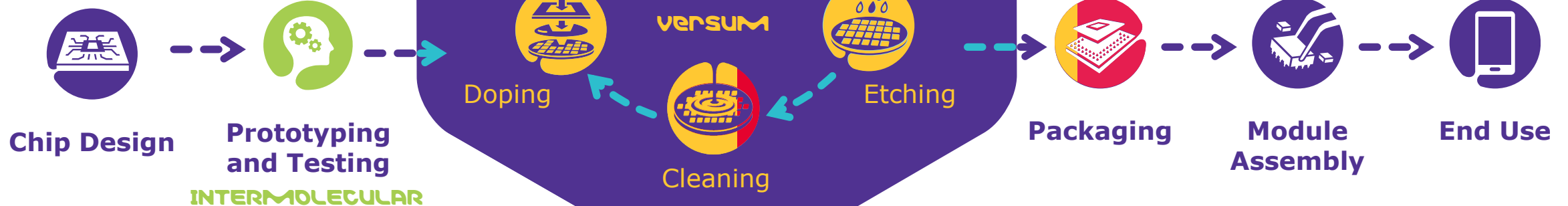
### Divest

- Regular review for better strategic owner

## Semiconductor Solutions even stronger with Versum and Intermolecular

Newly combined  
portfolio offers  
**End2End**  
solutions with  
leading positions  
in **high growth**  
segments

Wafer processing  
offers **highest value**  
**creation potential**  
along the  
semiconductor value  
chain

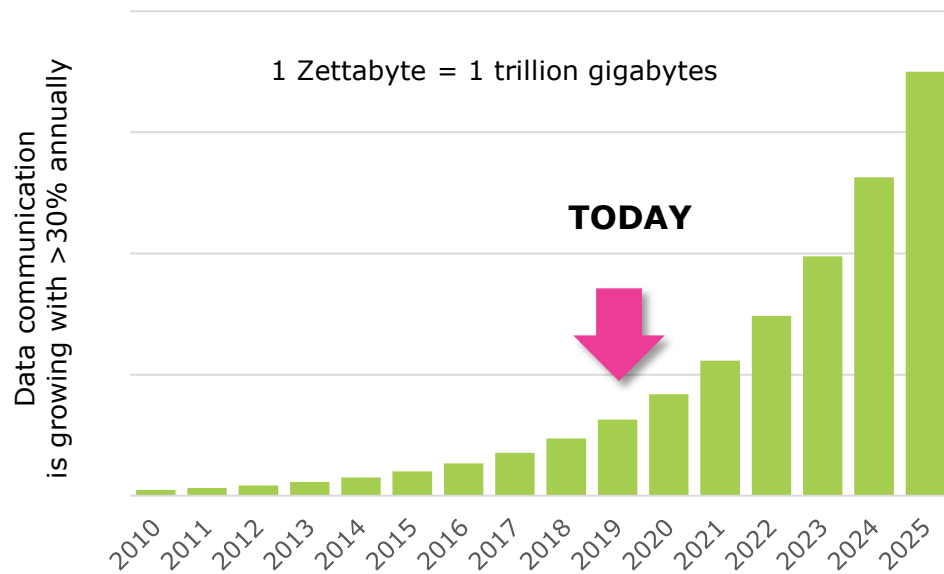


# Performance Materials

## Semiconductor Solutions – Data explosion driving secular growth

### End-market – Data driving growth of electronics industry<sup>1</sup>

Size of global data sphere in zettabytes<sup>1</sup>



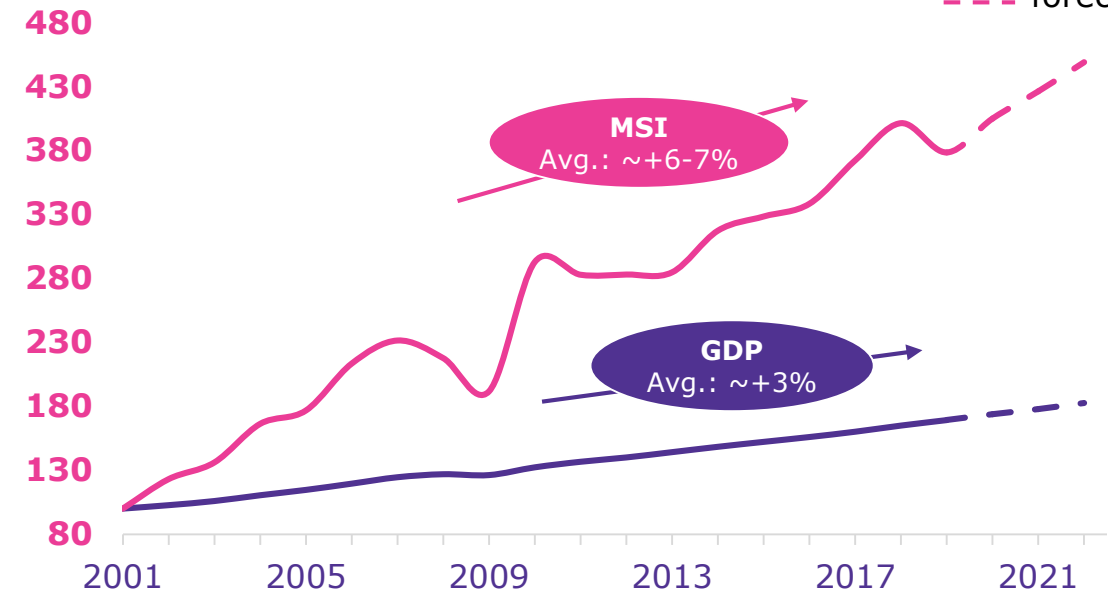
- Data **volumes growing at >30% annually**
- **Driving the digital revolution** as semiconductors are required for data processing and storage

### Silicon wafer area shipments– Sustainable long-term growth<sup>2</sup>

Silicon wafer area shipments (MSI) growth  
[indexed in 2001 = 100]

GDP growth  
[indexed in 2001 = 100]

--- forecast

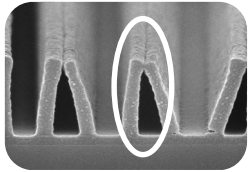


- Silicon wafer area shipments (MSI) **strongly correlated with semiconductor market growth**
- **MSI expected to return to growth as of 2020**

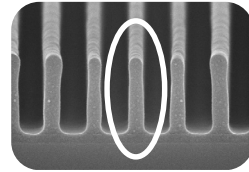
<sup>1</sup> IDC DataAge 2025 Whitepaper; <sup>2</sup> SEMI Silicon Manufacturers Group; Semi.org; ESF July 2019; Prismark; Linx June/July 2019, Silicon wafer area shipments are for semiconductor applications only and do not include solar applications; Acronyms: GDP = Gross Domestic Product, MSI = Million of Square Inches

# Expanding the limits of how small you can go

## Pattern collapse

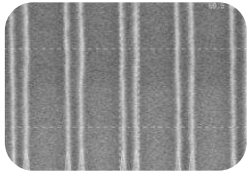


## AZ FIRM® rinse materials

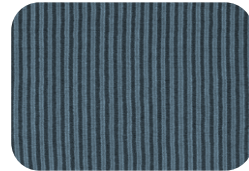


As lines get narrower and closer together in advanced chip generation, lines tend to “stick” due to surface tension.

## Lithography limitation

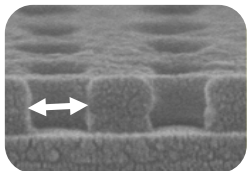


## Directed self-assembly (DSA)

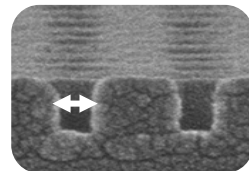


Block copolymer can generate small lines or contact holes by self-assembly. This allows miniaturization without expensive new equipment.

## Wide features



## AZ Relacs® shrink materials



Shrink materials “shrink” the gap between lines and, hence, allow the manufacture of narrower features otherwise not possible.

**Merck KGaA, Darmstadt, Germany delivers highly innovative solutions for complex customer problems**



# Semiconductor Solutions

## Overcoming technology barriers – supporting continued progression of technological mega trends

### Market drivers and technological trends

**Miniaturization:** Devices are becoming smaller with better performance

- Need for enabling materials to reduce size (Moore's law)

**Mobility:** Everyone is continuously connected without direct power supply

- More chips needed for local energy production
- Energy storage → smaller batteries with higher density

**Internet of Things:** Everything is continuously connected

- More gadgets and devices that include chips
- Increasing amount of communication and sensor chips

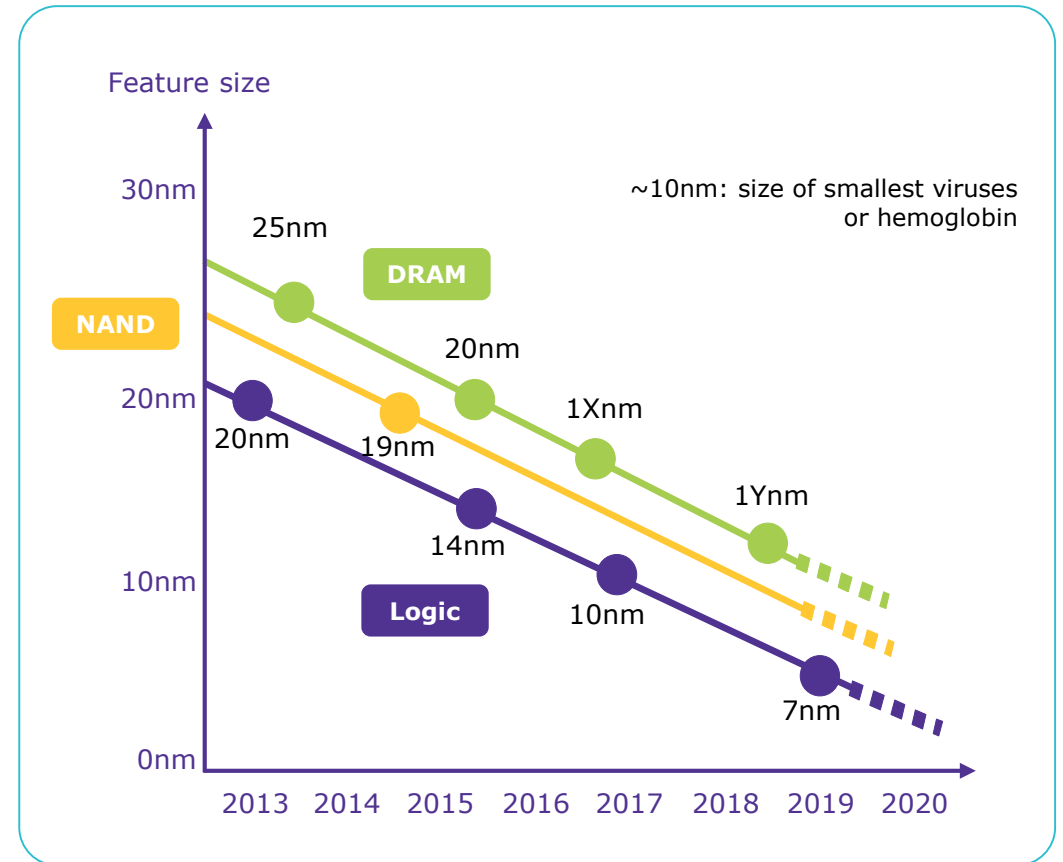
**Big Data:** Increasing need for intelligent data storage

