



# MERCK KGAA, DARMSTADT, GERMANY— Q2 2019 ROADSHOW

Investor Relations

August 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



### Healthcare

#### 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



### Life Science

#### Leading life science company

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



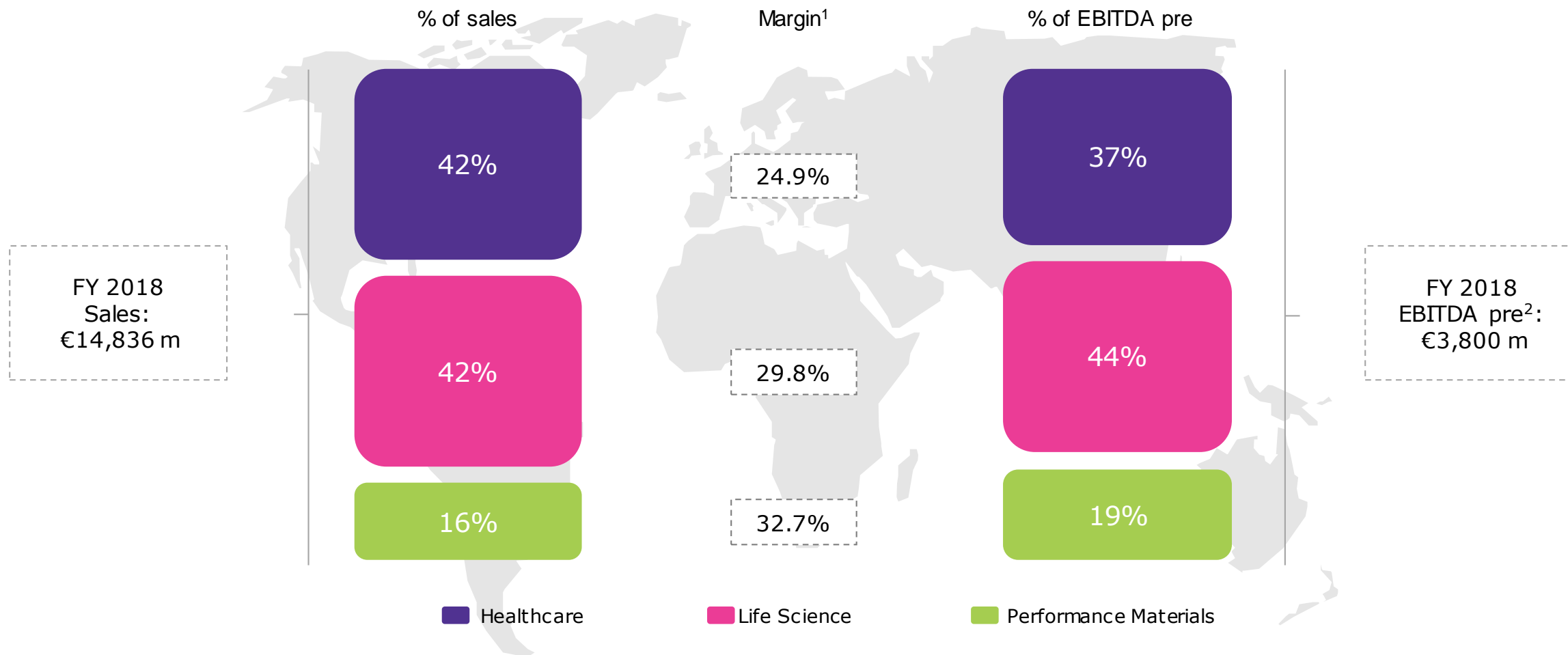
### Performance Materials

#### 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



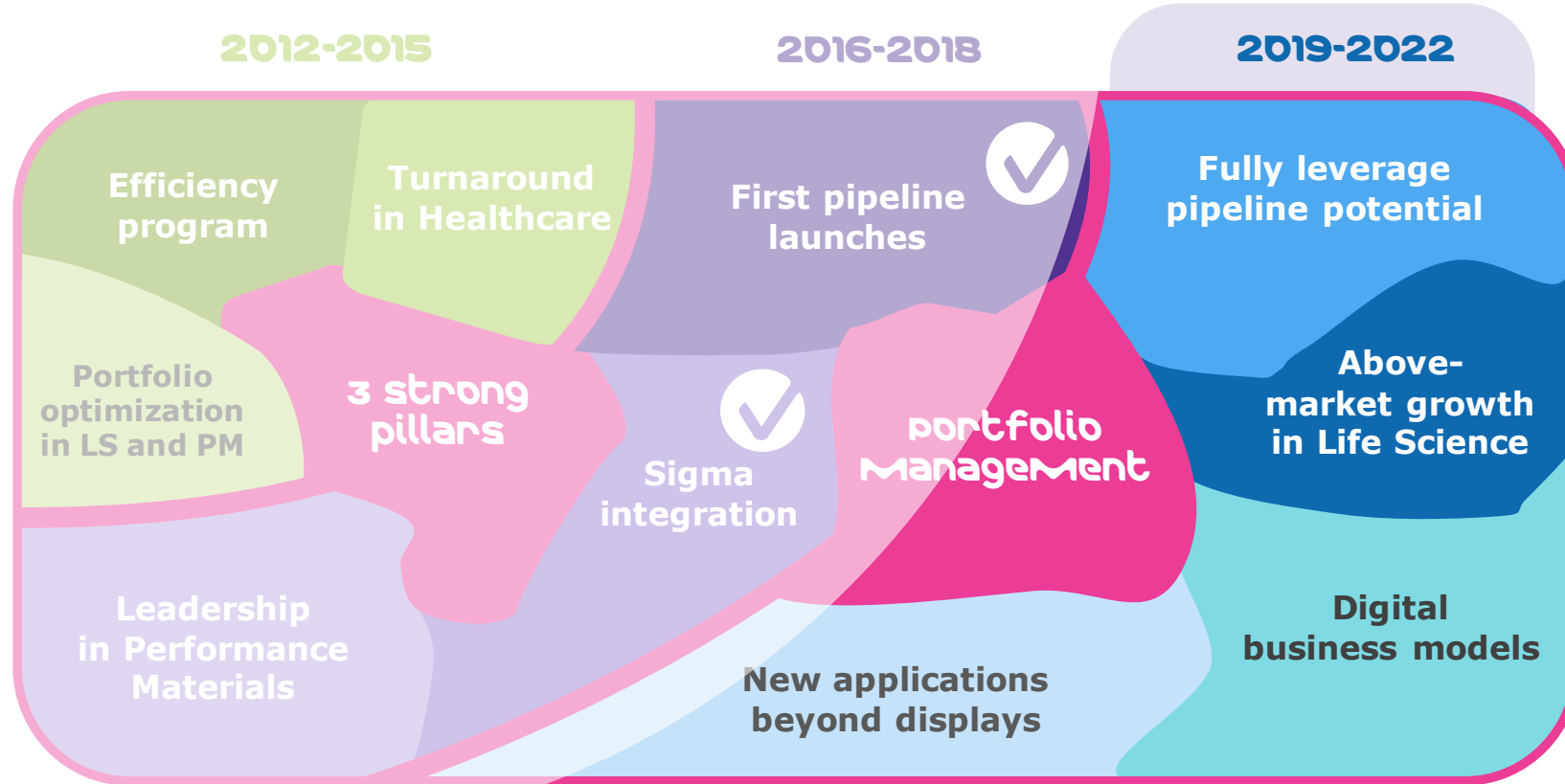
<sup>1</sup>EBITDA pre margin in % of net sales; <sup>2</sup>Including Corporate/Others (-€382 m)



## 02 TRANSFORMING THE COMPANY

# Group

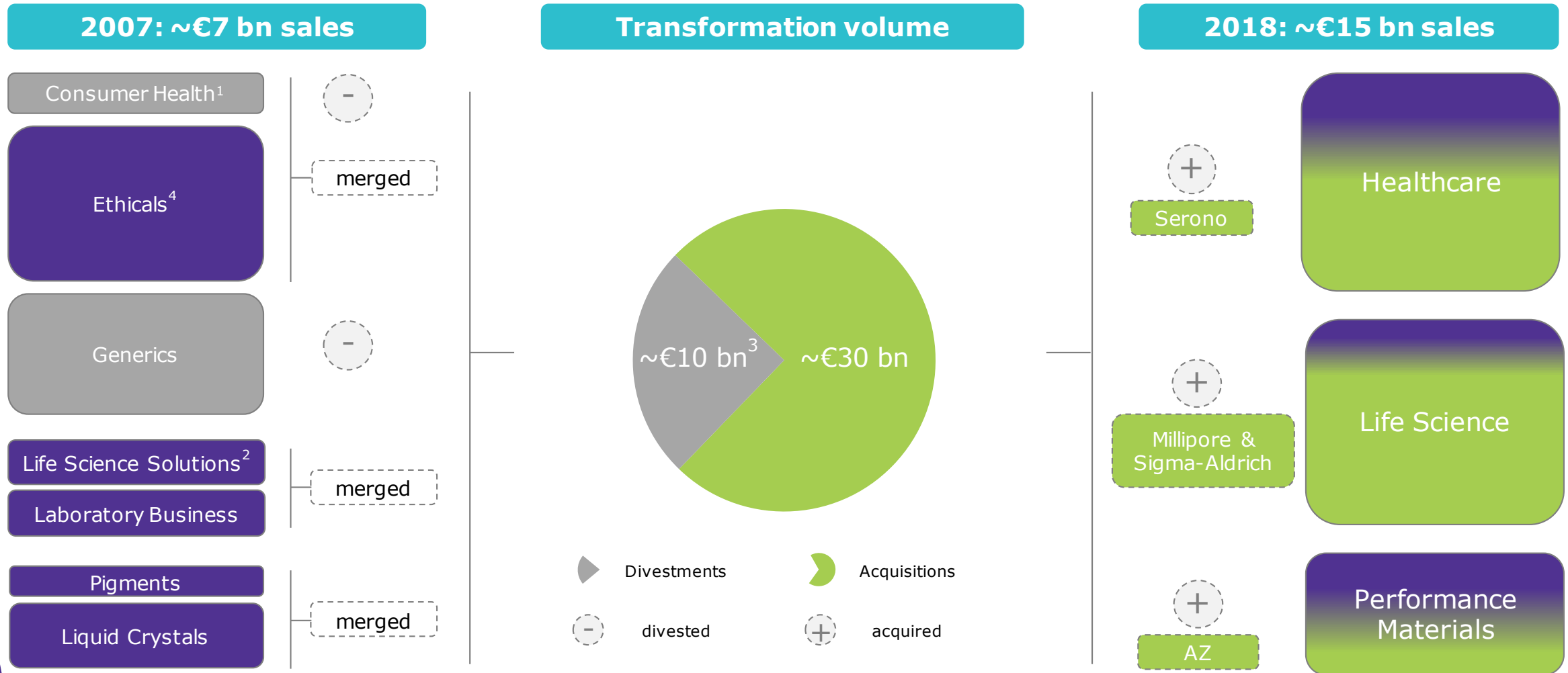
## Strategic roadmap 2016-2022



2019 – 2022 “Unite for growth”

## Group

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

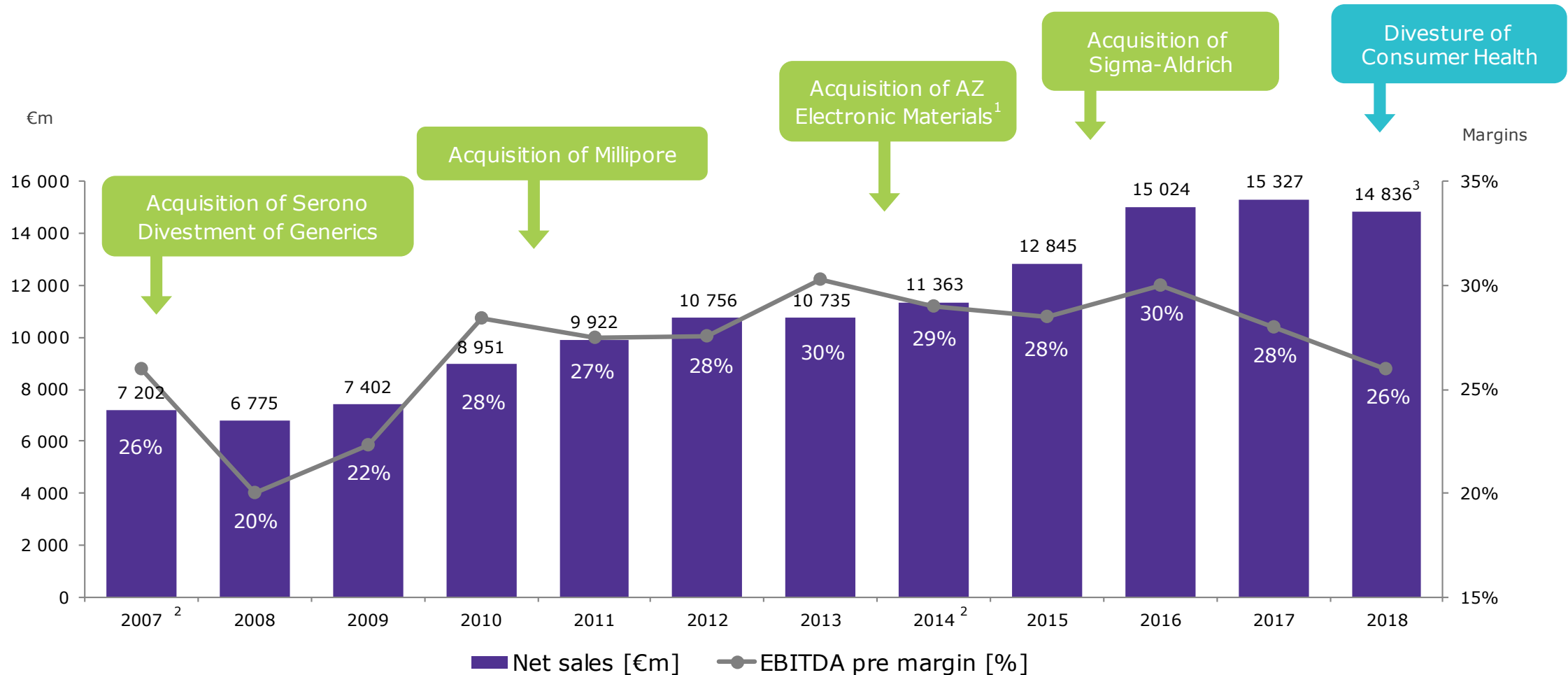


<sup>1</sup>Closing of sale of Consumer Health at a cash purchase price of € 3.4 billion completed as of December 1 2018; <sup>2</sup>Excluding "Crop Bioscience", which was divested;

<sup>3</sup>Proforma divestment volume includes cash proceeds for Consumer Health <sup>4</sup>Excluding "Theramex", which was divested;

## Group

# Continue to transform to a science and technology focused company



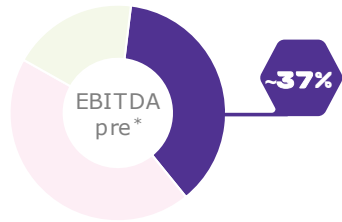
<sup>1</sup>Included since 2 May 2014; <sup>2</sup>2007 and 2014 EBITDA pre margin adjusted for comparability; <sup>3</sup>2018 net sales reflect Consumer Health divestiture (reduction of ~€1 bn net sales p.a.)