- Switch from hard disk drives (HDD) to solid state drives (SSD)

### Selected competitors

- Tokyo Ohka Kogyo
- Dow Electronic Materials
- Nissan Chemicals
- JSR

Feature sizes in memory market develop as predicted by Moore's law<sup>1</sup>

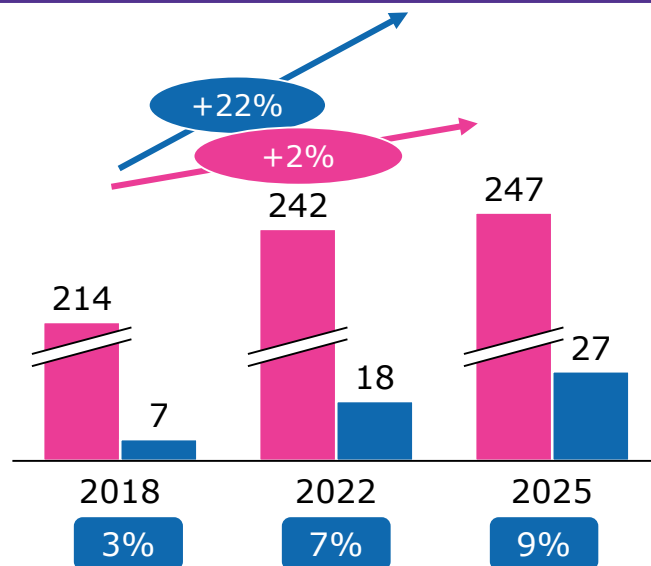


# Performance Materials

## Display Solutions - OLED material market to exceed LC material market by 2022

■ Liquid Crystals ■ OLED

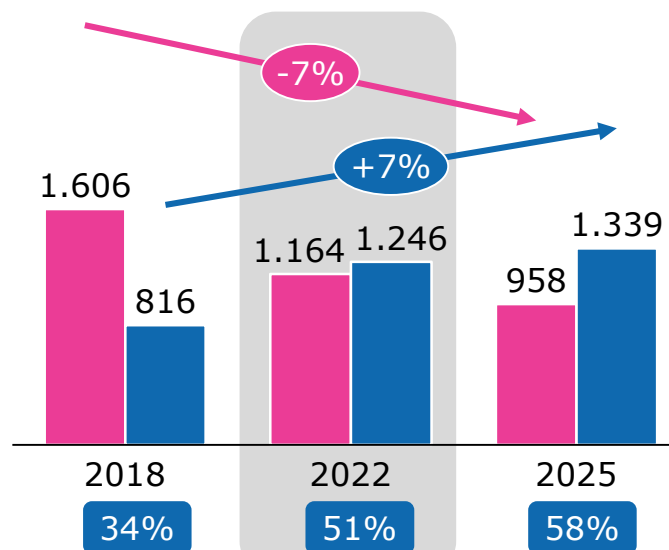
### Display shipment area<sup>1</sup> [km<sup>2</sup>]



- **Continued growth** across all technologies
- **OLED growing faster than LCD**, but **LCD to command 90+% area share** for foreseeable future

x% OLED shipment area / addressable material market [in % of total]

### Addressable material market<sup>2</sup> [€m]



- **Material value** per OLED display **higher** than in LCD
- **OLED material market to exceed LC material market by 2022**, but market split between **many more players**

### Portfolio Role

**Manage for cash**

Liquid Crystals  
Surface Solutions



**Invest for growth**

Semiconductor Solutions  
OLED



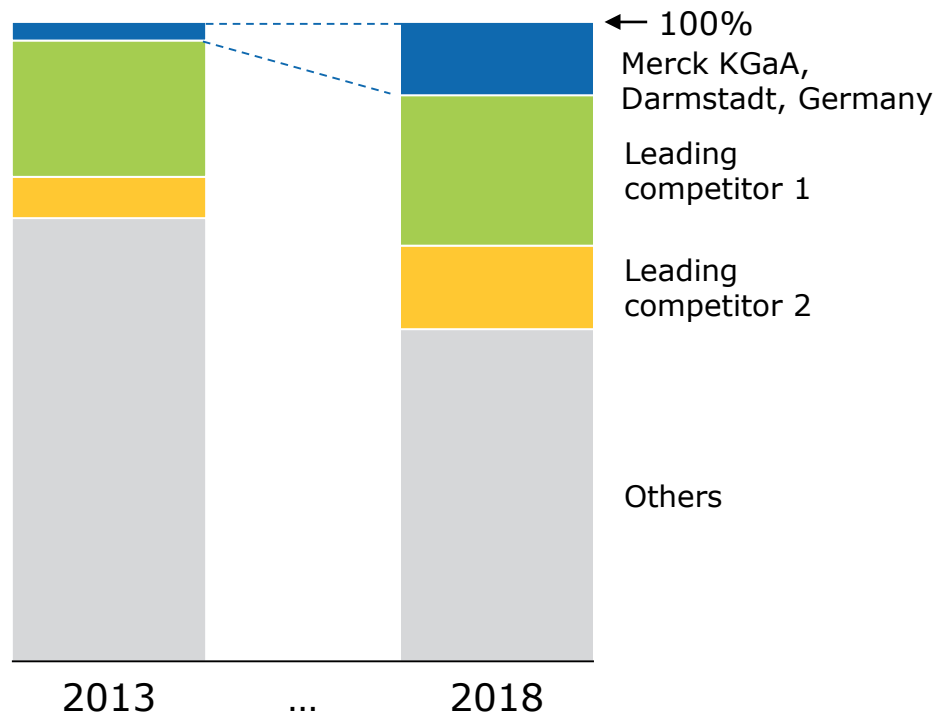
<sup>1</sup>IHS long term demand forecast Q1 2019; <sup>2</sup>Internal Business Intelligence; Acronyms: LCD = Liquid-Crystal Display, OLED = Organic Light Emitting

## Performance Materials

# OLED – A major driver of topline growth with significant potential

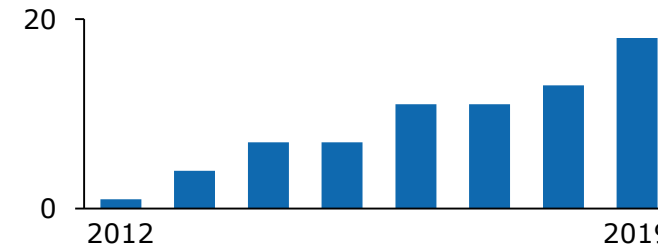


Market share (value) nearly quadrupled in 5 years<sup>1</sup>



Maintaining global top 3 position through ...

### Continuous portfolio development:



# of Merck KGaA, Darmstadt, Germany OLED materials in mass production with annual revenues >€1 m

### Strategic partnerships:



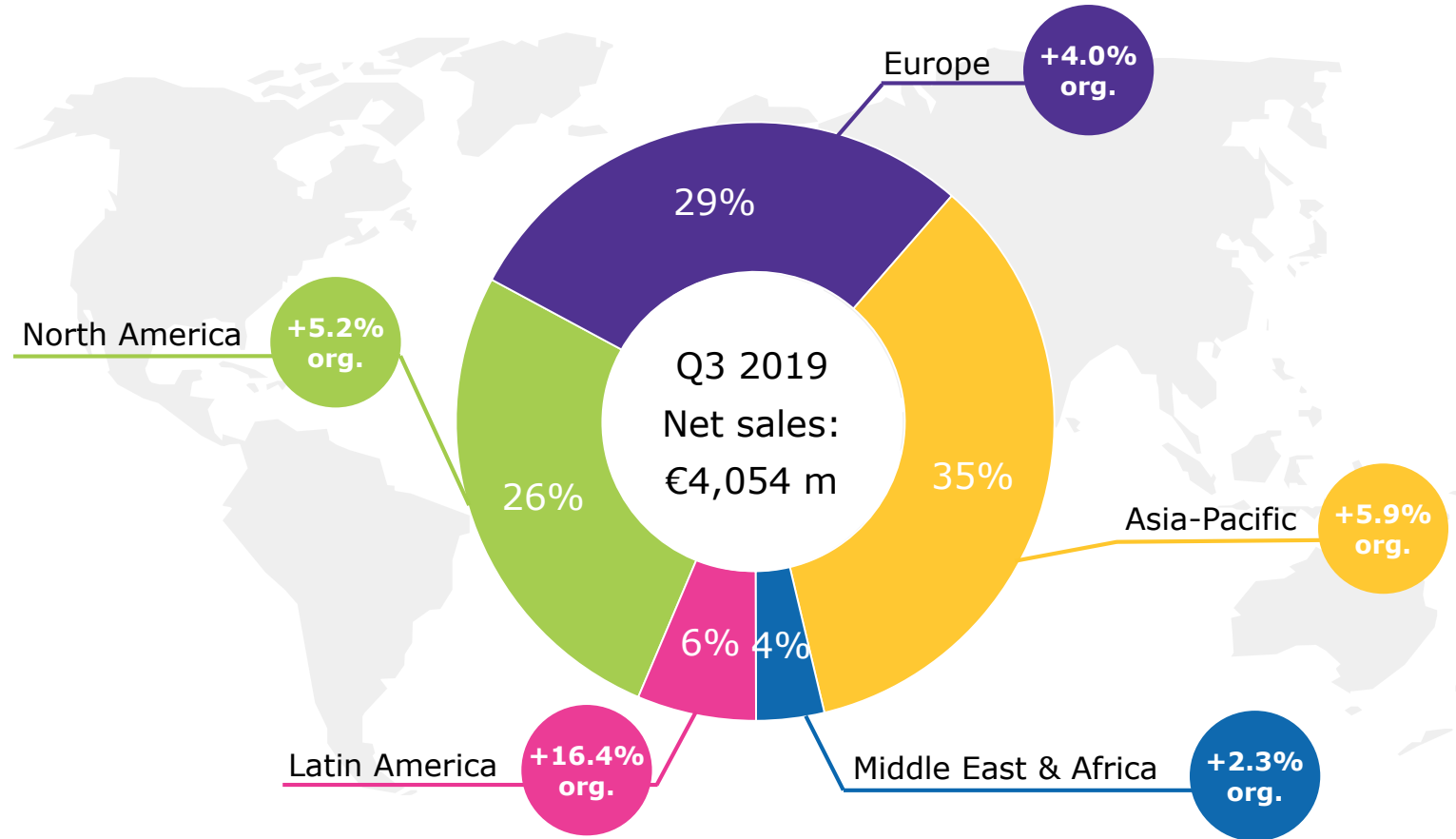
### Proximity to the customer:

- 2015: Opening of **OLED development center Korea**
- 2018: Opening of **OLED technology center China**
- 2018: Strategic cooperation with **important Chinese customer**

<sup>1</sup> 2013 UBI Research, 2018 Internal business intelligence, Uncertainty Merck KGaA, Darmstadt, Germany Market Share: +-2%; Acronyms: OLED = Organic Light Emitting Diode

# Solid organic growth driven by all regions

## Regional breakdown of net sales [€m]



## Regional organic development

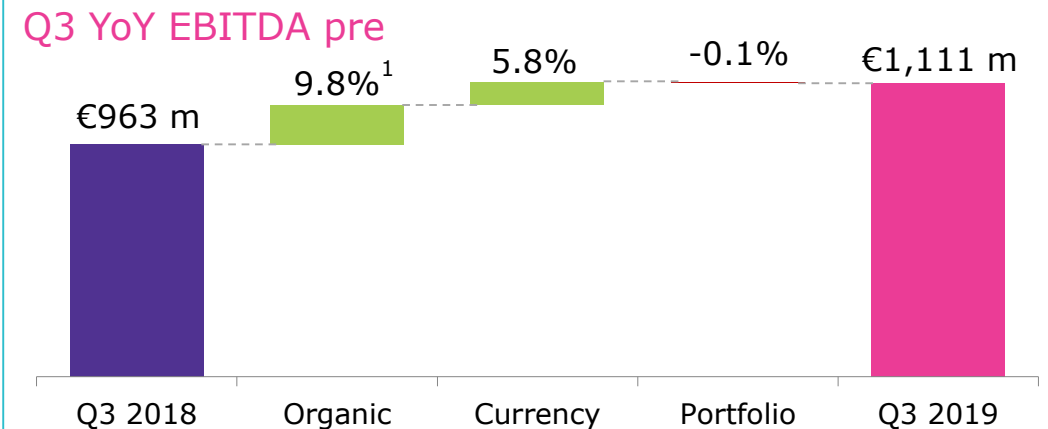
- Solid APAC due to double-digit growth of Life Science, Glucophage<sup>®</sup> and Erbitux<sup>®</sup> offset by decline in PM amid strong OLED
- Europe solid growth reflects strong demand in Life Science; strong Mavenclad<sup>®</sup> and GM more than offset Rebif<sup>®</sup> and Erbitux<sup>®</sup> decline
- Solid North America driven by strong Life Science; GM, Fertility and Mavenclad<sup>®</sup> ram-up outweighing double-digit decline of Rebif<sup>®</sup>
- Double-digit growth in LATAM due to strong performance of Healthcare core business and Life Science

# Life Science and Healthcare drive organic growth of top- and bottom-line, supported by FX tailwinds

Q3 2019 YoY net sales	Organic	Currency	Portfolio	Total
Healthcare	8.0%	2.0%	0.0%	<b>10.0%</b>
Life Science	10.0%	3.0%	-0.7%	<b>12.3%</b>
Performance Materials	-10.6%	3.7%	0.0%	<b>-6.9%</b>
Group	5.7%	2.7%	-0.3%	<b>8.1%</b>

- Strong growth in Healthcare driven by sound uptake of Mavenclad<sup>®</sup> and strong demand for General Medicine mainly in China
- Life Science posts double-digit growth fueled by all businesses and regions
- Performance Materials reflects decline in LC despite strong demand in OLED; soft market demand in Semiconductor and Surface Solutions

<sup>1</sup>Thereof IFRS 16 effect with +3.4% (+€33 m); Totals may not add up due to rounding



- Increased organic EBITDA pre due to strong top-line growth, cost consciousness and GSK income in Healthcare; Life Science with sustained strong performance
- Positive FX impact on EBITDA pre due to US dollar and Japanese yen

# Q3 2019: Overview

## Key figures

[€m]	Q3 2018	Q3 2019	Δ
Net sales	3,749	<b>4,054</b>	8.1%
EBITDA pre	963	<b>1,111</b>	15.4%
Margin (in % of net sales)	25.7%	27.4%	
EPS pre	1.32	<b>1.35</b>	2.3%
Operating cash flow	731	<b>931</b>	27.3%

[€m]	Dec. 31, 2018	Sept. 30, 2019	Δ
Net financial debt	6,701	<b>7,320</b>	9.2%
Working capital	3,486	<b>3,980</b>	14.2%
Employees	51,749	<b>54,042</b>	4.4%

## Comments

- Net sales growth driven by Healthcare and Life Science, offsetting Performance Materials decline
- EBITDA pre & margin reflect GSK deferred income (~€30 m), cost consciousness in HC and strong operating leverage in LS
- Strong operating cash flow due to higher EBITDA and Bavencio<sup>®</sup> milestone payment
- Working capital reflects increased inventory levels and FX
- Higher net financial debt driven by IFRS 16 adoption, dividends and temporary investment of cash proceeds from CH divestment

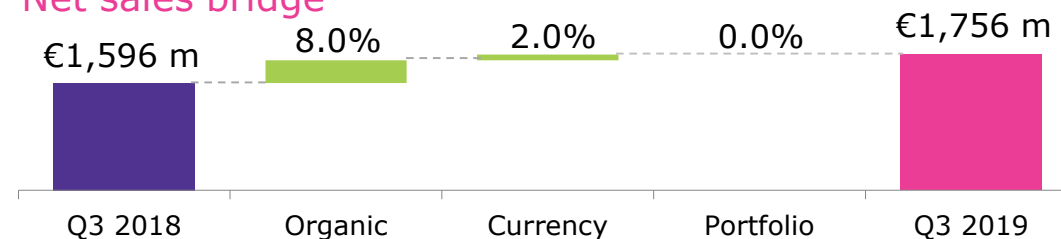
Totals may not add up due to rounding

# Healthcare: Prominent contribution from Mavenclad<sup>®</sup> and Bavencio<sup>®</sup>; solid core business

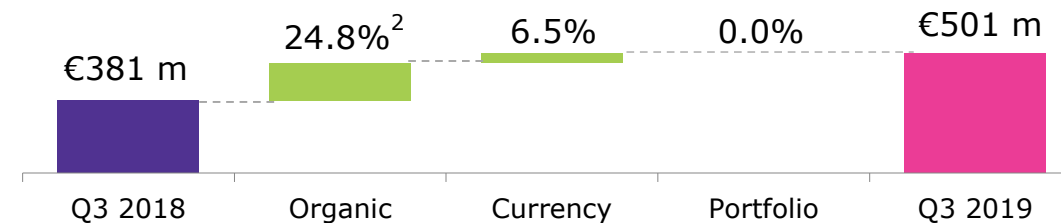
## Healthcare P&L

[€m]	Q3 2018 <sup>1</sup>	Q3 2019
Net Sales	1,596	<b>1,756</b>
Marketing and selling	-573	<b>-561</b>
Administration	-81	<b>-82</b>
Research and development	-409	<b>-429</b>
EBIT	191	<b>325</b>
EBITDA	372	<b>504</b>
EBITDA pre	381	<b>501</b>
Margin (in % of net sales)	23.9%	<b>28.5%</b>

## Net sales bridge



## EBITDA pre bridge



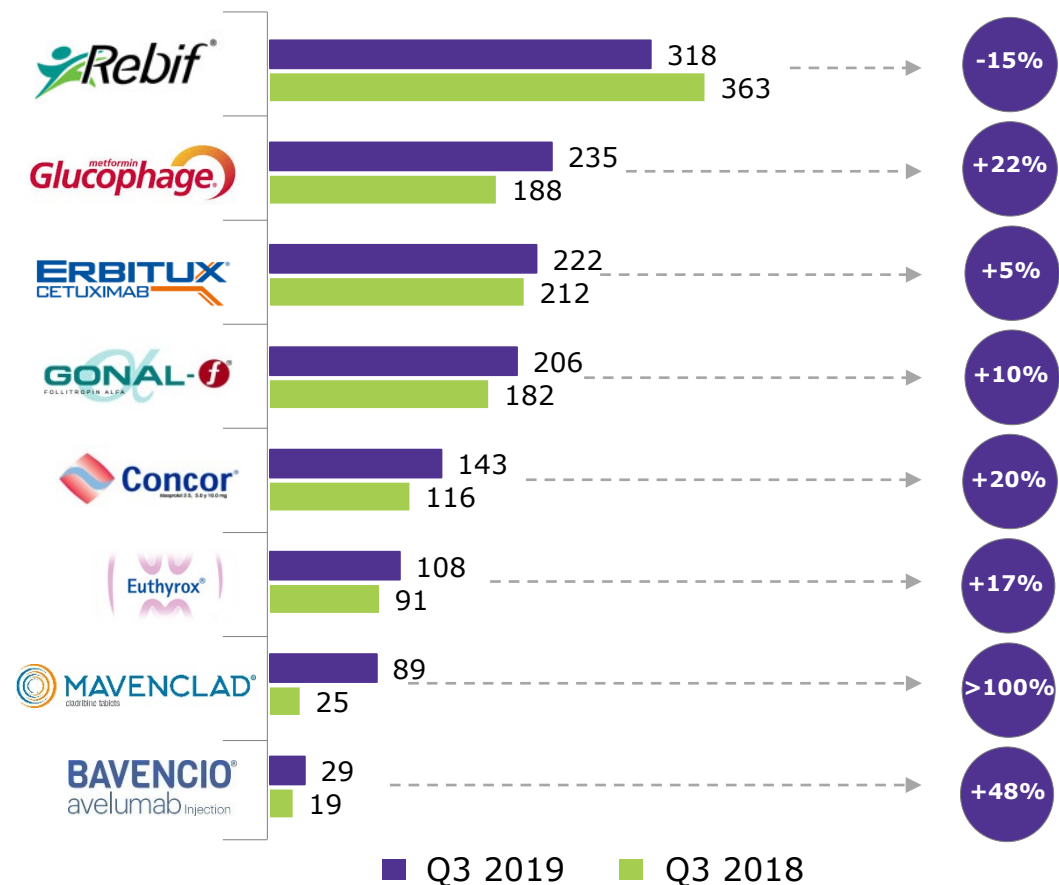
## Comments

- Strong growth in Healthcare reflects solid core business and all franchises contributing, N&I franchise back to growth globally
- Mavenclad<sup>®</sup> with continued strong uptake globally (+45% vs. Q2)
- Solid Erbitux<sup>®</sup> benefiting from China reimbursement; Bavencio<sup>®</sup> on track
- M&S decrease due to resource reallocation from core business to new product launches and stringent cost management
- Higher EBITDA pre driven by strong top-line performance, cost consciousness, GSK deferred income (~€30 m) and IFRS 16