# Group

## Clear set of priority goals



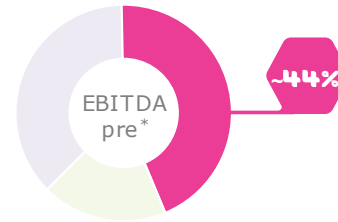
### Healthcare



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



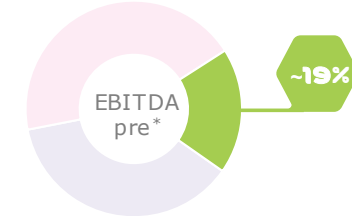
### Life science



- 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
- 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

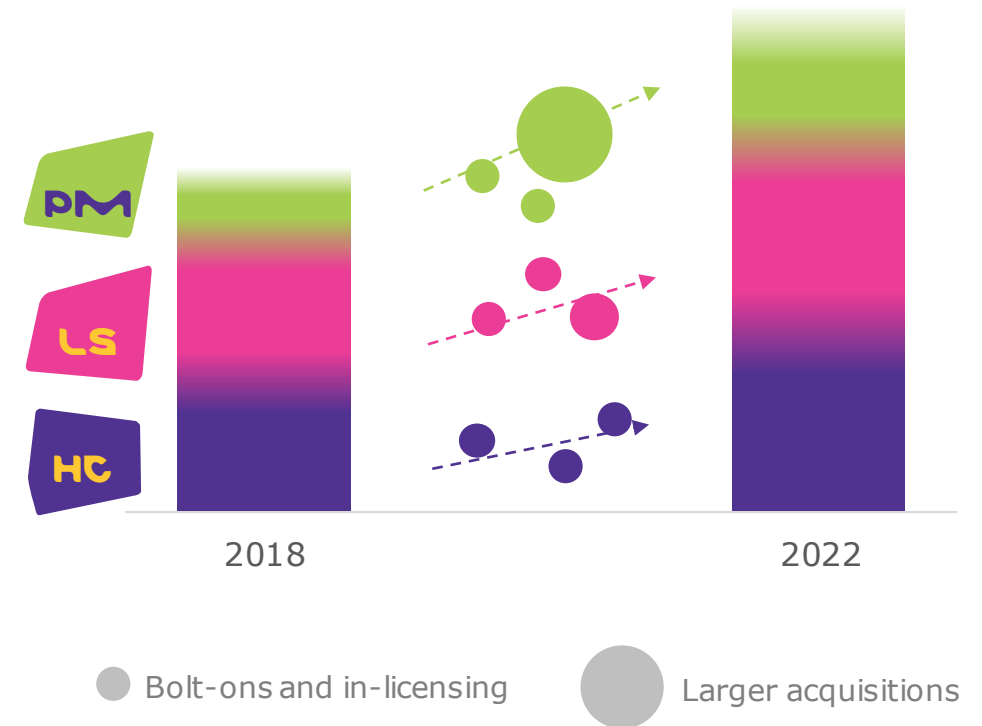
- Market attractiveness & capabilities
- Best strategic owner
- Risk profile

### 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's KGaA, Darmstadt, Germany sales and earnings drivers



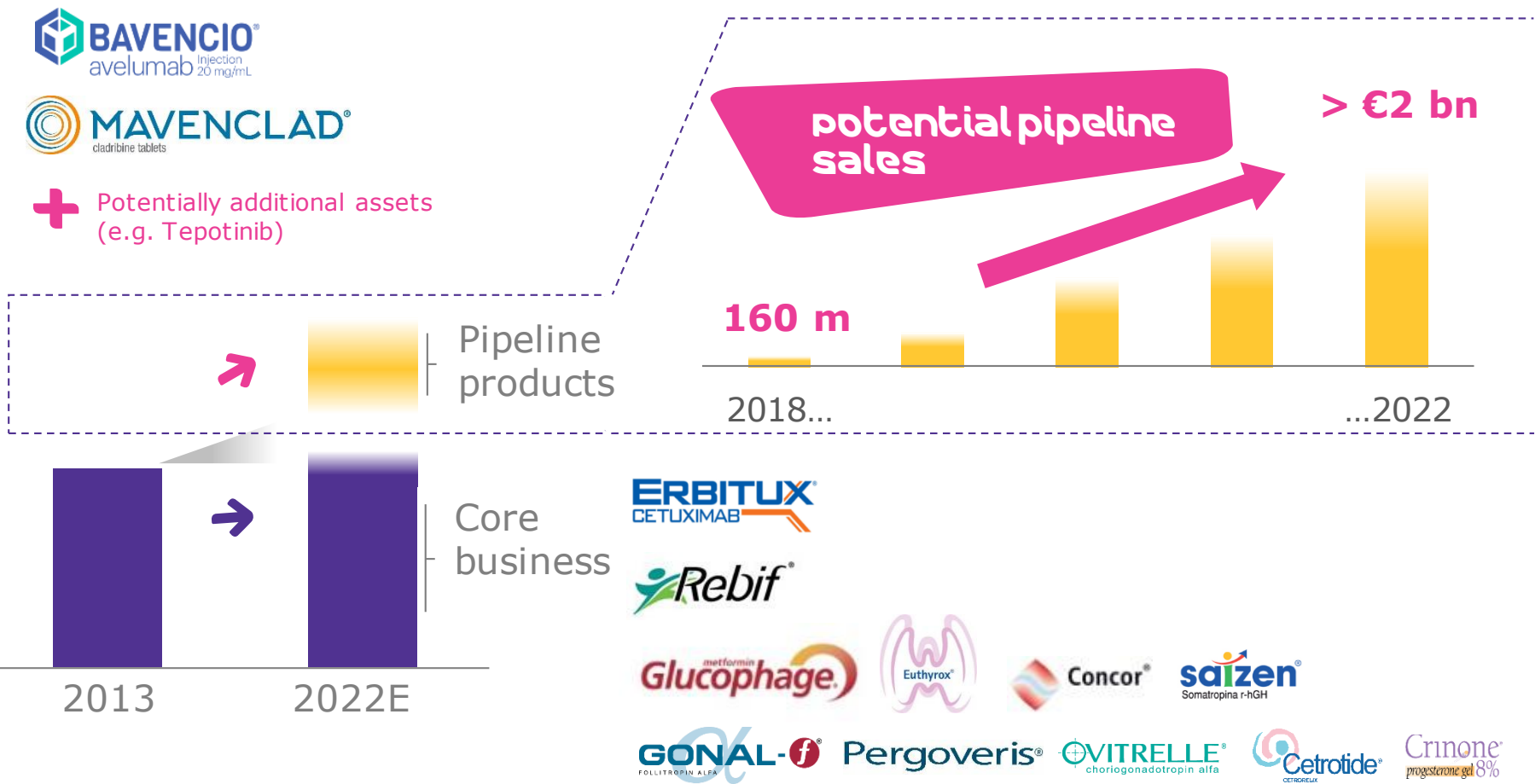


# Healthcare

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

Focus on the pipeline

Deliver organic growth



# Healthcare

## Mavenclad® and Bavencio® are ramping up nicely

### Global launches gaining traction ...

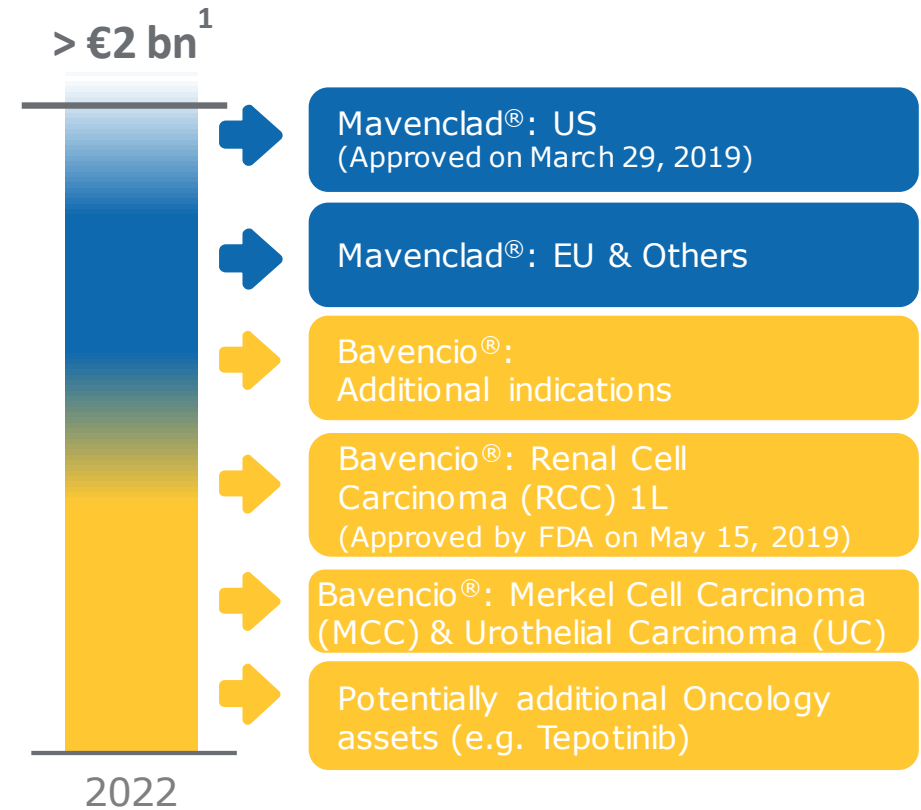
MAVENCLOUD®

- ✓ **Approved in 60 countries** since 2017 (incl. USA, Canada, EU, Australia and Switzerland)
- ✓ **Reimbursed in approx. 50% of markets**, payer negotiations ongoing
- ✓ **Global peak sales:** 1 – 1.4 bn €  
**2019 sales:** up to mid-triple-digit m €

BAVENCIO®

- ✓ **Approved:** Merkel cell carcinoma (US, EU, JP) and urothelial carcinoma (US)
- ➔ **Regulatory submission on track:** Filing validated by EMA, filing submitted in Japan
- ➔ **Upcoming Ph III read outs:** Gastric 1L, Urothelial 1L and NSCLC 1L

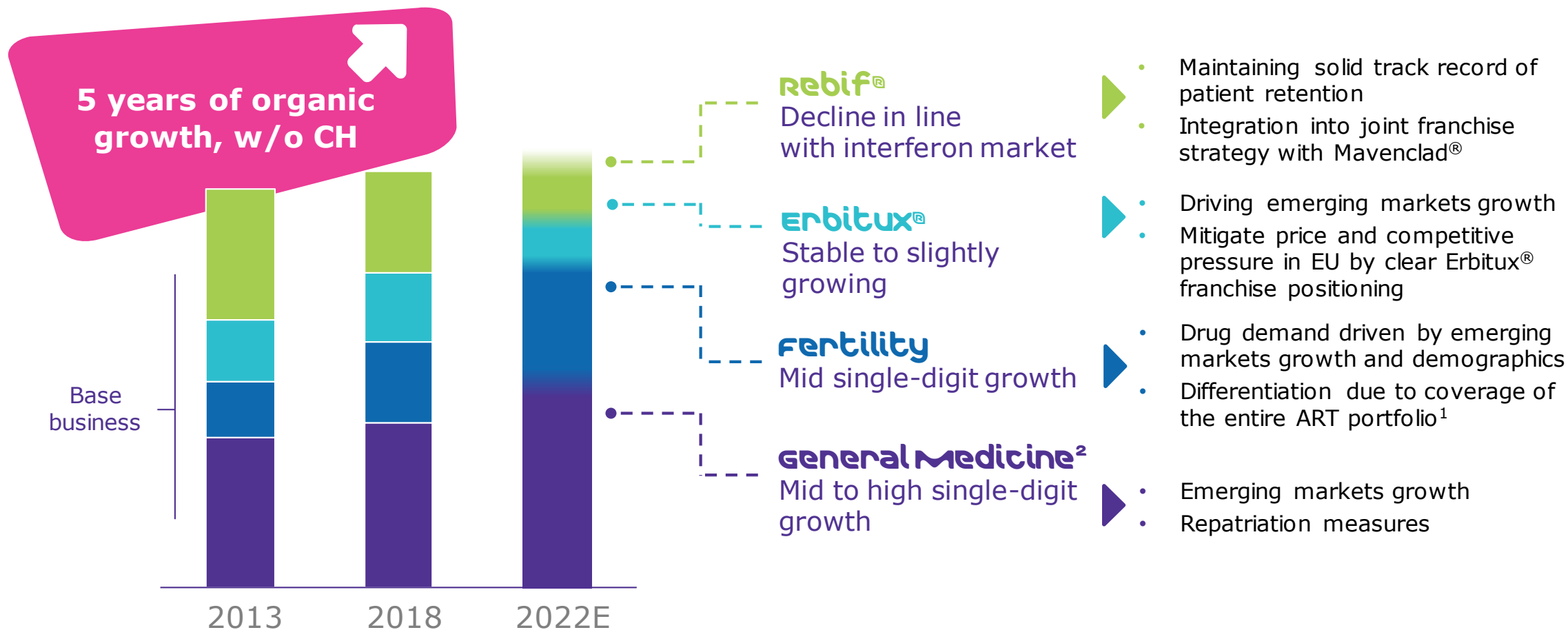
### ... and supporting €2 bn pipeline sales ambition



<sup>1</sup> Visualisation for illustrative purposes; Acronyms: FDA = US Food & Drug Administration, EMA = European Medical Agency, NSCLC = Non-small Cell Lung Cancer

# Ambition remains to keep core business sales organically stable from now until 2022

## Healthcare core business net sales until 2022

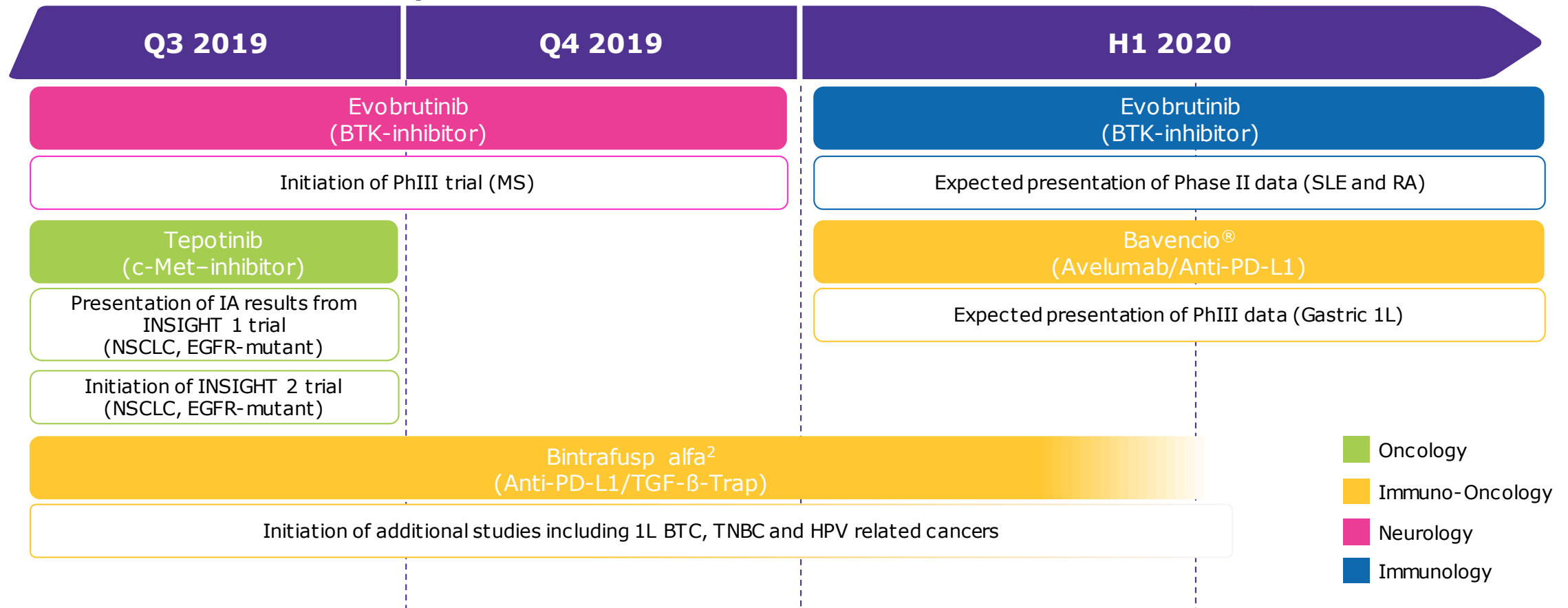


<sup>1</sup>ART: Assisted Reproductive Technology; <sup>2</sup>includes General Medicine, CardioMetabolic Care (CMC), Endocrinology & Allergopharma