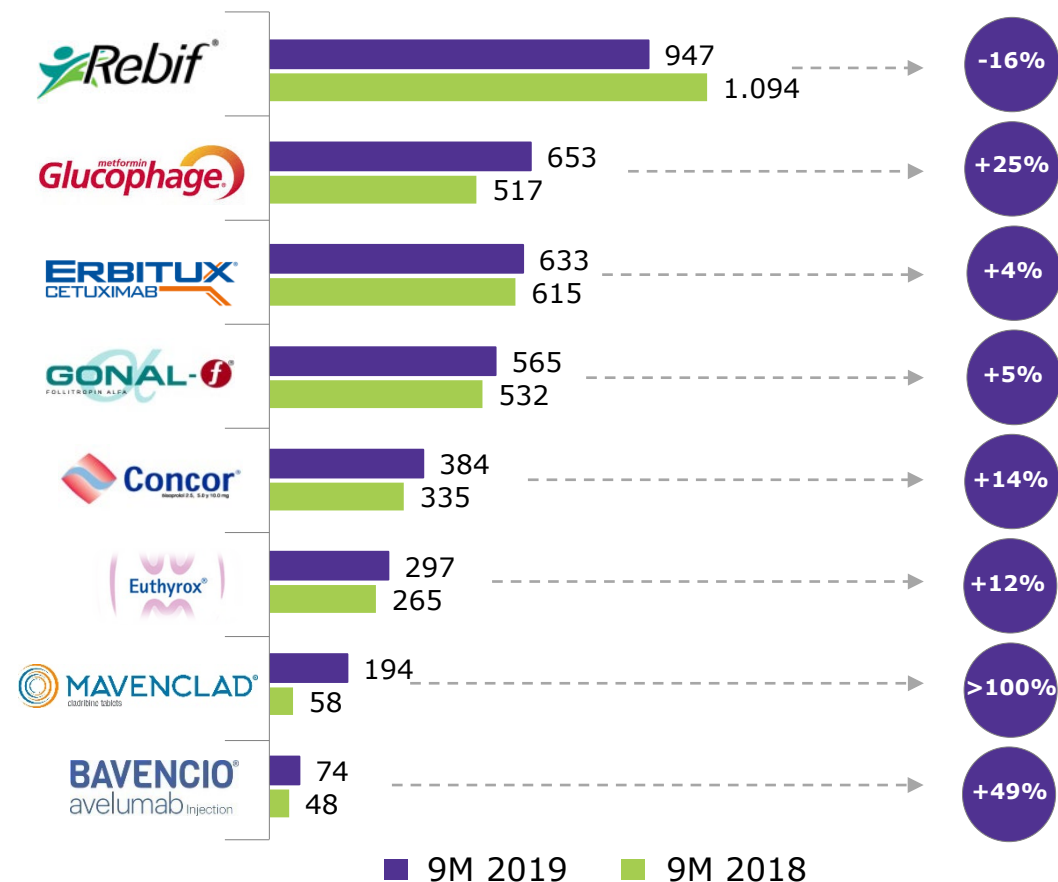
<sup>1</sup>LY numbers have been modified, due to disclosure changes of adjustments; <sup>2</sup>Thereof IFRS 16 effect with +3.1% (+€12 m); Totals may not add up due to rounding

# Healthcare organic growth by franchise/product

Q3 2019 organic sales growth [%]  
by key product [€m]



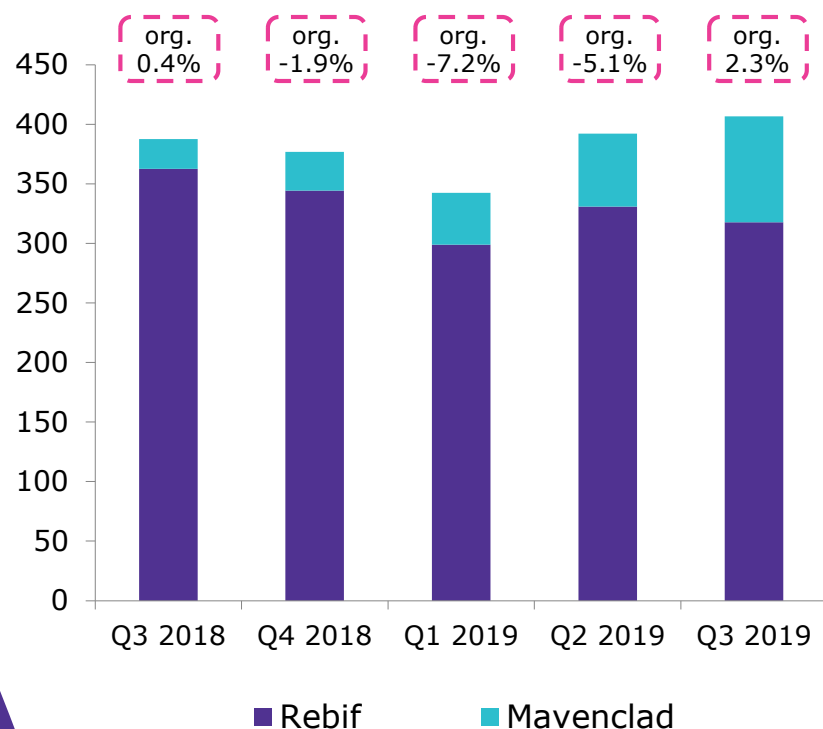
9M 2019 organic sales growth [%]  
by key product [€m]



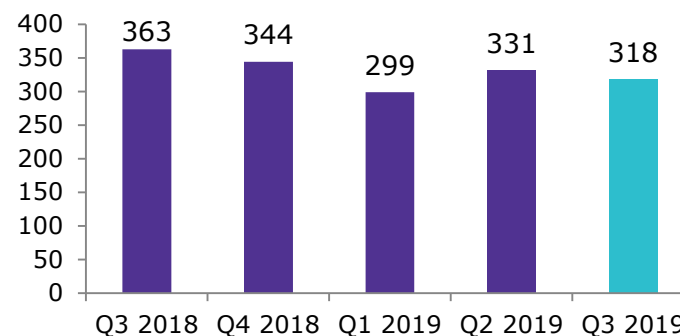


# Neurodegenerative Diseases: Strong growth of Mavenclad® starts to offset Rebif® decline

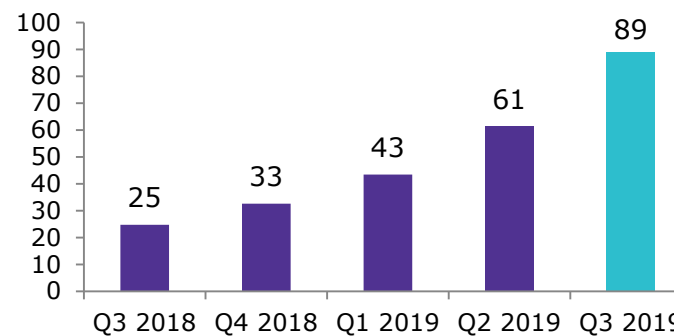
Sales development NDI, [€m]



Rebif® net sales, [€m]



Mavenclad® net sales, [€m]



- Rebif® sales of €318 m in Q3 2019 reflects organic decline of -15.1% mitigated by FX effect of +2.8%
- U.S. and European volume decline mainly due to competition
- U.S. decline in line with IFN market dynamics

**Mavenclad® ramp up accelerating across all regions**

**FY 2019 guidance of ~€300 m**

NDI = Neurodegenerative Diseases & Immunology; IFN = Interferon

# Multiple Sclerosis: Mavenclad® launch continues to make progress with sales +41% Q2 vs Q1 2019



## Global Launch Update

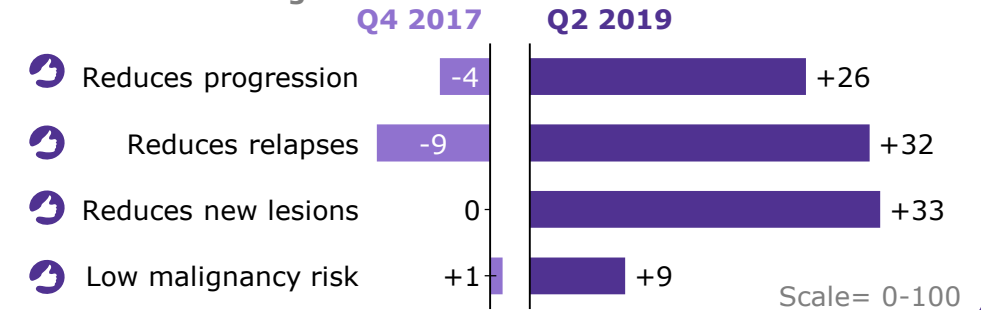
- **Approval in 61 countries with reimbursement in ~50% to date, consistent with expectations**
- **>3,000 neurologists have now prescribed Mavenclad®**
- **Advancing clinical perception:** relative perception vs approved high-efficacy agents continues to improve across major launch markets
- **Increasing share of high-efficacy dynamic patients (new + switch)<sup>1</sup> in major launch markets vs LY**
  - Germany: from 9% to 14% (Q1/18 vs Q1/19)<sup>2</sup>
  - UK: from 8% to 20% (Q1/18 vs Q1/19)<sup>3</sup>
- **Increasing use in earlier lines of therapy in major launch markets:** ~30% of starts are treatment naïve<sup>5</sup>; Switches predominantly from platform orals & platform injectables
- **MS Franchise in early launch markets returning to growth:** Mavenclad® complementing Rebif® to drive franchise growth

➤ **On track for up to mid-triple digit m€ sales in 2019**

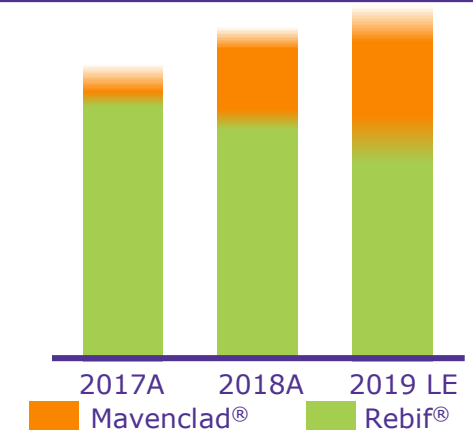


## Improved clinical perception versus leading HE oral (Germany)<sup>4</sup>

### Deviation vs leading HE Oral



- **MS Franchise sales evolution (Germany)**
- **Rebif maintaining share in IFN class**
- **Mavenclad competing in HE class**



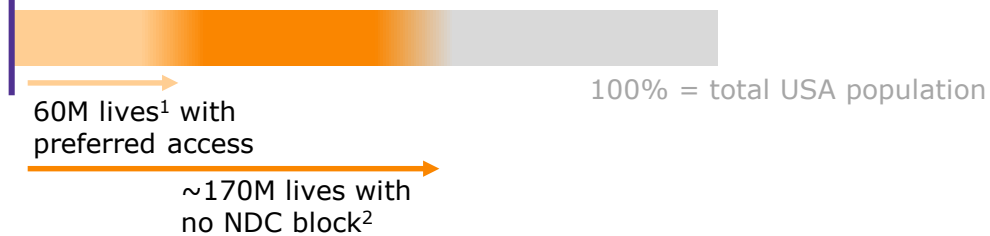
<sup>1</sup>High efficacy treatments include MAV, Gil, Ocr, Tys, Lem; <sup>2</sup>IQVIA LRx data; consolidated retail + hospital data; <sup>3</sup>IQVIA – fully consolidated Q1/19 data; <sup>4</sup>Global MAVENCLAD ATU, DE neurologists (n=62), bar charts indicate difference between Mavenclad® and leading HE oral: positive numbers imply Mavenclad® strength vs. competitor; <sup>5</sup>excludes US prescriptions

# Multiple Sclerosis: Mavenclad® gaining momentum in the first 13 weeks of launch in the USA



## Payer & Physician Feedback

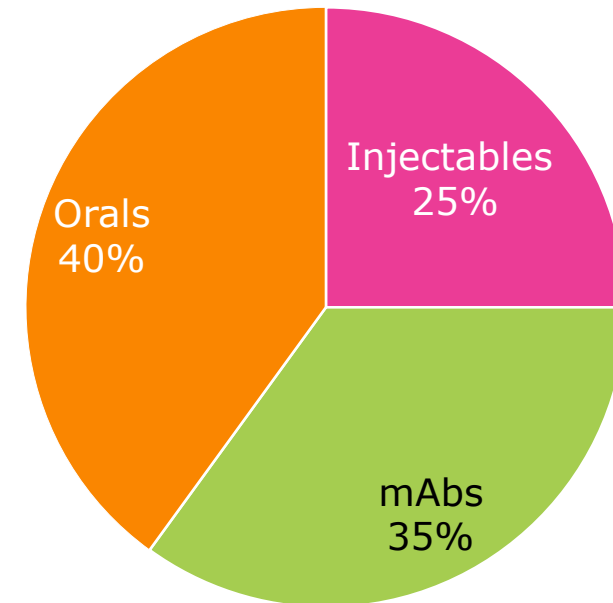
- **Positive, early payer acceptance:**



- **Strong physician access** resulting in **leading share of voice**<sup>3</sup>
- **86% of neurologists willing to prescribe Mavenclad®**<sup>4</sup>
- **~ 3% high efficacy dynamic share in RRMS,** and **~11% high efficacy dynamic share in SPMS/other** (new + switch, April to June)<sup>3</sup>
- **Broad spectrum of early adopters:** both neurologists from **academic centers** and from **community practices** initiating patients on Mavenclad® (equal proportions to date)
- **Mavenclad®'s novel mechanism, posology, and efficacy profile** have made it a **candidate for switches from all approved agents**



## Source of Prescription<sup>5</sup>



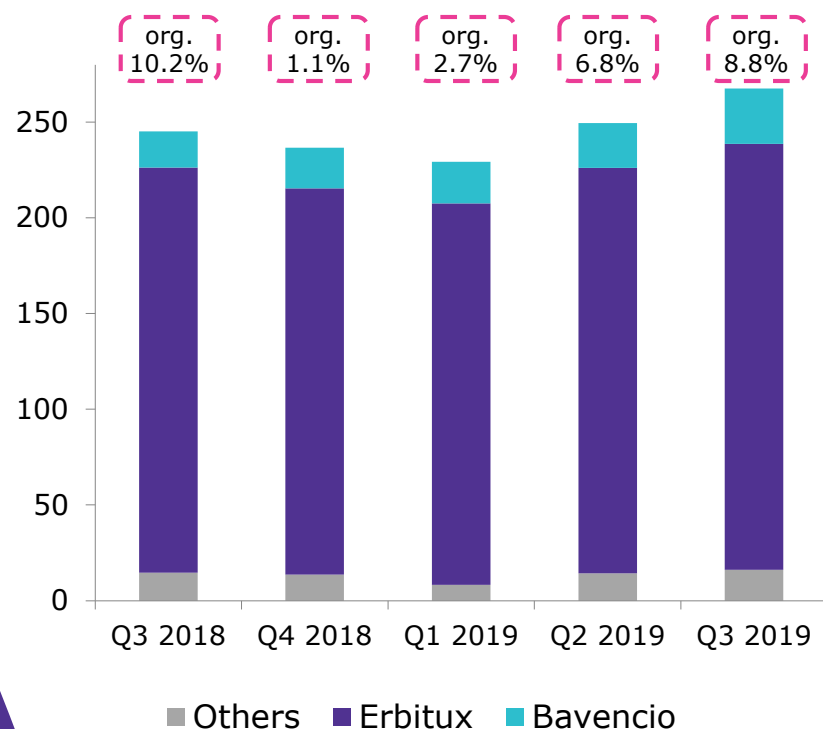
<sup>1</sup>Appropriate USA patients as per MAVENCLAD FDA label; <sup>2</sup>The NDC (National Drug Code) is a unique product identifier code for all drugs in the USA;

<sup>3</sup>IQVIA/BrandImpactRx rolling 3 months end June: MAVENCLAD ranked 2nd across full panel on SOV, and shares reflecting NWRx, HE incl. Tys, Gil, Ocr, May, Mav, Lem;

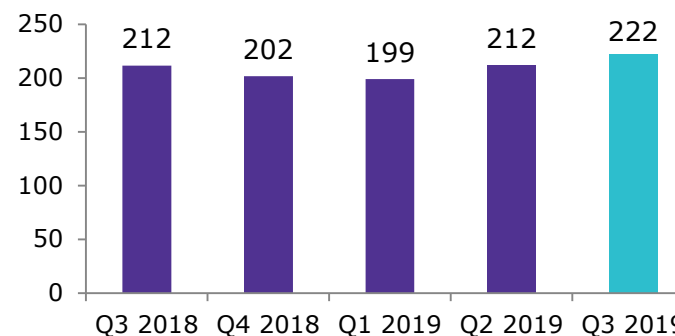
<sup>4</sup>Spherix Global Insights RealTime Dynamix – MS Q2/19; <sup>5</sup>Company data based on MAVENCLAD patient support program "MS Life Lines"

# Oncology: Solid organic growth reflects strong demand for Erbitux® in China and Bavencio® ramp up

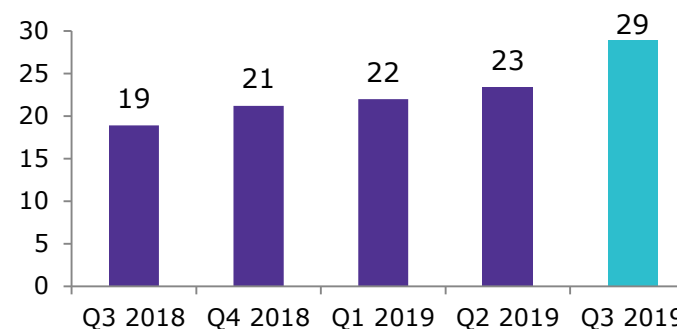
Sales development Oncology, [€m]



Erbitux® net sales, [€m]



Bavencio® net sales, [€m]



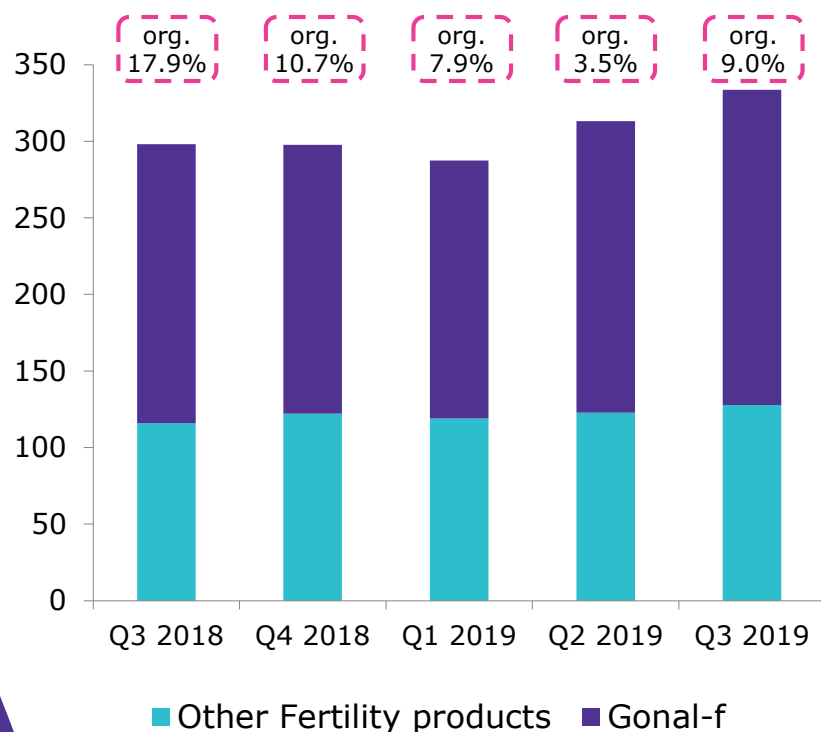
- Absolute sales of €222 m reflect solid growth (org. 5.1%; FX 0.0%)
- Strong APAC mainly driven by China reimbursement recognition
- LATAM strong, while MEA affected by tender phasing due to import permit
- Decline in Europe reflects ongoing competition, price reductions and shrinking market size