# Healthcare

## A year of continued pipeline development ahead<sup>1</sup>

 **Capital Markets Day  
September 11**



<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, FDA = US Food & Drug Administration, IA = Interim Analysis, MS = Multiple Sclerosis, NSCLC = Non-small Cell Lung Cancer, RA = Rheumatoid Arthritis, SLE = Systemic Lupus Erythematosus, TNBC = Triple-Negative Breast Cancer



## **LIFE SCIENCE**

Focus on profitable growth

## Life Science

### Serving customers across the highly attractive life science industry

#### RESEARCH

~€45-50 bn

Low single-digit growth



Academic and government institutions

Biopharma R&D

Industry R&D

#### PROCESS

~€50 bn

High single-digit growth



Pharmaceutical companies

Small biotech

Contract manufacturing organizations

#### APPLIED

~€55 bn

Mid single-digit growth



Diagnostic manufacturers

Clinical testing labs

Food & Beverage manufacturers

~€150 bn\* market growing at ~4% CAGR

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

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

- Volume growth from
  - Population growth
  - Rise in quality standards
  - Increased testing needs

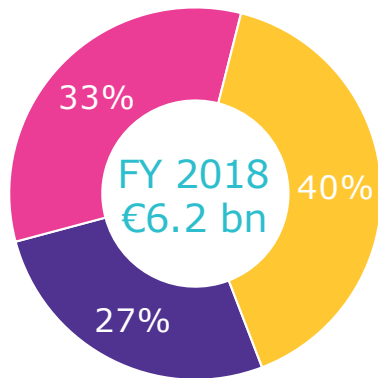
\*Source: Merck KGaA, Darmstadt, Germany estimate 2018

# Life Science

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

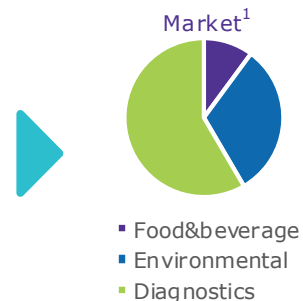
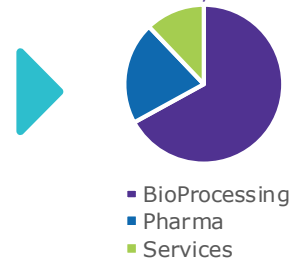
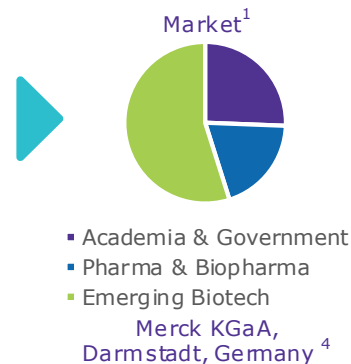
Merck KGaA, Darmstadt, Germany  
Life Science

Research Solutions  
Low single digit growth



Process Solutions  
High single digit growth

Applied Solutions  
Mid single digit growth



### 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

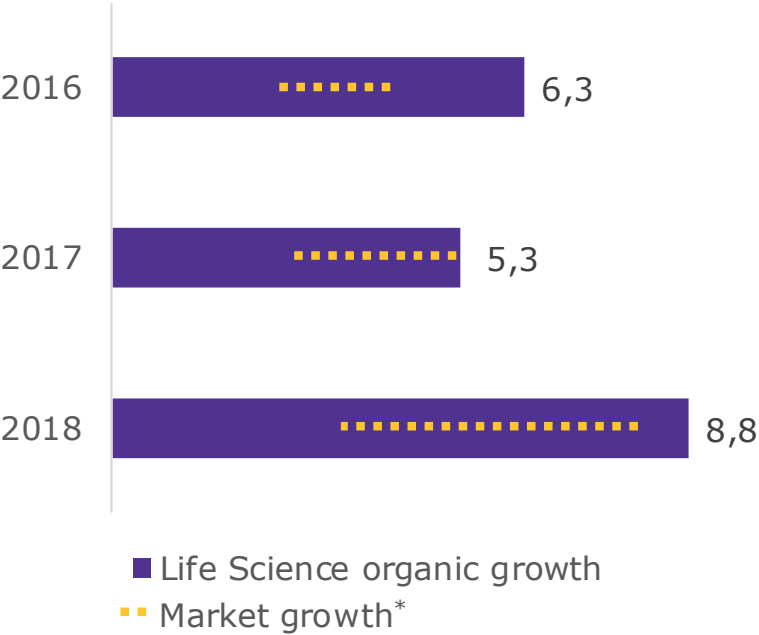
<sup>1</sup>Source: Merck KGaA, Darmstadt, Germany Factbook; <sup>2</sup>Source: PhRMA; <sup>3</sup>CRO = Contract Research Organization; <sup>4</sup>Indicative only; <sup>5</sup>mAbs = monoclonal antibodies; <sup>6</sup>Source: EvaluatePharma September 2018

# Life Science

## Market leading growth and profitability

### Consistent above-market growth

Organic sales growth vs market\* [% YoY]



**Ambition to grow above market through to 2022**

### Key industry player

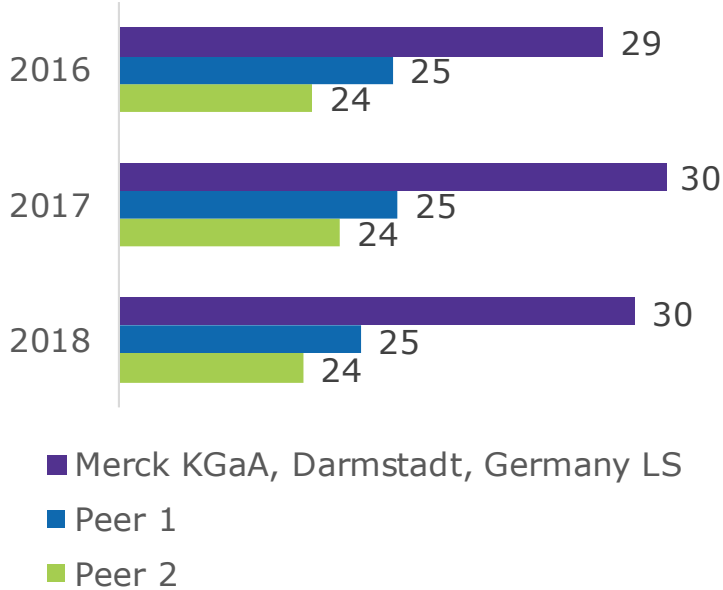
Life Science net sales [€m]



**Secure leading market position**

### Superior profitability

EBITDA pre margin [%]



**Maintaining industry-leading margin**

\*Based on integrated life science peers' performance, analyst reports and Laboratory Products Association report

## Portfolio and focus are key drivers of above-market growth

### Life Science net sales organic CAGR 2015-2018\*

#### Out-Performance

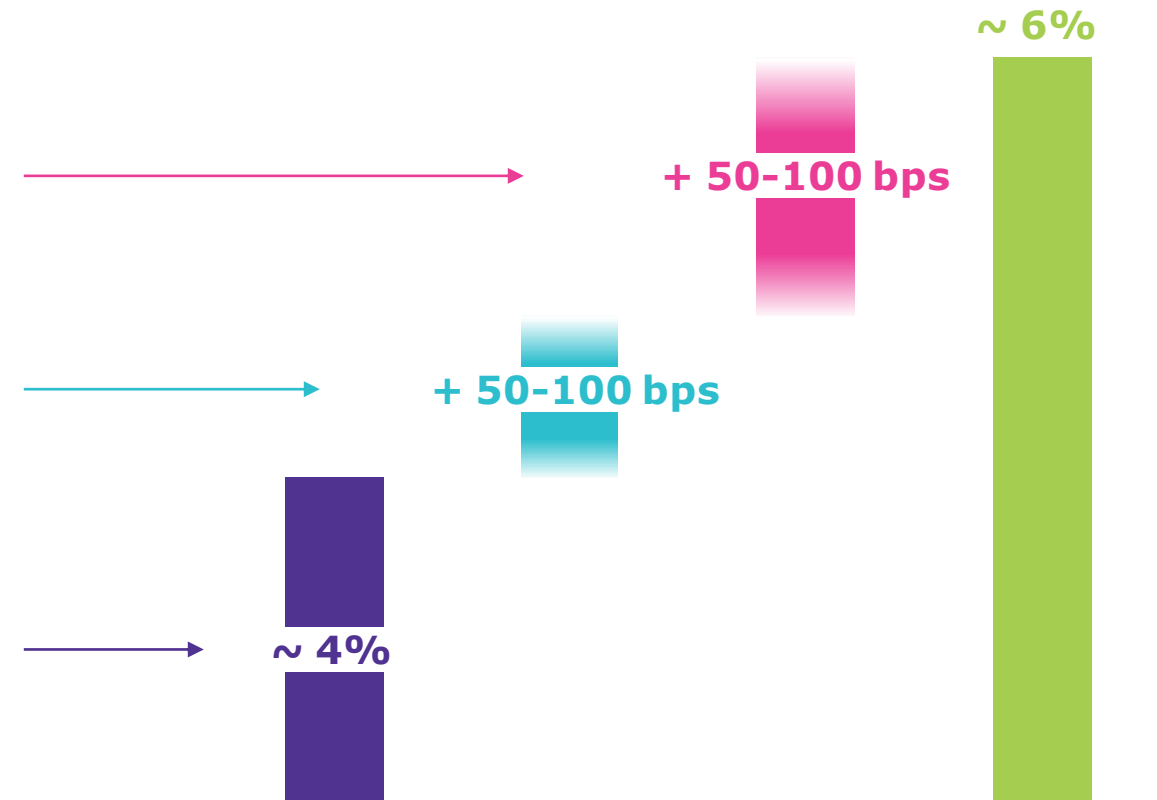
- We grow within the relevant market segments
- Broad range of differentiated products and services
- E-commerce platform

#### Portfolio advantage

- We focus on higher-growth segments of the market
- E.g. bioprocessing, lab water, diagnostics offerings

#### Life science market

- The life science industry grows rapidly and develops dynamically



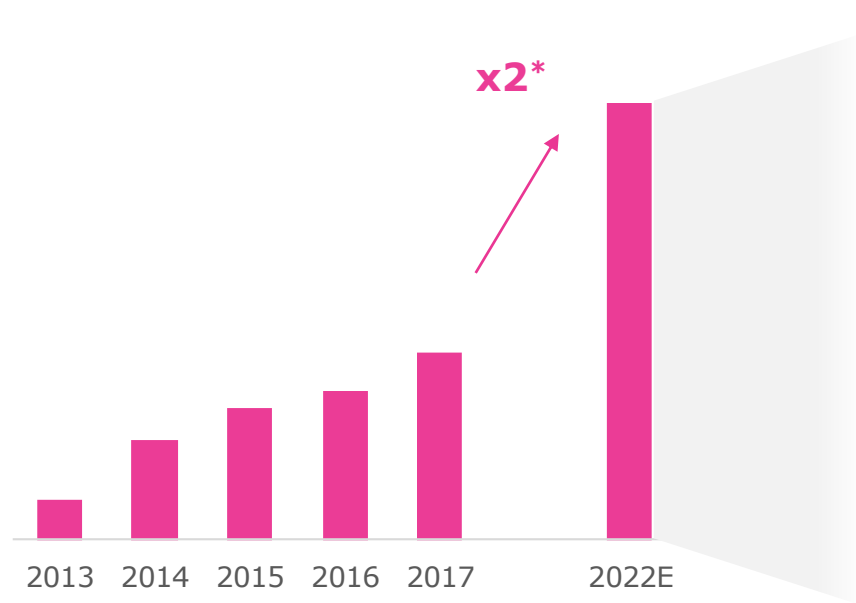
\*Indication

## Life Science

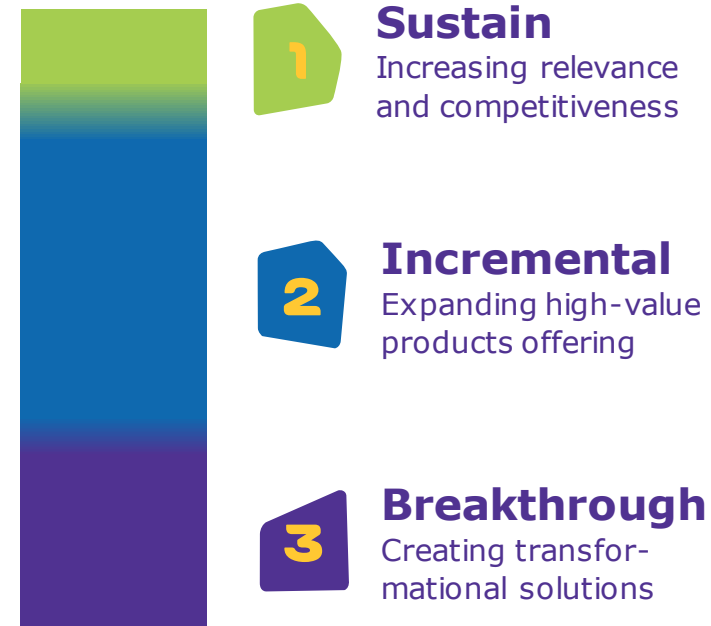
# Innovation underpins Life Science's position as growth engine for us

### Products launched after 2013

% of total net sales



### Categories of innovation



### Industry trends

Customer requirements, scientific standards and therapies are evolving continuously

Our strong and innovative portfolio ensures well-balanced strategic growth

**Innovation pipeline is key to differentiate in the market in order to sustain Life Science's above-market growth trajectory**

\*Indication



05

## **PERFORMANCE MATERIALS**

Maintaining leadership and innovation

# Performance Materials

## A leading player in the electronic materials market

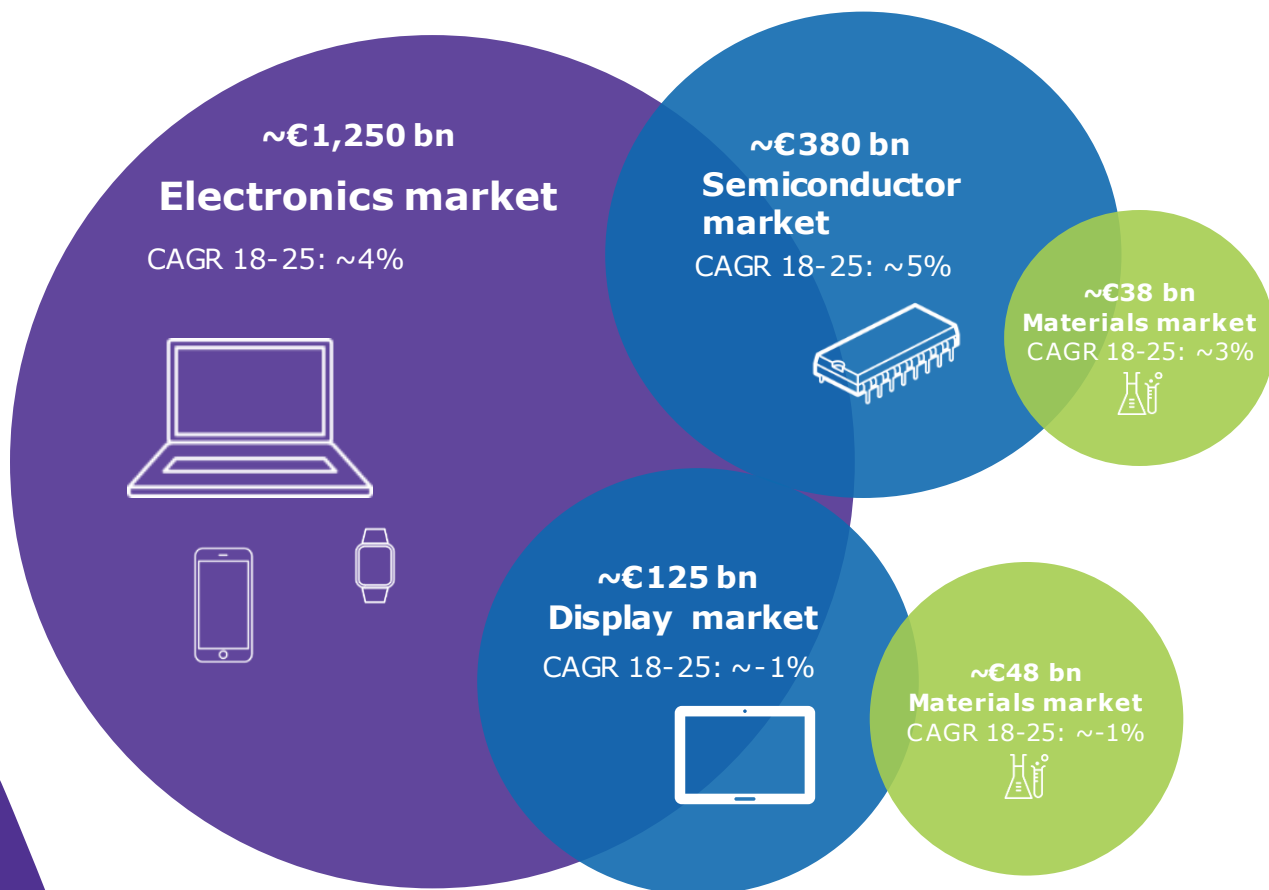
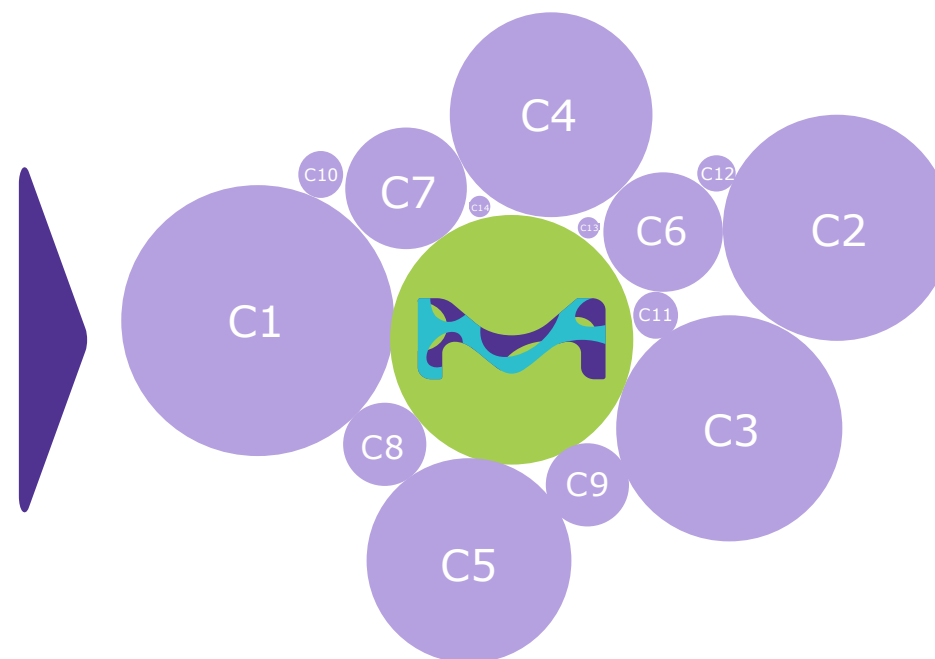


Illustration of the electronics market and thereof its selected sub markets

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



<sup>1</sup>Bubble size in competitive landscape illustrates share of semiconductor and display material sales of indicated competitors (C1 – C14)

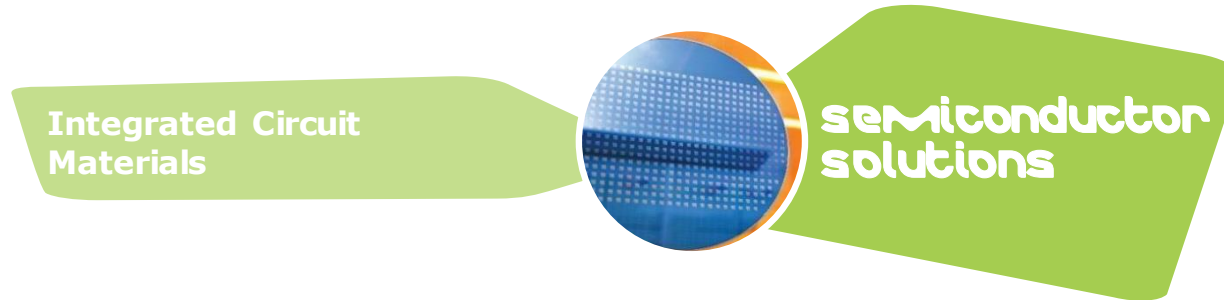
# Performance Materials

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

### Business allocation within Performance Materials

% sales FY2018

### Products



- Dielectrics, colloidal silica, lithography materials, yield enhancers, edge-bead removers
- Polyimide raw materials and printing materials



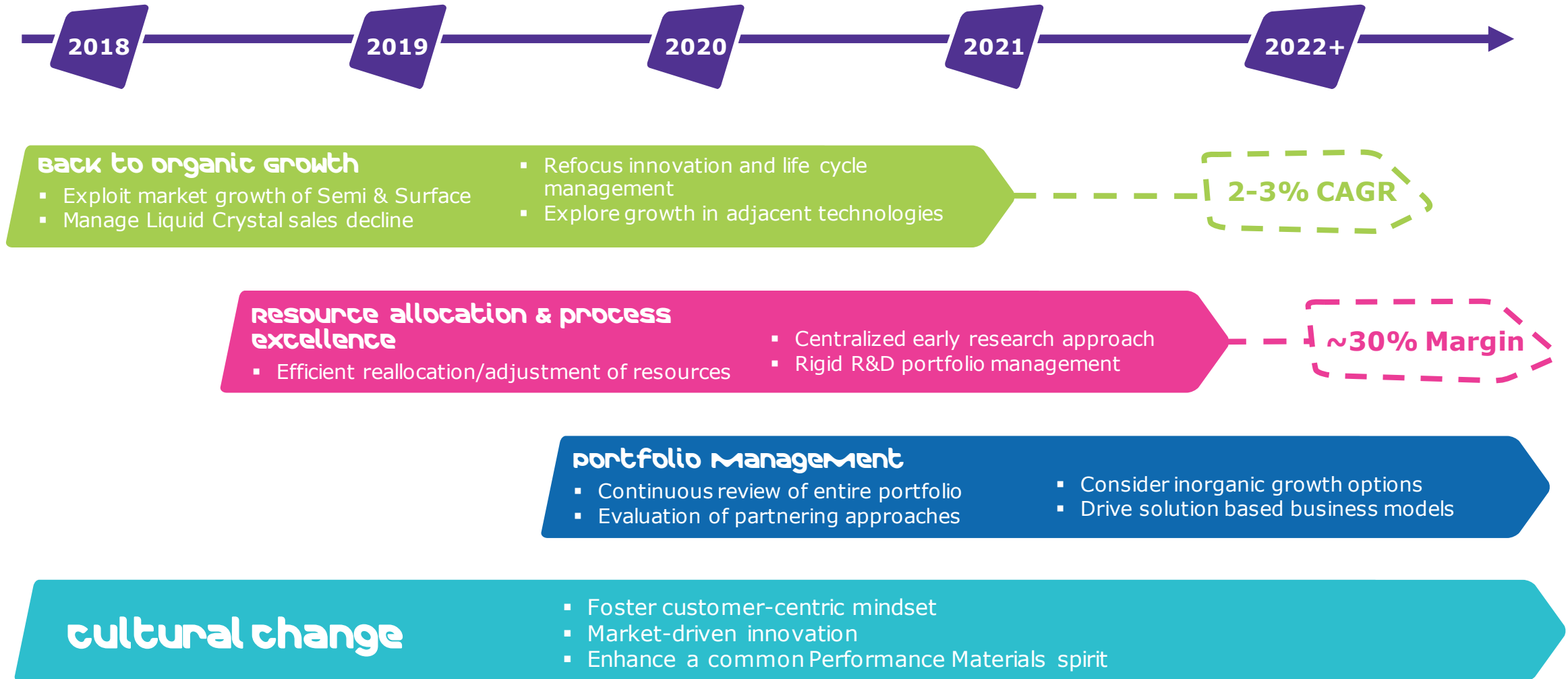
- Liquid crystals (LC) and photoresists for TVs, smartphones and tablet computers
- Other display and non-display applications (e.g. LC Windows)
- Organic and inorganic light emitting diodes



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

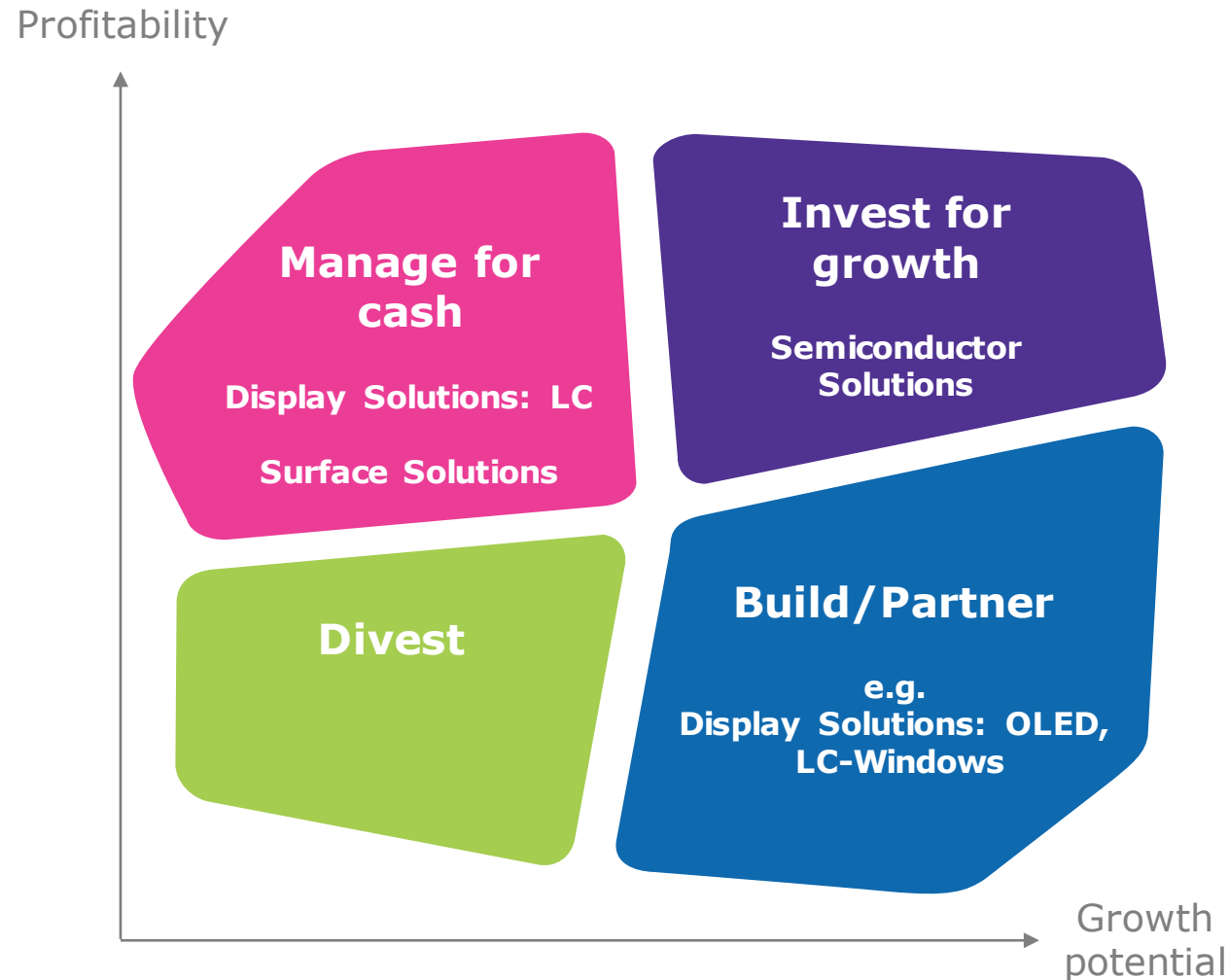
## "Bright Future"