**Bavencio® approved for RCC in US mid May 2019**

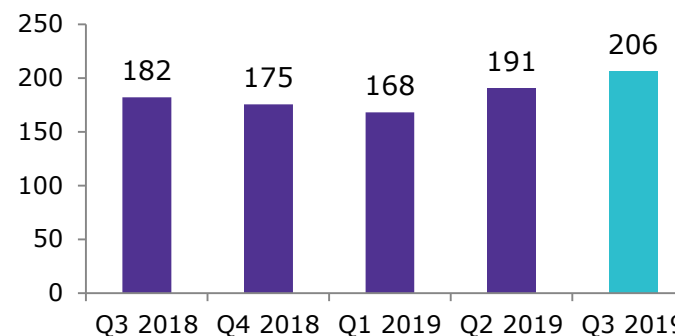
**FY 2019 guidance of ~ €100 m**

# Fertility: Strong organic growth driven by ongoing demand for Gonal-f in the U.S. and China

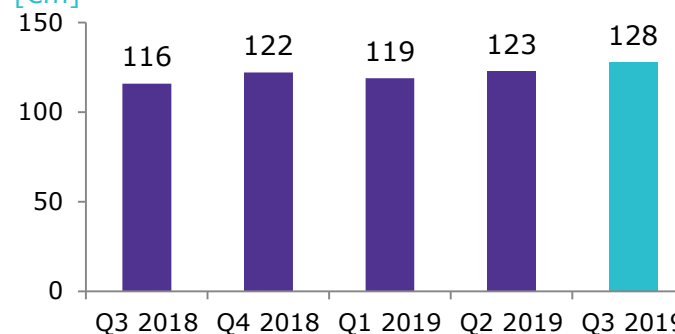
Sales development Fertility, [€m]



Gonal-f<sup>®</sup> net sales, [€m]



Other Fertility products net sales, [€m]

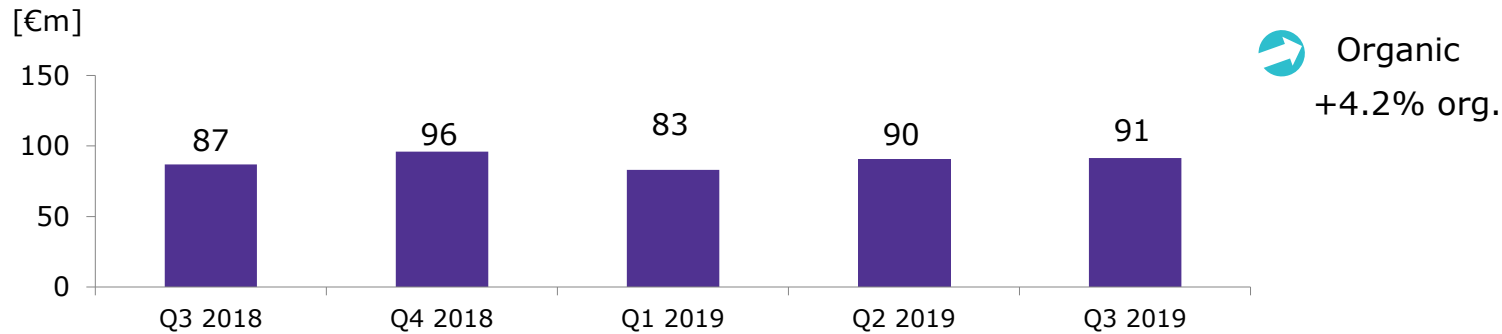


- Fertility posts strong organic growth driven by APAC, North America and MEA
- Double-digit growth of Gonal-f<sup>®</sup> results in €206 m absolute sales (org. 10.0%; FX 3.2%)
- Gonal-f<sup>®</sup> driven by ongoing strong demand in the U.S. and China
- Other Fertility products with strong growth mainly driven by APAC and LATAM

# China, Europe and LATAM fuel double-digit growth of General Medicine

## Sales evolution

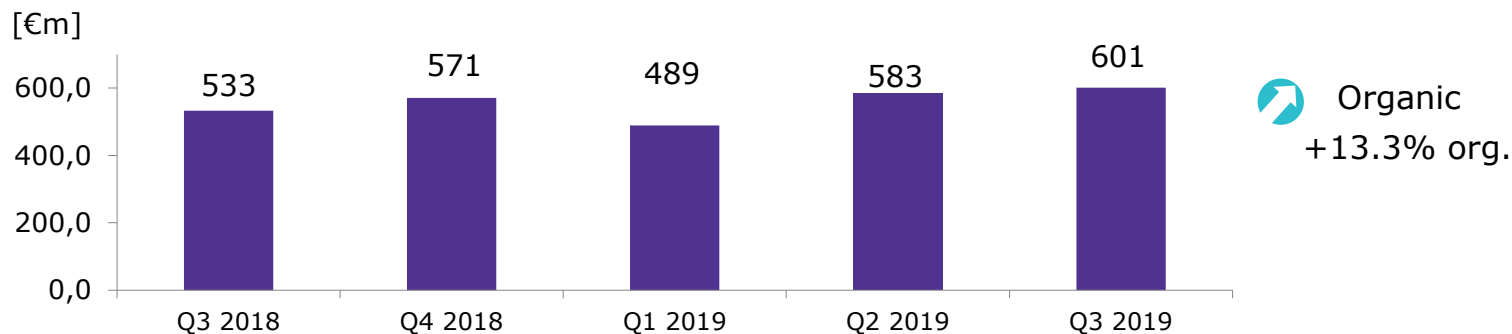
### Endocrinology



## Q3 2019 organic drivers

- Endocrinology with solid organic growth driven by all major regions, especially LATAM

### General Medicine\*



- Ongoing strong demand for Glucophage<sup>®</sup>, Concor<sup>®</sup> and Euthyrox<sup>®</sup> especially in China, Europe and LATAM drive double-digit growth of General Medicine

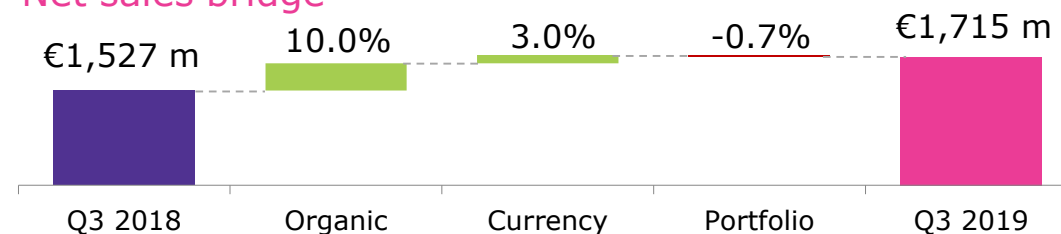
\*includes CardioMetabolic Care & General Medicine and Others

# Life Science: All major businesses and regions fuel double-digit growth

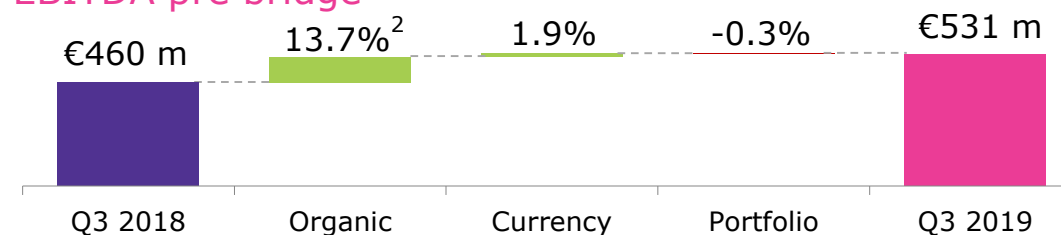
## Life Science P&L

[€m]	Q3 2018 <sup>1</sup>	Q3 2019
Net Sales	1,527	<b>1,715</b>
Marketing and selling	-443	<b>-474</b>
Administration	-85	<b>-83</b>
Research and development	-59	<b>-67</b>
EBIT	277	<b>316</b>
EBITDA	449	<b>511</b>
EBITDA pre	460	<b>531</b>
Margin (in % of net sales)	30.1%	<b>31.0%</b>

## Net sales bridge



## EBITDA pre bridge



## Comments

- Strong demand for Process Solutions drives double-digit growth, especially filtration and single-use, across all regions
- Solid organic growth of Applied Solutions mainly driven by advanced analytical and lab water
- Research Solutions with solid organic growth reflecting strong demand for lab separation and workflow tools, especially APAC and North America
- Strong volume growth and investments in eCommerce drive higher M&S
- EBITDA pre and margin increase driven by sustained strong top line, operating leverage and IFRS 16

<sup>1</sup>LY numbers have been modified, due to disclosure changes of adjustments; <sup>2</sup>Thereof IFRS 16 effect with +3.0% (+€14 m); Totals may not add up due to rounding

# Life Science: Ongoing strong demand driving Q3 performance of Process, Applied and Research Solutions



## Research Solutions

+5.2 %  
org.

- Lab Separation and Workflow Tools driving growth, especially with filtration based products in protein research
- eCommerce growing at 2x the rate of offline
- Synthia: Retrosynthesis tool in Lab and Specialty Chemicals

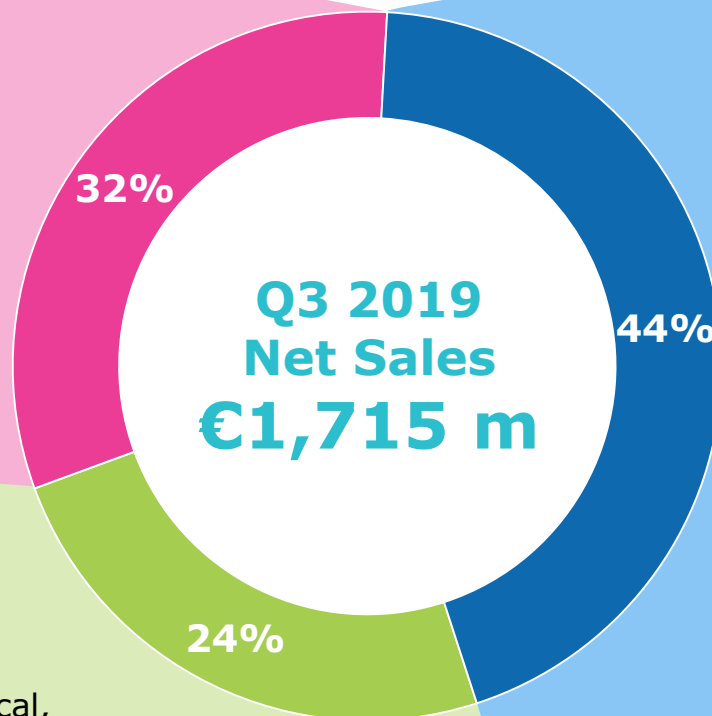


## Applied Solutions

+6.8 %  
org.