### 5-year transformation program drives long-term performance



## 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

# 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

- Closing of Chilworth site expected during September 2019



#### 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**

#### INTERMOLECULAR®

- 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**

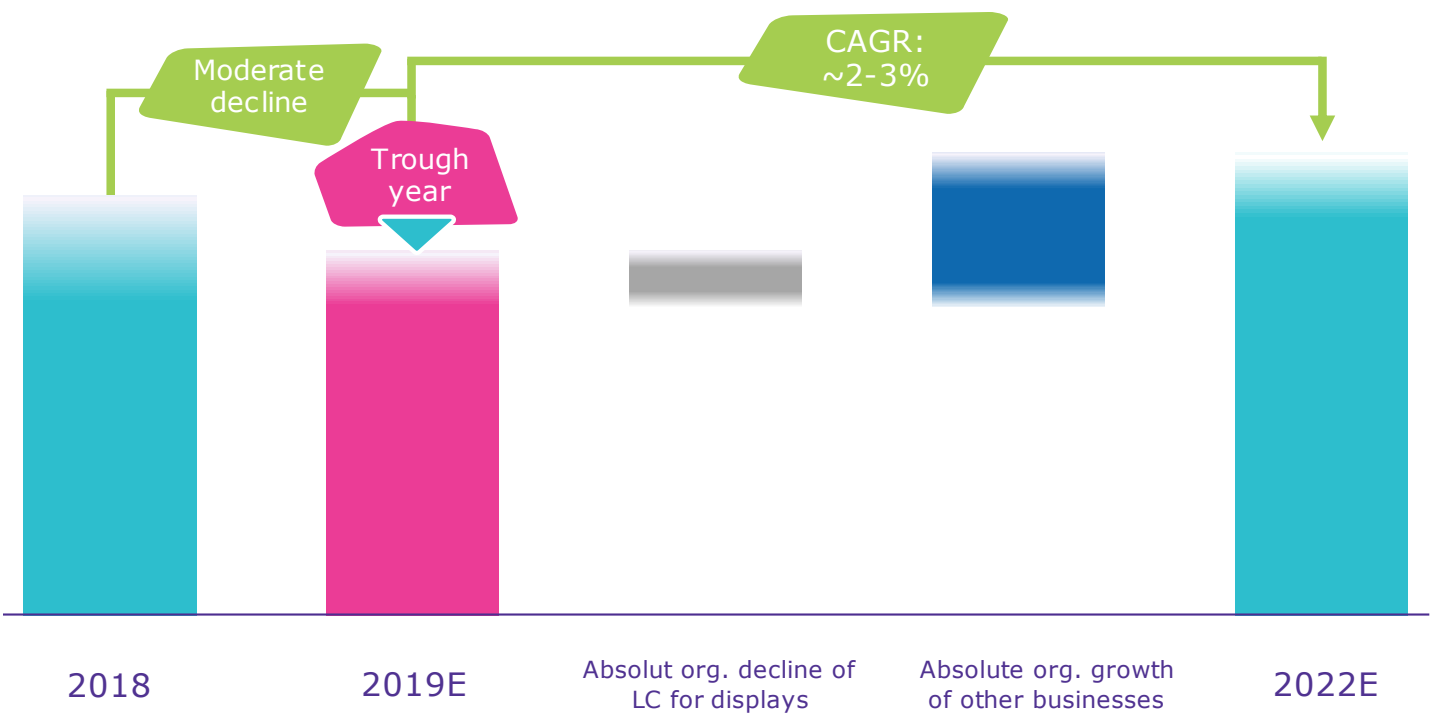


**Both transactions are expected to close in H2 2019**

**Merck KGaA**  
Darmstadt, Germany

# Performance Materials will return to sales growth after 2019

Performance Materials sales development, in €m



2019-2022 sales growth trajectory



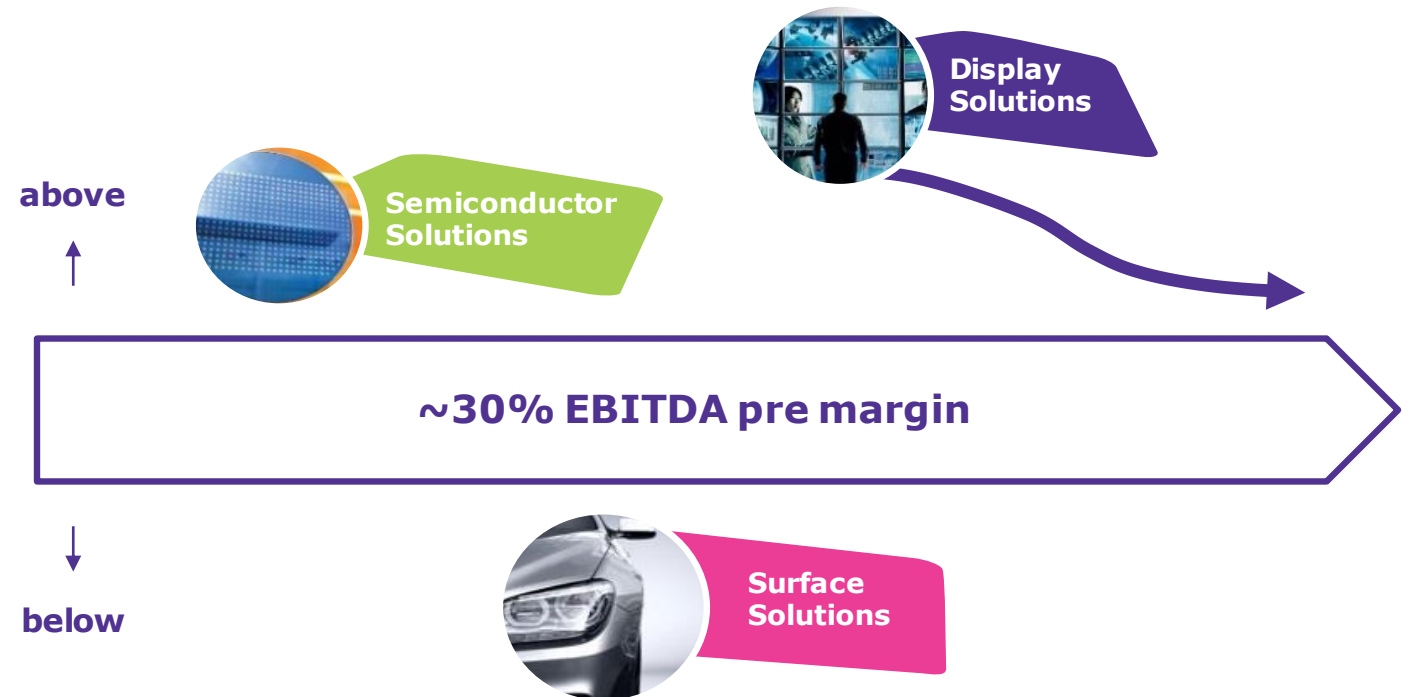
**After 2019 sales growth of Semiconductor, OLED and Photoresists will overcompensate the decline of Liquid Crystals for displays**

# Margins of PM will remain around 30% in the long-run

## profitability indication

- Display Solutions will adjust towards PM average margin
- Bottom-line management to support margin
- Strong FX exposure will cause fluctuations

EBITDA pre margin indication by business





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 7% to 8% 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: 1.12-1.16)



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

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)

- Healthcare underlying margins negatively impacted by product mix

NEW

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<sup>1</sup>

### Net sales:

Organic +3% to +5% YoY

FX ~ 0% to +2% YoY

~ € 15.3 – 15.9 bn

### EBITDA pre:

Organic +10% to +13% YoY<sup>2</sup>

FX 0% to +2% YoY

~ € 4,150 – 4,350 m<sup>3</sup>

### EPS pre:

~ € 5.30 – 5.65

<sup>1</sup>Merck KGaA, Darmstadt, Germany stand-alone, i.e. without acquisition of Versum Materials and Intermolecular Inc.; <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>CO guidance 2019: -€420 m to -€480 m (assuming FX adjusted CO costs -€390 m to -€400 m)



# Group

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



### Healthcare

#### Net sales

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

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

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



### Life Science

#### Net sales

- Organic growth +7% to +8%, above expected market growth
- Main growth driver Process Solutions but all businesses contributing

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

- Organic +11% to +13% YoY
- FX +0% to +2% YoY
- ~ €2,020 – 2,120 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 Semiconductor, return to growth in 2020

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

- Organic -9% to -13% YoY
- FX +1% to +4% YoY
- ~ €685 – 745 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

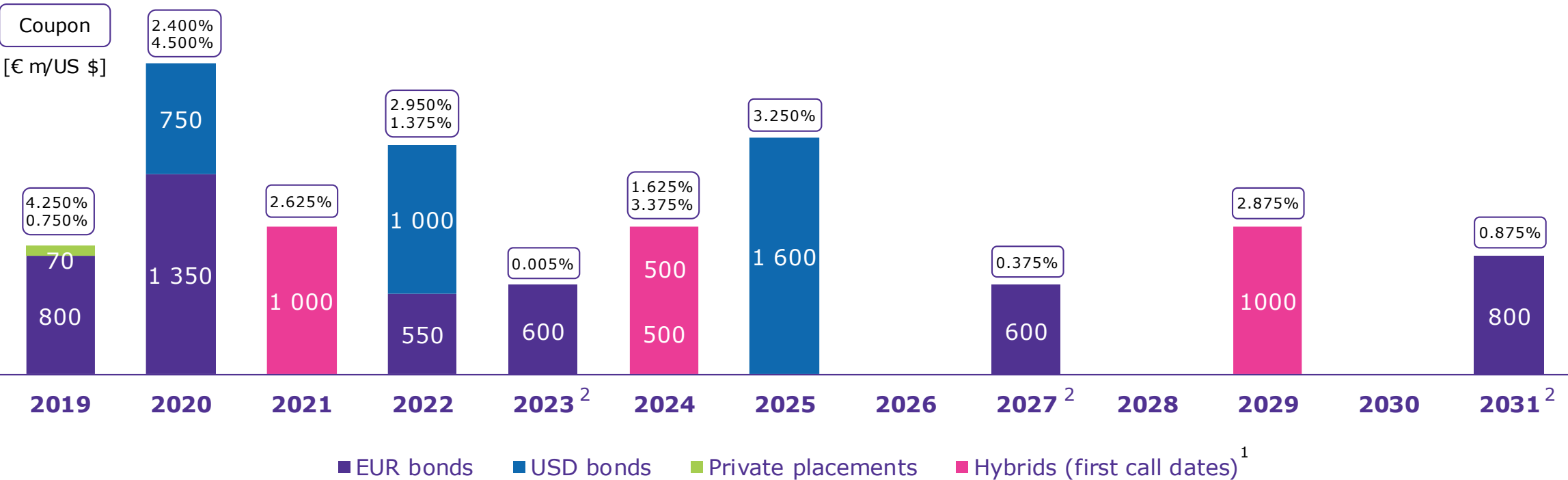
Corporate & Other EBITDA pre <sup>1</sup>	~ -€420 – -480 m
Interest result <sup>2</sup>	~ -€260 – -280 m
Effective tax rate	~ 24% to 26%
Capex on PPE	~ €1.1 bn – 1.2 bn
Hedging/USD assumption	<b>FY 2019 hedge ratio ~60% at EUR/USD ~1.20</b>
2019 Ø EUR/USD assumption	~ 1.12 – 1.16

<sup>1</sup>CO guidance 2019: -€420 m to -€480 m (assuming FX adjusted CO costs -€390 m to -€400 m);

<sup>2</sup>Interest result includes Versum Materials financing expenses

# Maturity profile reflects Sigma-Aldrich and Versum financing transactions

Maturity profile as of June 30, 2019



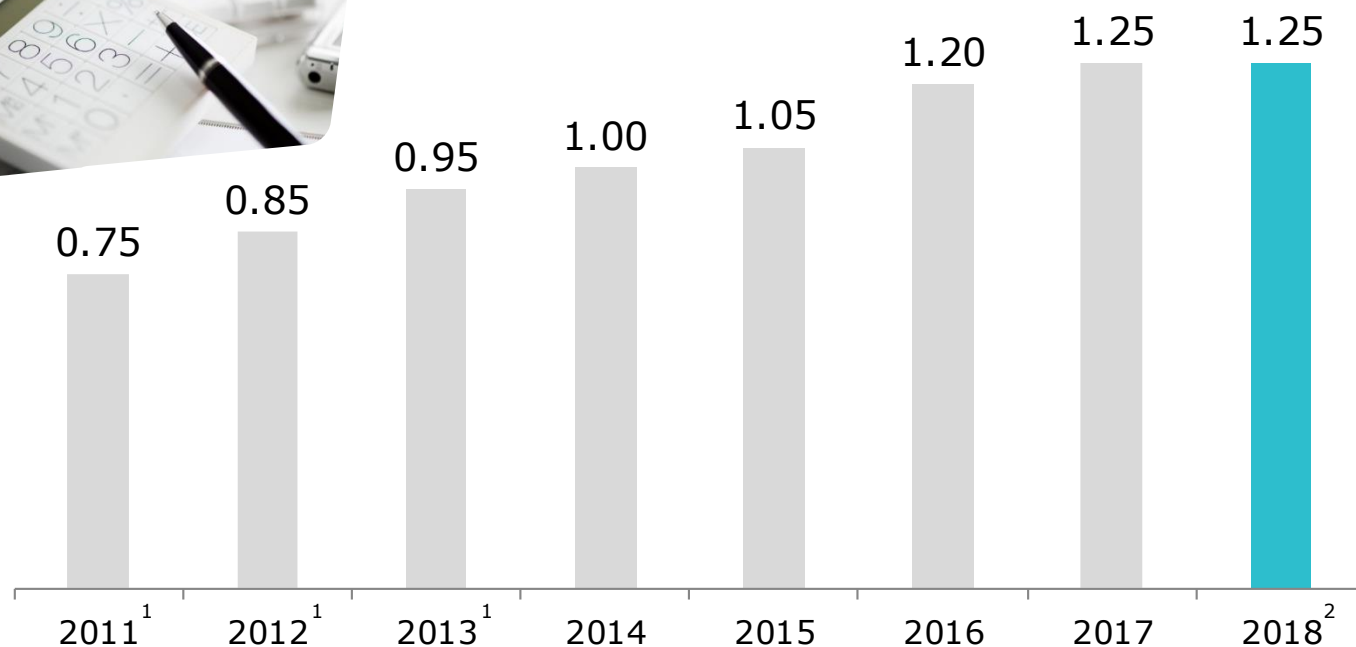
Balanced maturity profile in upcoming years avoids refinancing risks and provides sufficient flexibility for deleveraging

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

<sup>2</sup>EUR bonds had been placed at July 1<sup>st</sup>, 2019

# 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

# Healthcare pipeline

August 5, 2019

## Phase I

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

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

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

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

**M6620 (VX-970)**  
**ATR inhibitor**  
Solid tumors

**M7583**  
**BTK inhibitor**  
Hematological malignancies

**M8891**  
**MetAP2 inhibitor**  
Solid tumors

**avelumab**  
**anti-PD-L1 mAb**  
Solid tumors

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

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

**M5049**  
**Immune receptor inhibitor**  
Immunology

**M6495**  
**anti-ADAMTS-5 nanobody**  
Osteoarthritis

**M5717**  
**PeEF2 inhibitor**  
Malaria

## Phase II

**tepotinib**  
**MET kinase inhibitor**  
Non-small cell lung cancer

**tepotinib**  
**MET kinase inhibitor**  
Hepatocellular cancer

**M3814**  
**DNA-PK inhibitor**  
Rectal cancer

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

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

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

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

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

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

**bintrafusp alfa**  
**TGFbeta trap/anti-PD-L1**  
Non-small cell lung cancer 1L

**bintrafusp alfa**  
**TGFbeta trap/anti-PD-L1**  
Non-small cell lung cancer 1L/2L

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

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

**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**  
Gastric cancer 1L-M

**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<sup>5</sup>

## Registration

**avelumab**  
**anti-PD-L1 mAb**  
Renal cell cancer 1L<sup>6</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, abtuzumab 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> Enrollment anticipated in Q3 2019. <sup>6</sup> As announced on May 15 2019, the US Food and Drug Administration (FDA) has approved avelumab in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC) and as announced on March 8 2019, the European Medicines Agency (EMA) validated for review the Type II variation application for avelumab in combination with axitinib for patients with advanced RCC.

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.

Merck KGaA  
Darmstadt, Germany

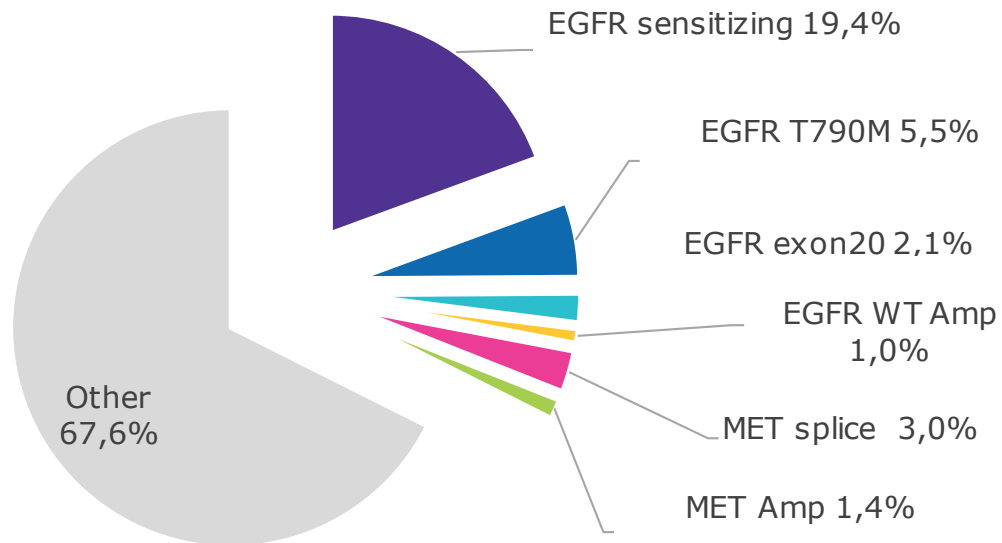
## Tepotinib: Significant unmet need

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

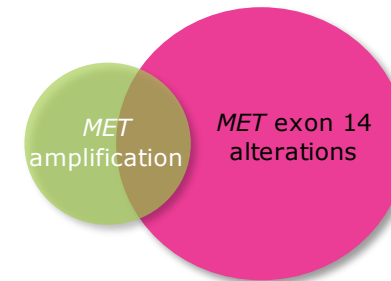


- Preclinical and clinical evidence support MET activation as a **primary oncogenic driver in lung cancer subsets** and as a **secondary driver** of acquired resistance to targeted therapy in other lung cancer subsets<sup>2</sup>
- Higher **prevalence of MET alterations amongst elderly patients in Lung** (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**

### Gene alterations identified by MSK-IMPACT<sup>1</sup> (n=860):



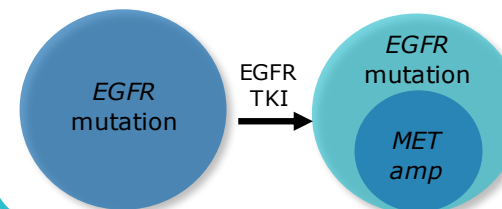
### MET as a primary driver



- Mutually exclusive with other oncogenic drivers<sup>1</sup>
- **8-30%** of sarcomatoid lung carcinomas<sup>3,4</sup>
- **15-20%** of patients have both MET amplification and METex14 alterations<sup>5</sup>

### MET as a secondary/co-driver

Acquired Resistance (AR) to TKIs

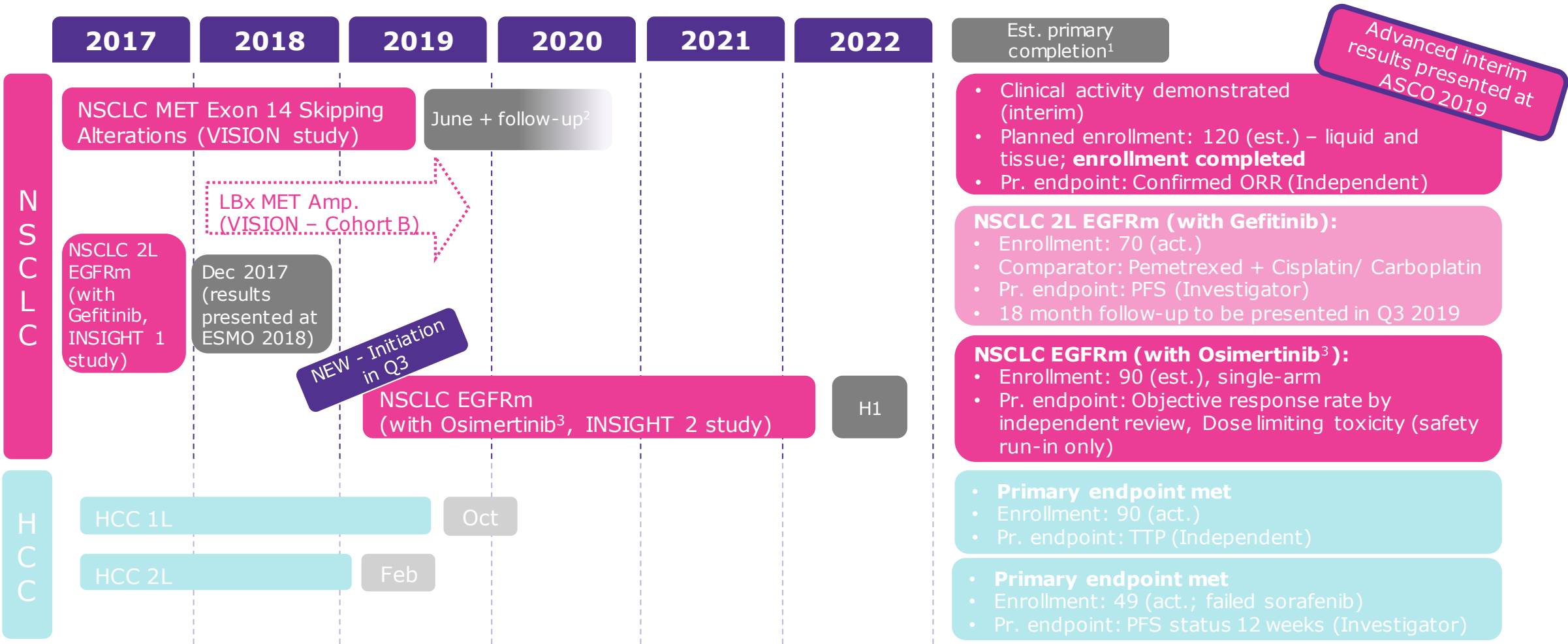


- **3%** MET amplification in AR to 1<sup>st</sup> generation EGFR TKI<sup>6</sup>
- **30%** MET amplification in AR to 3<sup>rd</sup> generation EGFR TKI<sup>7</sup>

<sup>1</sup> Jordan E et al., Cancer Discov. 2017; <sup>2</sup>Drilon A et al., J Thoracic Oncol. 2016; <sup>3</sup>Tong et al., Clin Canc Res. 2016; <sup>4</sup>Liu et al., J Clin Oncol. 2016; <sup>5</sup>Caparica R et al., J Thoracic Oncol. 2016; <sup>6</sup>Yu et al., Clin Cancer Res. 2013; <sup>7</sup>Piotrowska et al., ASCO 2017; Acronyms: MSK-IMPACT = Memorial Sloan Kettering - Integrated Mutation Profiling of Actionable Cancer Targets

# Tepotinib: Program overview

## Development focused on biomarker enriched patient populations



<sup>1</sup> Timelines are event-driven and may be subject to change; <sup>2</sup> Confirmed ORR expected approx. in June 2019, subsequent durability of response/follow-up period pending outcome of discussions with health authorities; <sup>3</sup> brand name: Tagrisso®

# Data presented at ASCO 2019

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

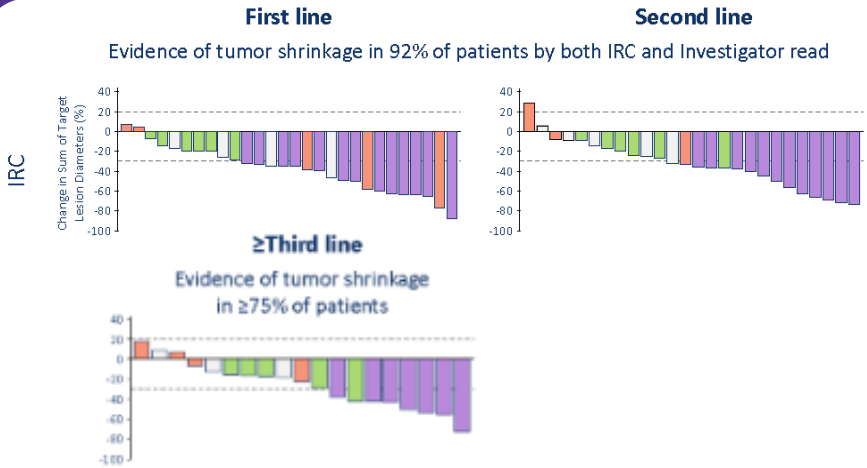
### Durable clinical activity across treatment lines<sup>2</sup>

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)
	IRC	IRC	IRC
<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>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

Data from INSIGHT 1 study  
(data presented at ESMO 2018)<sup>1</sup>

- MET-amp population:** Compared with chemotherapy, **Tepotinib plus gefitinib improved PFS** (median 21.2 vs 4.2 months; HR 0.17 [90% CI 0.05, 0.57]) **and ORR** (66.7% vs 42.9%; OR 2.67 [90% CI 0.37, 19.56])
- Discussant presentation** (E.F. Smit)<sup>2,3</sup>:

How do results compare to prior clinical studies?

Author	N	EGFR TKI	MET	Marker	ORR	PFS
Camidge 2006	89	Erlotinib	Emibetuzumab	IHC	2%	3.3 mo
Ahn 2017	45	Osimertinib	Savolitinib	GCN ≥ 5 MET/CEP7 ≥2	20% 53%	NR
Wu 2018	100	Gefitinib	Capmatinib	GCN ≥ 5 IHC 2+/3+	29%	5.6 mo
Wu 2018	36	Gefitinib	Capmatinib	GCN ≥6	47%	5.3 mo
Cheng 2018	19	Gefitinib	Tepotinib	IHC 3+	68%	8.3 mo
	12			GCN≥5/MET/CEP7 ≥2	67%	21.2 mo
AACR 2019						
Sequist 2019	46 (1 <sup>st</sup> /2 <sup>nd</sup> gen)	Osimertinib	Savolitinib	GCN≥5/MET/CEP7 ≥2	52%	NR
	48 (3 <sup>rd</sup> gen)			GCN≥5/MET/CEP7 ≥2	25%	NR

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> Y. Cheng et al., PHASE 2 STUDY OF TEPOTINIB+ GEFITINIB IN MET-POSITIVE/ EPIDERMAL GROWTH FACTOR RECEPTOR-MUTANT NSCLC, presented at ESMO 2018; <sup>2</sup> E.F. Smit, Targeting cMET in EGFR TKI resistant NSCLC, presented at ESMO 2018; <sup>3</sup> Table adapted to include more recent Savolitinib data presented at AACR 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

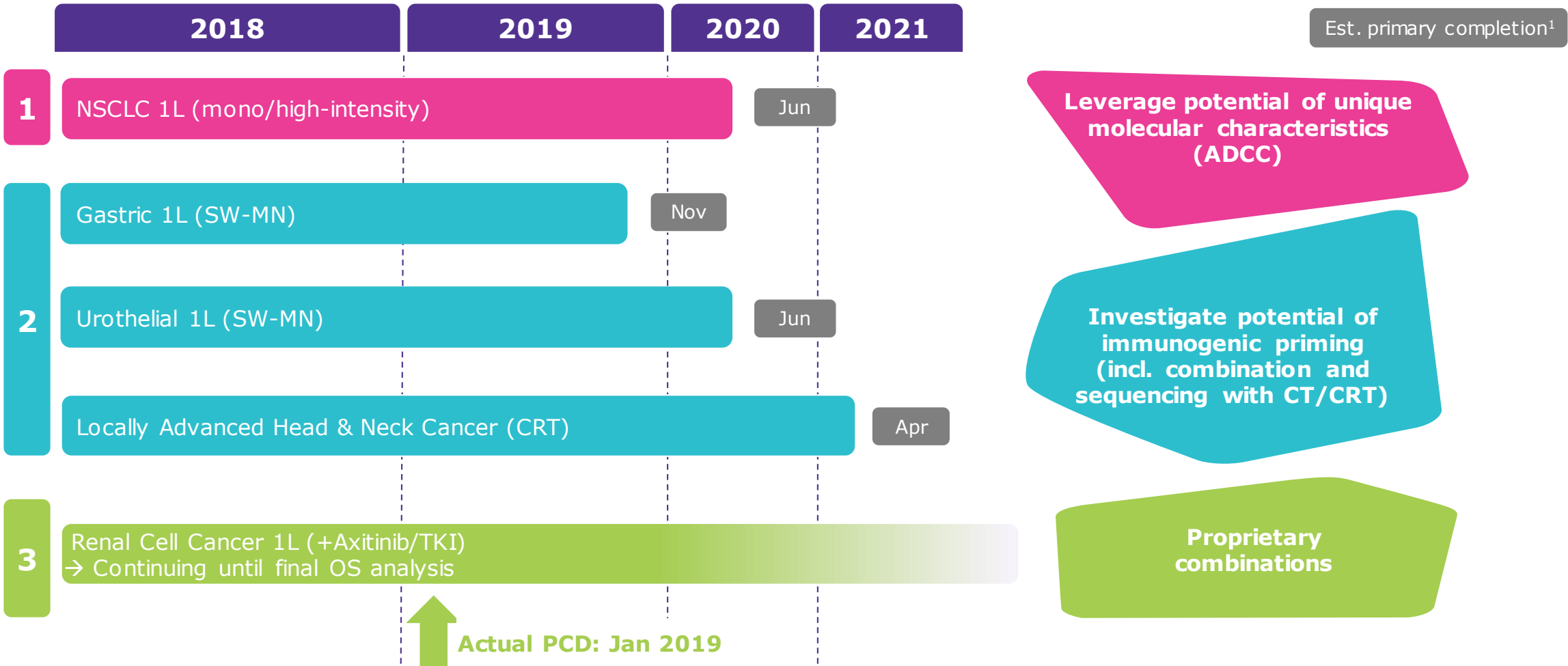


### Patients prospectively recruited with validated liquid biopsy (LBx) test in VISION

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

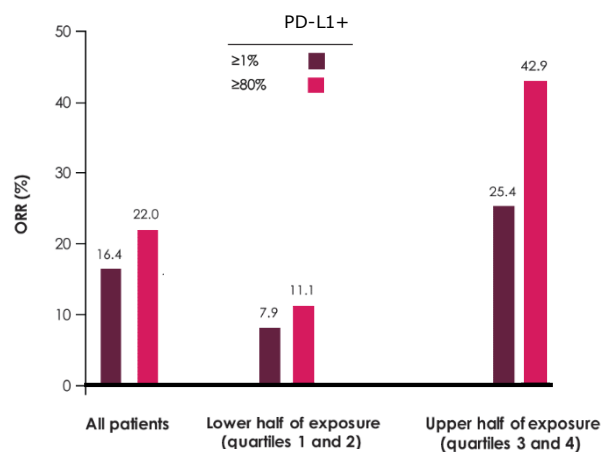
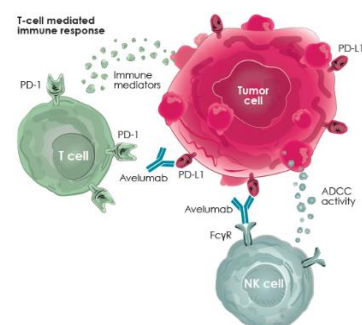


<sup>1</sup> Estimated primary completion date according to clinicaltrials.gov as of July 24, 2019, timelines are event-driven and may be subject to change;  
 Acronyms: NSCLC = Non-small Cell Lung Cancer, CT = Chemotherapy, CRT = Chemoradiotherapy, MN = Maintenance, SW = Switch, TKI = Tyrosine Kinase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

# Avelumab: NSCLC 1L

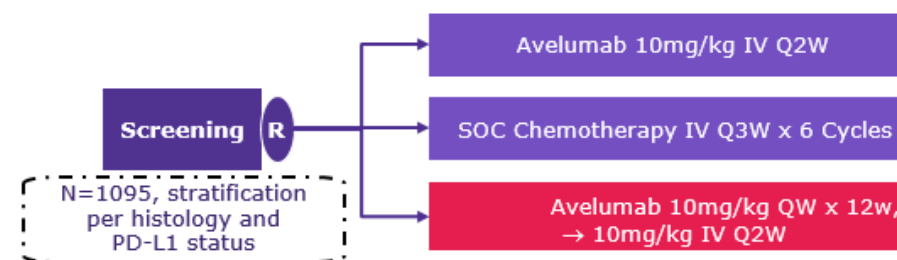
## Assessing potential efficacy upside in mono-therapy<sup>1</sup>