- Double-digit growth for Advanced Analytical, and high single-digit growth for Lab Water Solutions
- High single-digit growth in APAC and Emerging markets, with double-digit growth in China
- Acquisition of BSSN Software to accelerate customers' digital transformation in the lab

## Net sales by BU, in %



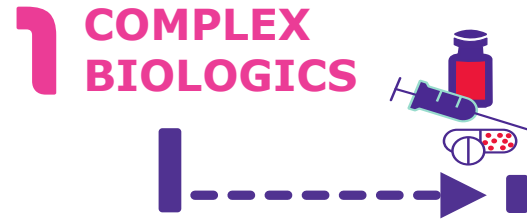
## Process Solutions

+15.6 %  
org.

- BioProcessing growth driven by Single-Use, CDMO, and Process Solutions Services
- All regions growing in the double-digits, with Asia and Americas in the high-teens and Europe/MEA in the low-teens
- Acquisition of ProcessPad technology to advance our BioContinuum™ platform
- >20 New product launches in 2019 so far



# Acting to capitalize on three life science trends



## Single Use / End to End

Opened Wuxi site in 2018,  
and expanded Danvers facility

## Viral Vectors

Expanded Carlsbad viral  
vector manufacturing site in  
2016

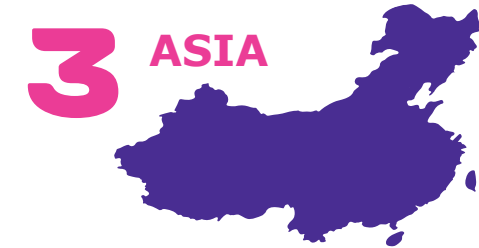
## Antibody Drug Conjugates (ADC)

Launched ADC Express™ for  
the rapid production of ADCs



## #1 eCommerce site in Life Science<sup>1</sup>

- **>90%** of Millipore products on eCommerce platform
- **x2** net sales growth of eCommerce vs. non-eCommerce<sup>2</sup>



Manufacturing/Distribution  
Nantong, Wuxi Single use

Commercial expansion  
Tier 2 cities

eCommerce partnership



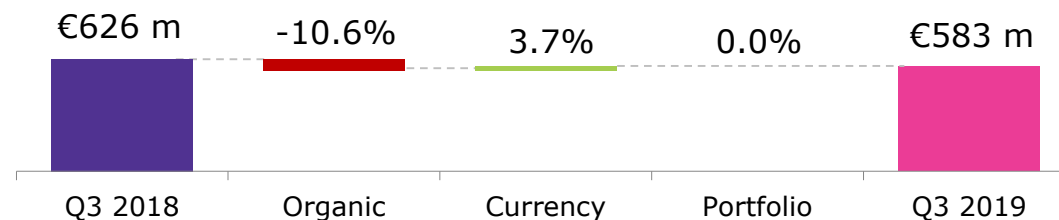
<sup>1</sup>Measured by traffic, rated by external service SimilarWeb; <sup>2</sup>By business segment within Life Science

# Performance Materials: Expected LC decline starts to materialize amid continued market slowdown in Semiconductor and Surface

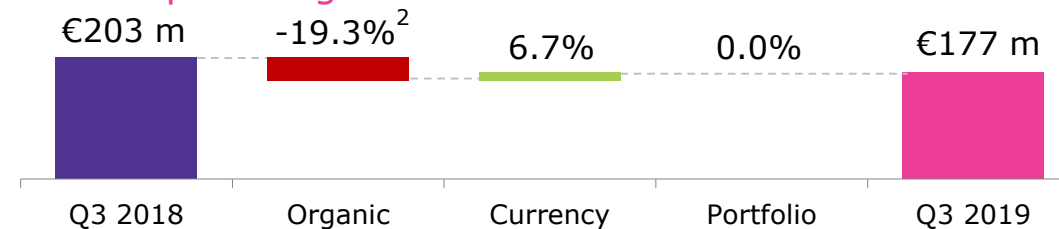
## Performance Materials P&L

[€m]	Q3 2018 <sup>1</sup>	Q3 2019
Net Sales	626	<b>583</b>
Marketing and selling	-62	<b>-61</b>
Administration	-23	<b>-30</b>
Research and development	-65	<b>-48</b>
EBIT	142	<b>98</b>
EBITDA	202	<b>169</b>
EBITDA pre	203	<b>177</b>
Margin (in % of net sales)	32.5%	<b>30.5%</b>

## Net sales bridge



## EBITDA pre bridge

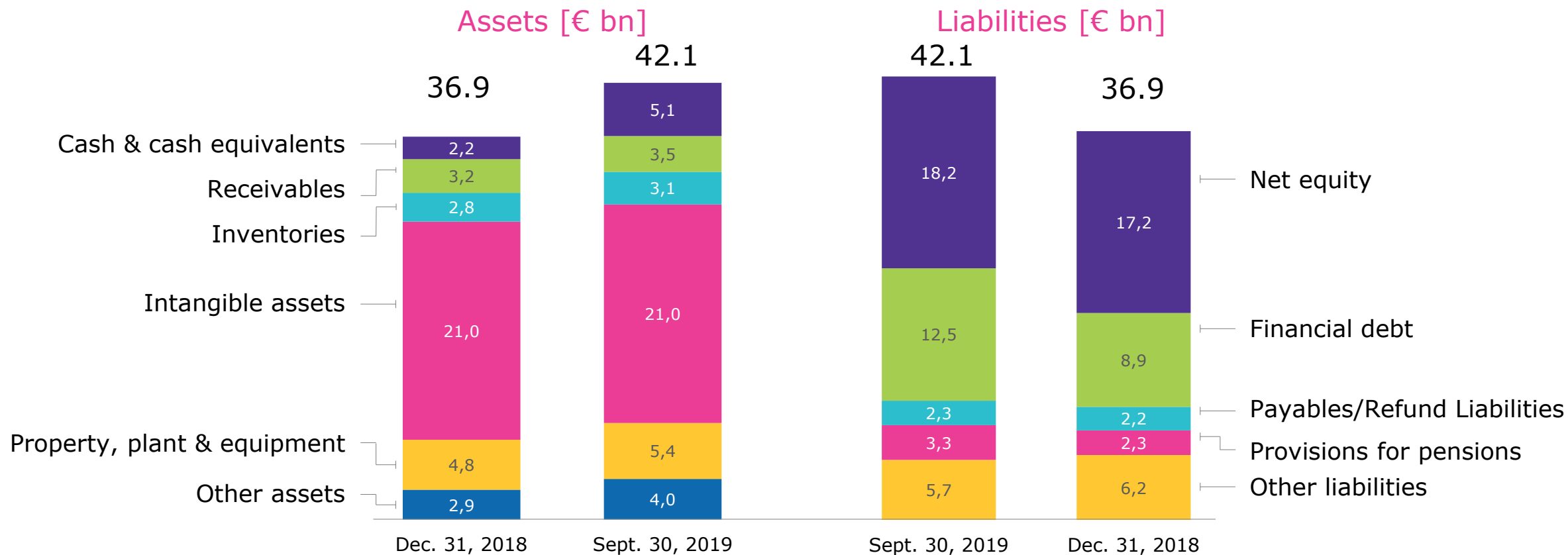


## Comments

- Double-digit decline of Display Solutions: LC back to negative underlying trajectory with high last year base, OLED again strong
- Ongoing softness of Semiconductor Solutions due to market slowdown
- Surface Solutions decline reflects weak demand of automotive market increased industrials portfolio-focus amid Bright Future transformation
- Provisions related to Bright Future program drive admin expense
- Lower R&D reflects strong cost focus and impact of Bright Future program
- EBITDA pre margin decline reflects reduced top line and negative business mix

<sup>1</sup>LY numbers have been modified, due to disclosure changes of adjustments; <sup>2</sup>Thereof IFRS 16 effect with +1.1% (+€2 m); Totals may not add up due to rounding

# Balance sheet – Reflecting bond placements and IFRS 16 adoption



- Higher cash & cash equivalents reflects bond placements and repayment of a due bond (~€2.8 bn)
- Increase in property, plant and equipment mainly due to IFRS 16 adoption
- Other assets reflect temporary investment of cash proceeds from Consumer Health divestment

Totals may not add up due to rounding

- Increase in equity reflects profit after tax (equity ratio of 43.2%)
- Higher financial debt due to bond placements (~€3.5 bn) and IFRS 16 reclassification of lease liabilities
- Increase in provisions for pensions reflects decline in interest rate

# Reported figures

## Reported results

[€m]	Q3 2018	Q3 2019	Δ
EBIT	491	<b>608</b>	23.8%
Financial result	-56	<b>-135</b>	141.1%
Profit before tax	435	<b>473</b>	8.7%
Income tax	-112	<b>-134</b>	19.8%
<i>Effective tax rate</i>	25.7%	<b>28.3%</b>	
Net income <sup>1</sup>	340	<b>343</b>	0.8%
EPS (€)	0.78	<b>0.79</b>	1.3%

## Comments

- Higher EBIT due to strong top-line contribution from LS and HC, cost consciousness, and GSK deferred income
- Increase in financial result reflects higher LTIP<sup>2</sup> provisions, increased interest expense due to Versum financing and interest effect on long term provisions
- Effective tax rate reflects a higher tax reserve for tax audits

<sup>1</sup>From continuing and discontinued operations; <sup>2</sup>LTIP = Long term incentive plan;  
Totals may not add up due to rounding

# Cash flow statement

## Q3 2019 – cash flow statement

[€m]	Q3 2018	Q3 2019	Δ
Profit after tax	345	<b>342</b>	-3
D&A	428	<b>464</b>	37
Changes in provisions	69	<b>81</b>	12
Changes in other assets/liabilities	6	<b>129</b>	123
Other operating activities	-9	<b>9</b>	18
Changes in working capital	-107	<b>-94</b>	13
Operating cash flow	731	<b>931</b>	199
Investing cash flow	-218	<b>-209</b>	9
thereof Capex on PPE	-215	<b>-193</b>	23
Financing cash flow	-287	<b>934</b>	1,221

## Cash flow drivers

- D&A increase mainly due to IFRS 16 reclassification
- Changes in other assets/liabilities driven by Bavencio<sup>®</sup> milestone payment; last years' low base due to neutralization of receivables
- Higher financing cash flow reflects the issuance of new bonds (€2 bn) partially offset by repayment of a due bond (€800 m)

Totals may not add up due to rounding

# Adjustments in Q3 2019

## Adjustments in EBIT

[€m]	Q3 2018		Q3 2019	
	Adjustments	thereof D&A	Adjustments	thereof D&A
Healthcare	9	0	-3	0
Life Science	16	5	20	0
Performance Materials	1	0	16	8
Corporate & Other	23	0	13	0
Total	49	5	47	8

Totals may not add up due to rounding

# ESG

## We are working on ambitious goals

### ENVIRONMENT

#### Climate

We endeavor to reduce direct and indirect emissions to mitigate our impact on the climate.