### 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**

# 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

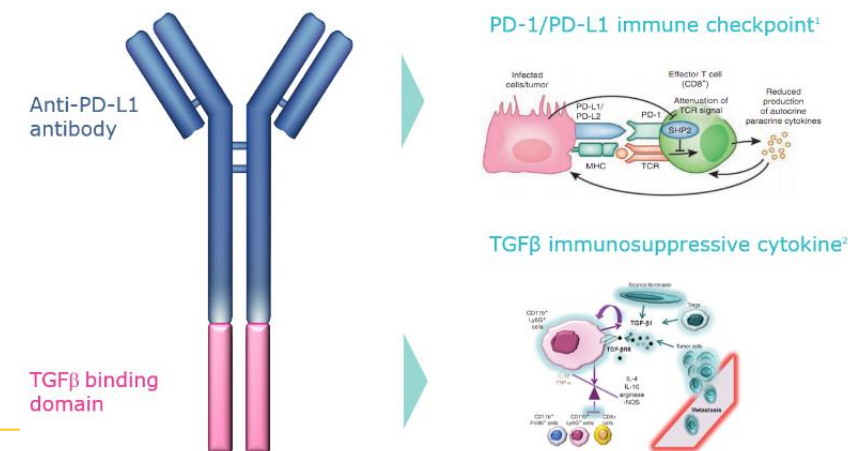
# Bintrafusp alfa<sup>1</sup> (M7824)

## 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

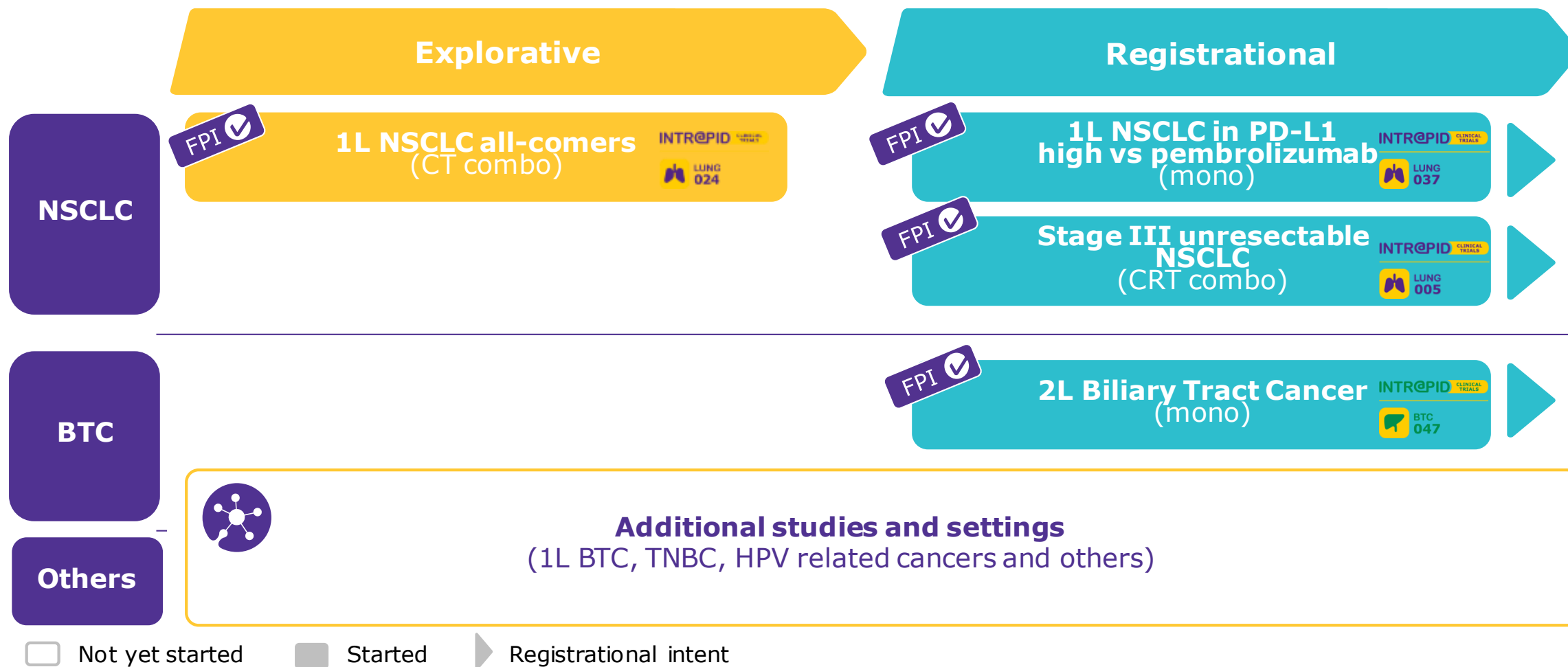


#### profit & cost sharing

- **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

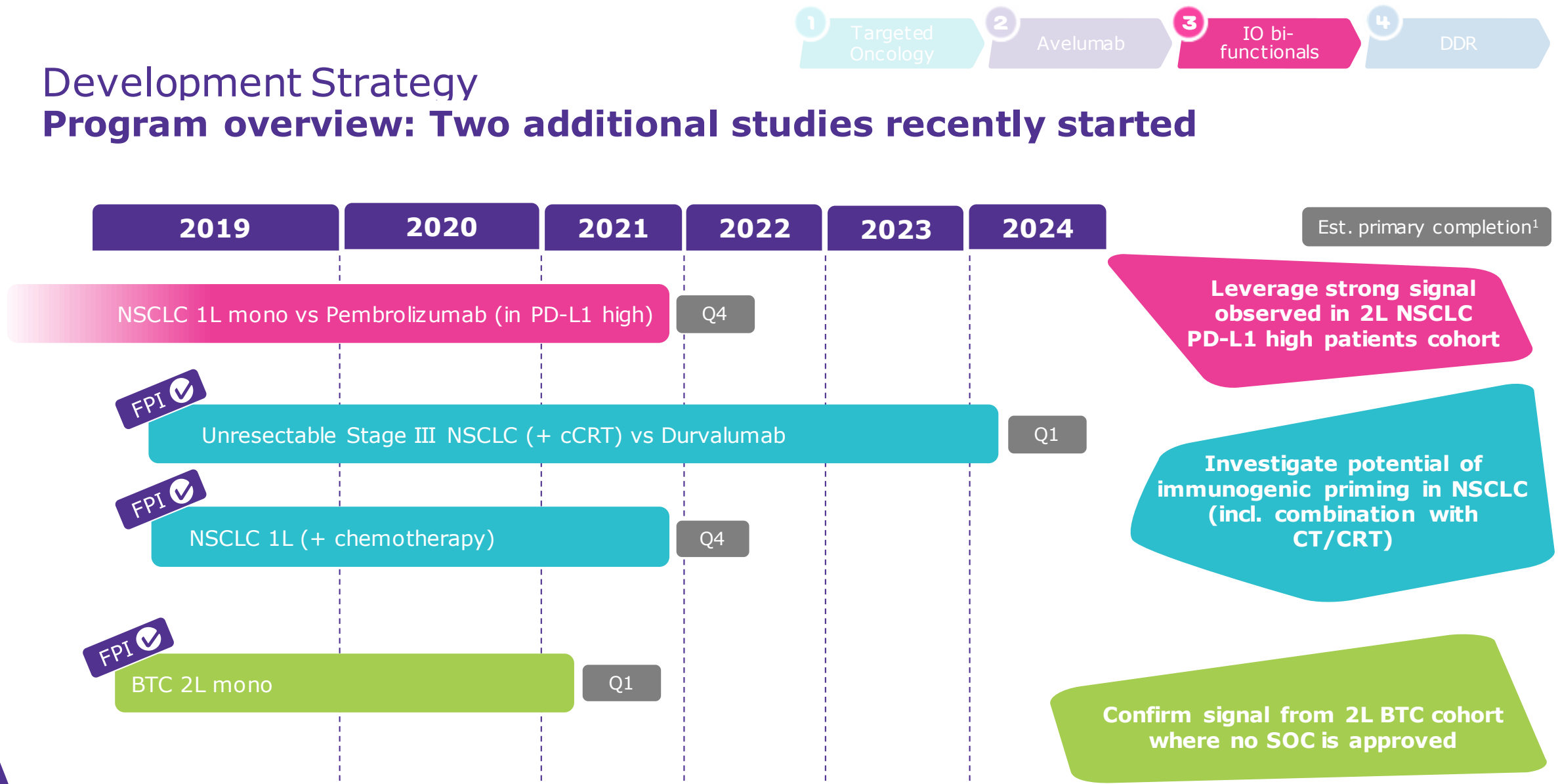
## Four studies ongoing with additional studies expected to commence in 2019



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 May 12, 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



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> Bauml 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

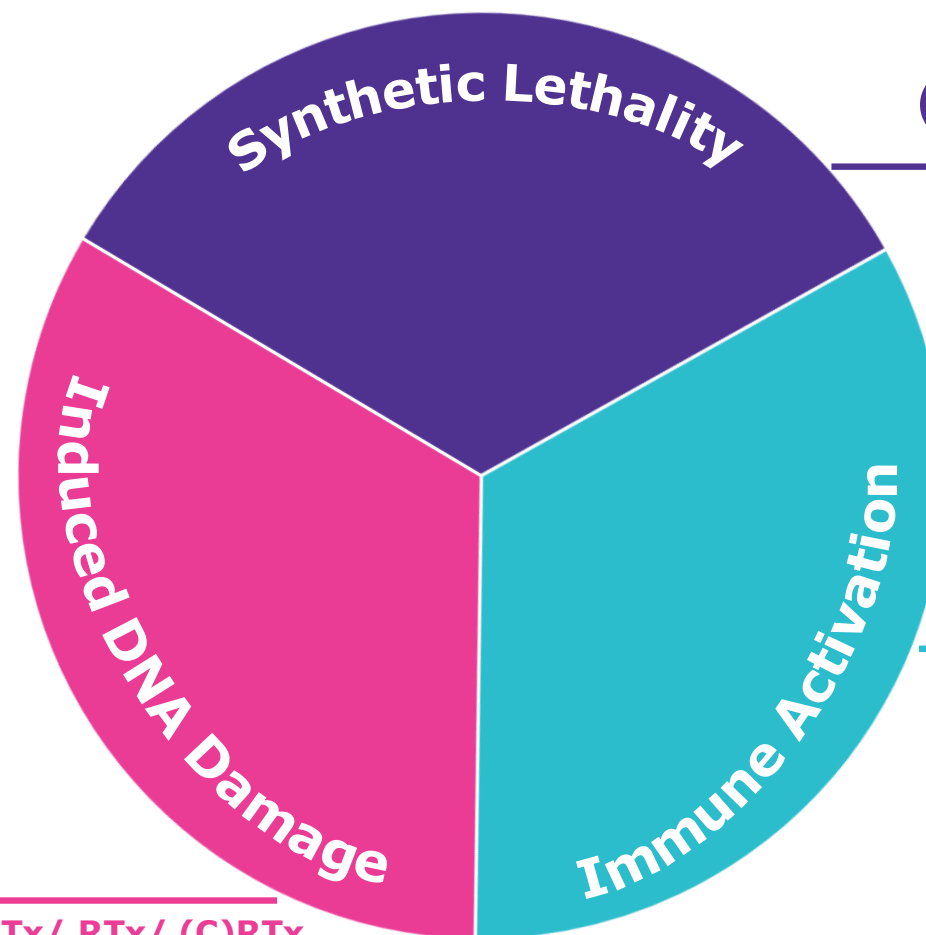
Increased levels of  
replication stress

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

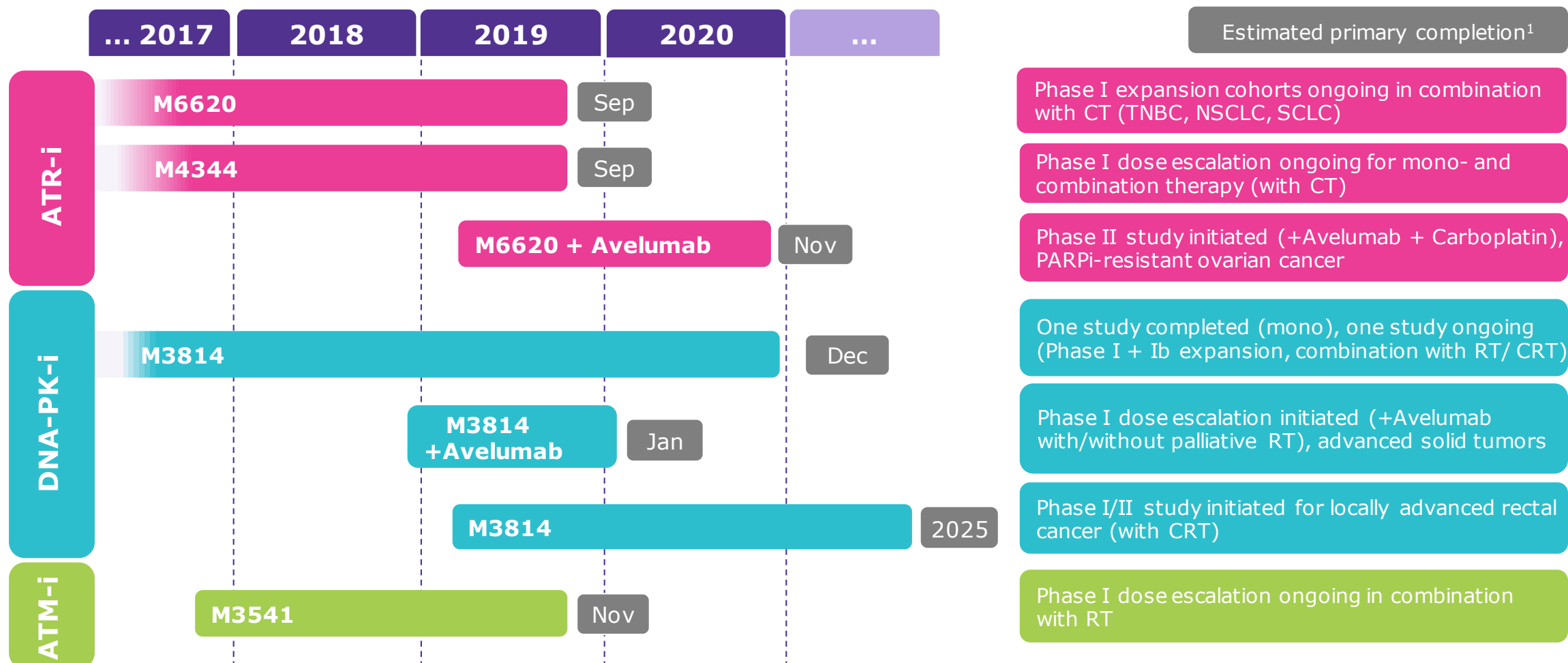
2

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 June 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

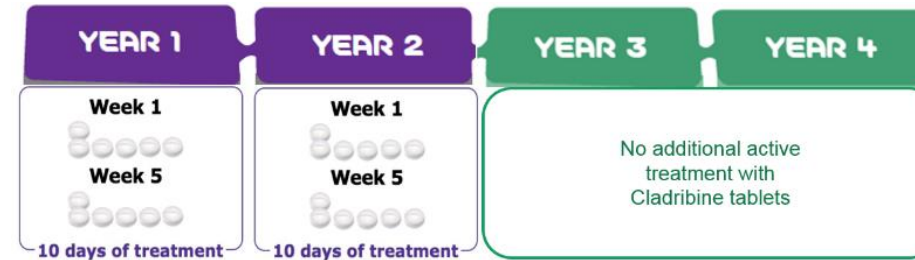
Mavenclad

# Mavenclad could change the MS treatment paradigm

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

Selective reduction in B & T lymphocytes...