#### Waste

We consider it fundamental to both prevent and recycle as much of our waste as possible.



#### Water

For us, sustainable water management means not negatively impacting the aquatic ecosystems



### social

#### Product safety

Product safety is one of our top priorities: From safe handling of hazardous substances to ensuring patient safety.



#### Employees

We aim to be an attractive employer, encouraging creativity and development under ideal working conditions.



#### Access to Medicine

We support a variety of initiatives that improve access to health particularly for people in low- and middle-income countries.



### GOVERNANCE

#### Growth & Profit sharing

Our growth results from innovations and acquisitions strengthening our position in important markets, supported by strong cash-flow, long-term margins of >30% and a conservative but reliable dividend.



#### Risk management

We are focusing on a diversified business model: Our 3 sectors have pioneering knowledge to develop products to improve life for patients, further the success of our customers and meet global challenges.



#### Steering

Our core values along with the external regulations lead to business-guiding charters and principles for our responsible governance, documented in our Corporate Responsibility strategy and report.

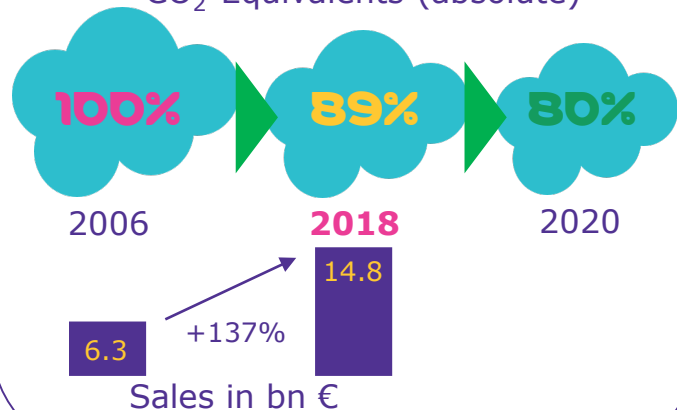


# Emissions, Water, Waste reduced despite growing business

## Emission-Target:

- Growth-independent reduction of Group's greenhouse gas emissions of 20% until 2020 vs. 2006
- Despite sales growth of 137% 2006 vs. 2018 we achieved a 11% reduction of CO<sub>2</sub> equiv.
- We still confirm our goal for 2020 expecting positive impact from latest initiatives, e.g. process optimizations and change to renewable energy

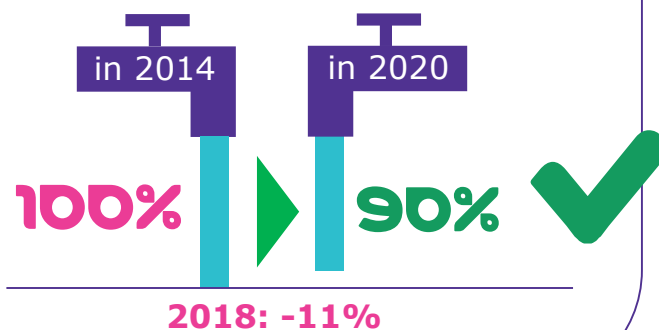
CO<sub>2</sub>-Equivalents (absolute)



## Water-Target:

- At 24 sites with relevant water use in areas of high water stress we aim to cut water consumption by 10% until 2020 vs. 2014
- 2018, we lowered our water consumption by 11% resulting from sustainable water management and re-usage
- All pharmaceutical manufacturing facilities have wastewater treatment plants

Water consumption in water stress areas



## Waste-Target:

- We reduce waste and recycle as much as possible - we aim to reduce the environmental impact of our waste by 5% until 2025 compared to 2016
- The Company Waste Score allows us to compare the amount of waste our sites are producing
- We ensure that raw materials are recycled and that unrecyclable waste is discarded

Merck KGaA, Darmstadt, Germany Waste Score





## External stakeholders value our engagement

In 2018, **Our share was again included in STOXX Global ESG Leaders Index**, a sustainability index that assesses companies based on key environmental, social and governance criteria.

**STOXX**



Merck KGaA, Darmstadt, Germany was confirmed as a constituent of the **Ethibel Sustainability Index (ESI) Excellence Europe** in 2018, calculated and managed by Standard & Poor's.

We were ranked on **4th place at Vigeo Eiris** among its peer companies and is a **Euronext Vigeo Europe 120** member since 2015, including companies with high performance in 38 sustainability drivers.



We received **Gold status in 2019**, among the **top 1% of companies**.

**EcoVadis** examines 45,000 suppliers from 150 countries. The rating focuses is highly valued by customers and suppliers.

**Since 2008**, Our shares have been included in the **FTSE4Good Index**, measuring the performance of companies demonstrating strong ESG practices



access to  
medicine  
Index

In the **2018 Access to Medicine Index** we maintained **4th place** (9th in 2012, 6th in 2014 and 4th place in 2016). The ranking appreciates us supporting low and middle income countries.

In 2018, **Oekom** research AG gave us a "B-" rating which means we have once more achieved **prime status**.



Participation in CDP (formerly Carbon Disclosure Project) since 2008.

**CDP Climate:** In 2018, we scored "C" (2017: B).

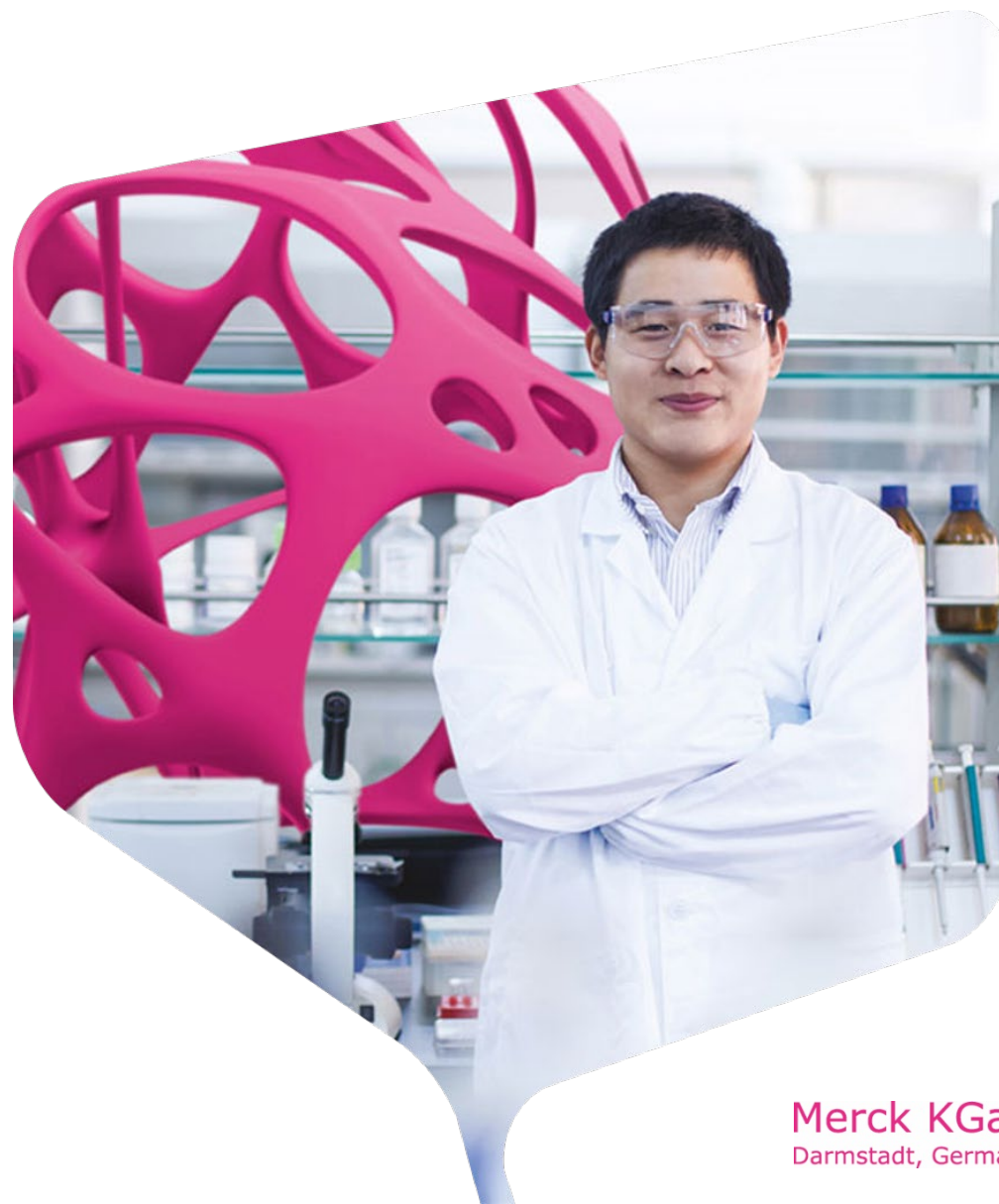
**CDP Water:** In 2018 we received a "B-" (2017: B).

2018, **Sustainalytics** awarded us 79 out of 100 points, putting us among the **leading pharmaceutical companies:** high marks in CG, community outreach, and environmental performance.



# Financial calendar

Date	Event
March 5, 2020	FY 2019 Earnings release
April 24, 2020	Annual General Meeting
May 14, 2020	Q1 2020 Earnings release
August 6, 2020	Q2 2020 Earnings release



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