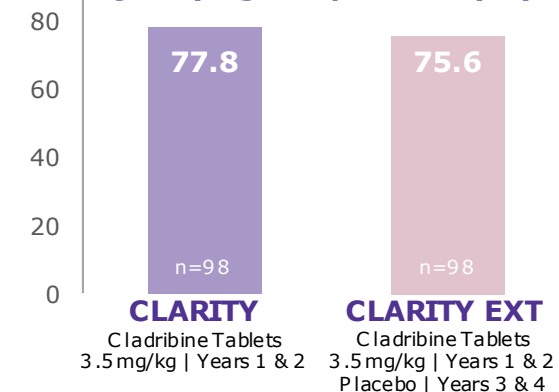
... followed by reconstitution



**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
	TB/HSV/HCV screening <sup>4</sup>	5 days of treatment	5 days of treatment										
Year 1													
Year 2													

**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

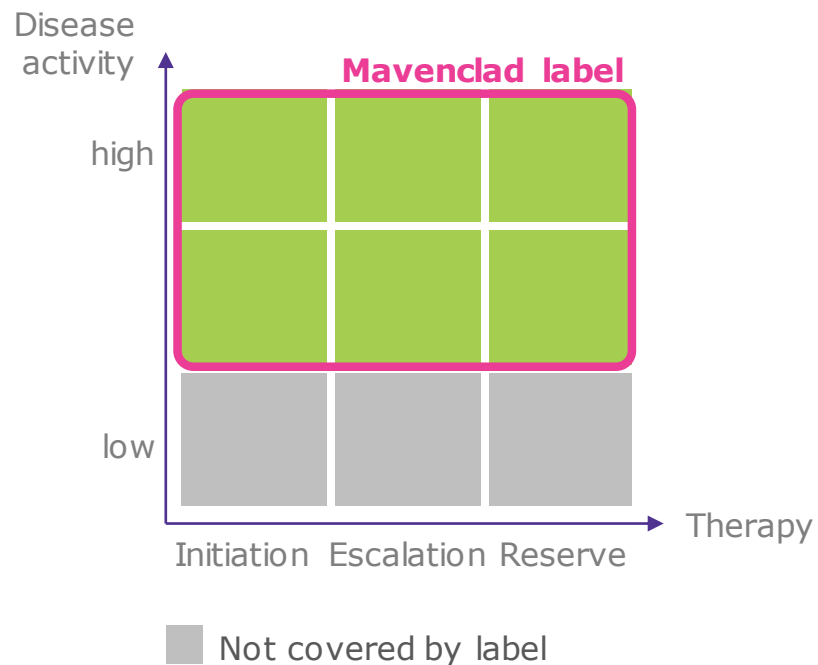
# Mavenclad's attractive label in Europe supports integrated franchise strategy

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

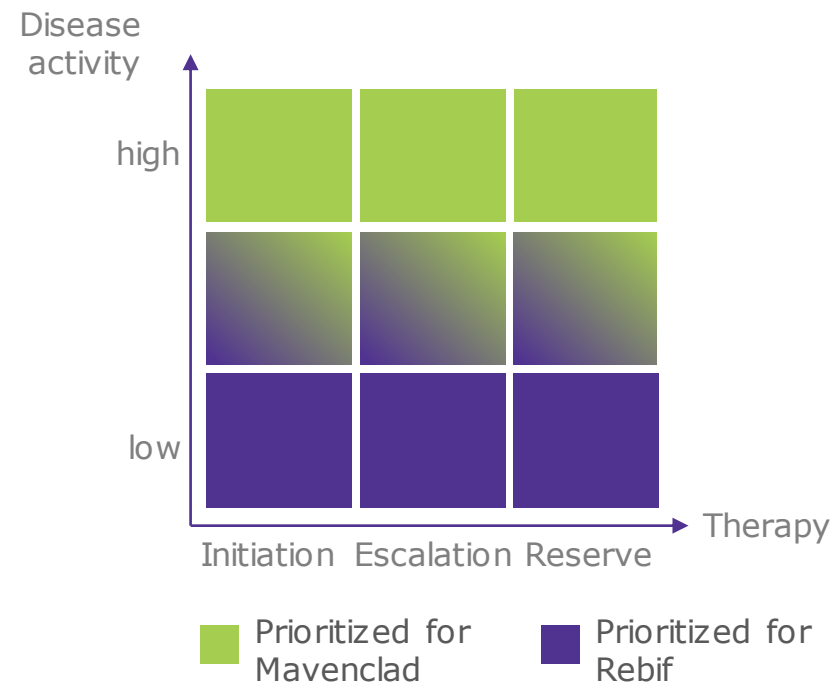
**Merck's KGaA, Darmstadt, Germany overall NDD franchise will cover a broad MS patient pool**

**Integrated franchise strategy**

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



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



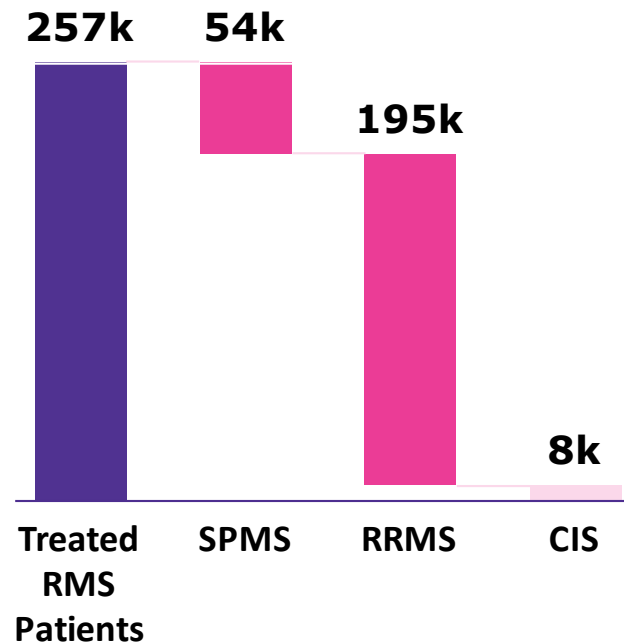
- ✓ At patient level: Rebif and Mavenclad are **highly complementary**
- ✓ At physician level: High overlap
- ✓ Franchise infrastructure investment benefits both brands

<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

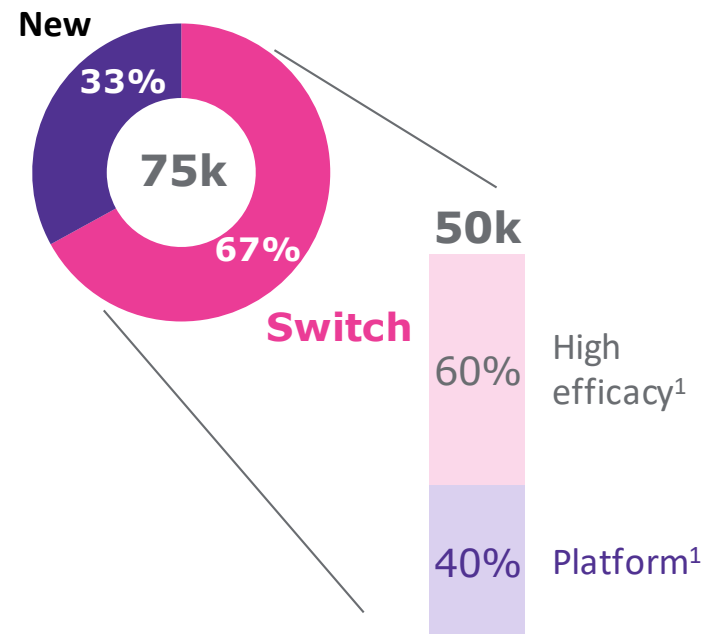
## Mavenclad

**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

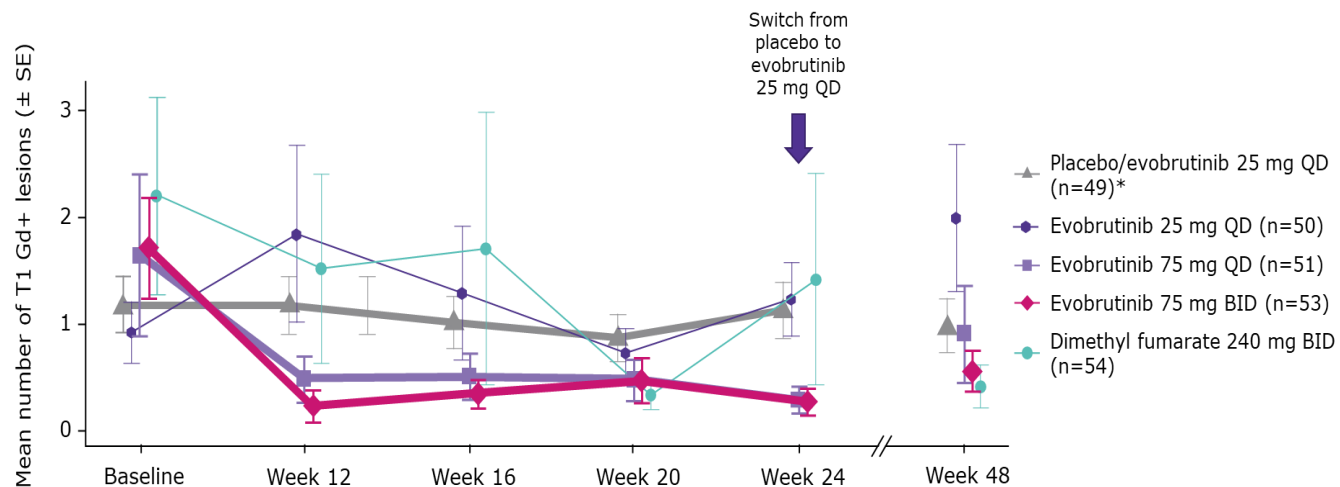
- **Novel dual Mechanism** – thought to address the **innate and adaptive immune compartments** with the prospect of both **peripheral and CNS** effects
- **Robust effect on MRI and relapses** in Phase II randomized control trial (RCT) over 48 weeks
- **No systemic side effects** (e.g. GI disturbance)
- **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

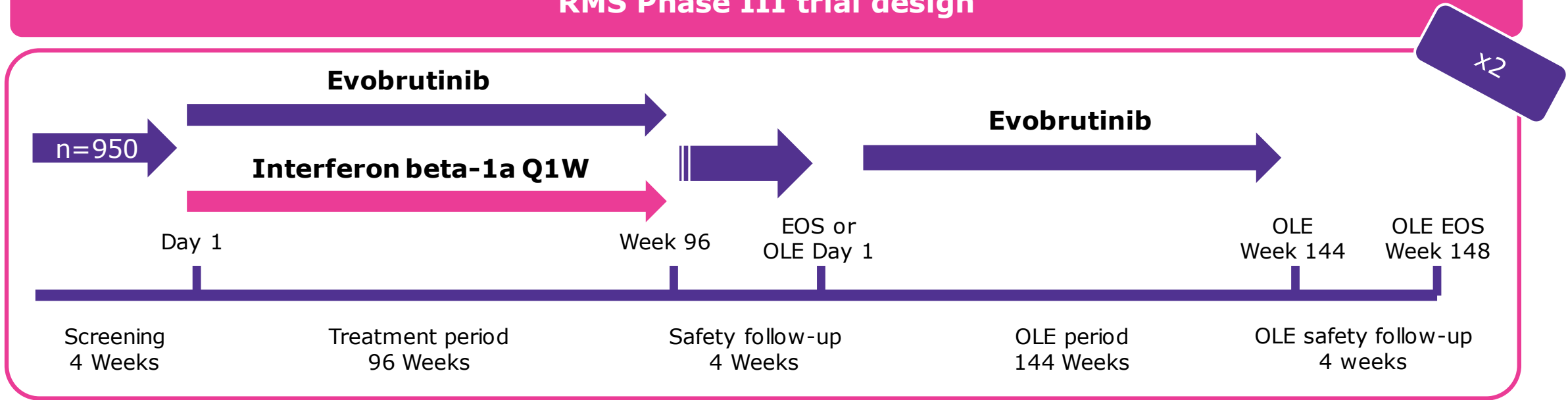
- ✓ **robust effect on relapse rate** - ARR reduction maintained over 48 weeks with Evobrutinib 75mg BID (0.11 at 48 weeks)
- ✓ **rapid reduction in mean number of T1 Gd+ lesions** - Early onset at Week 12 and persistence to Week 48 in the evobrutinib 75 mg BID arm
- ✓ **no new safety signals**
- ✓ **results 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 to commence in H2 2019 with goal to rapidly advance BTKi into clinical practice**

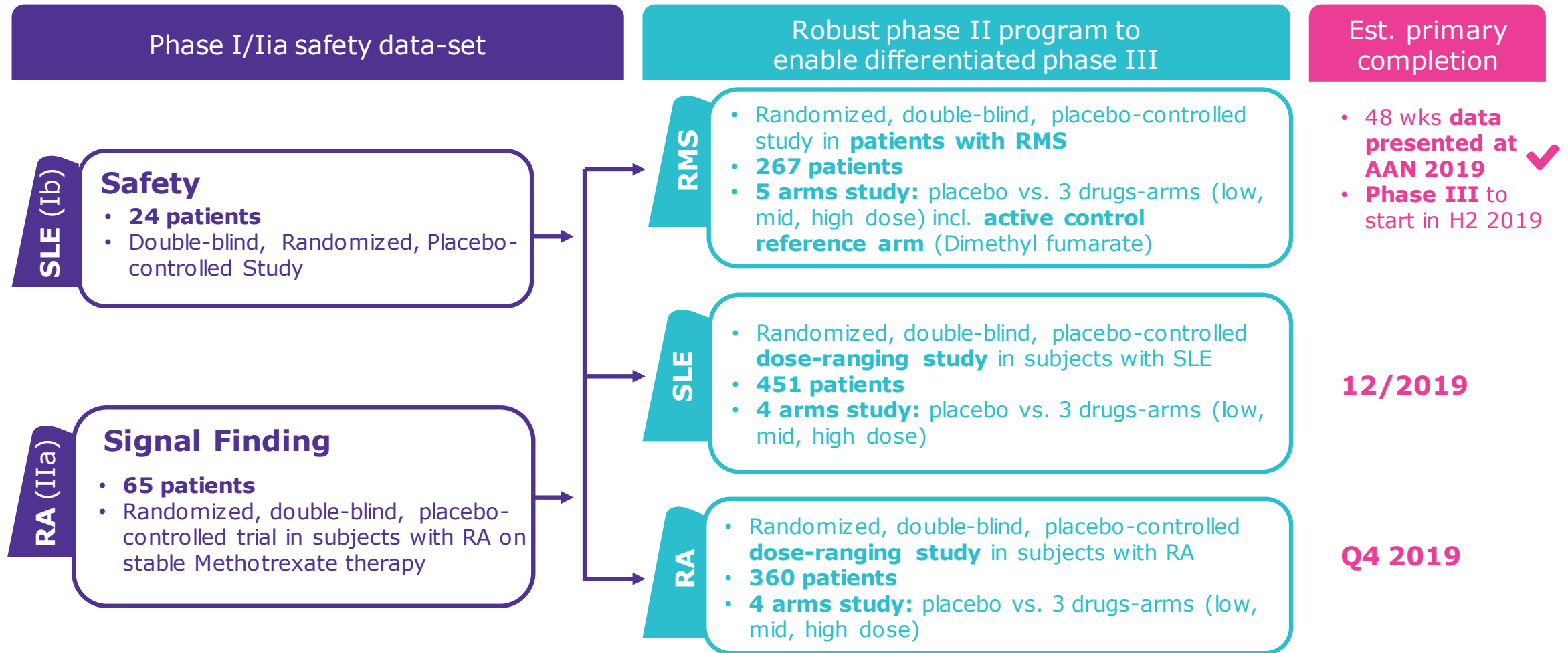
### RMS Phase III trial design



- 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

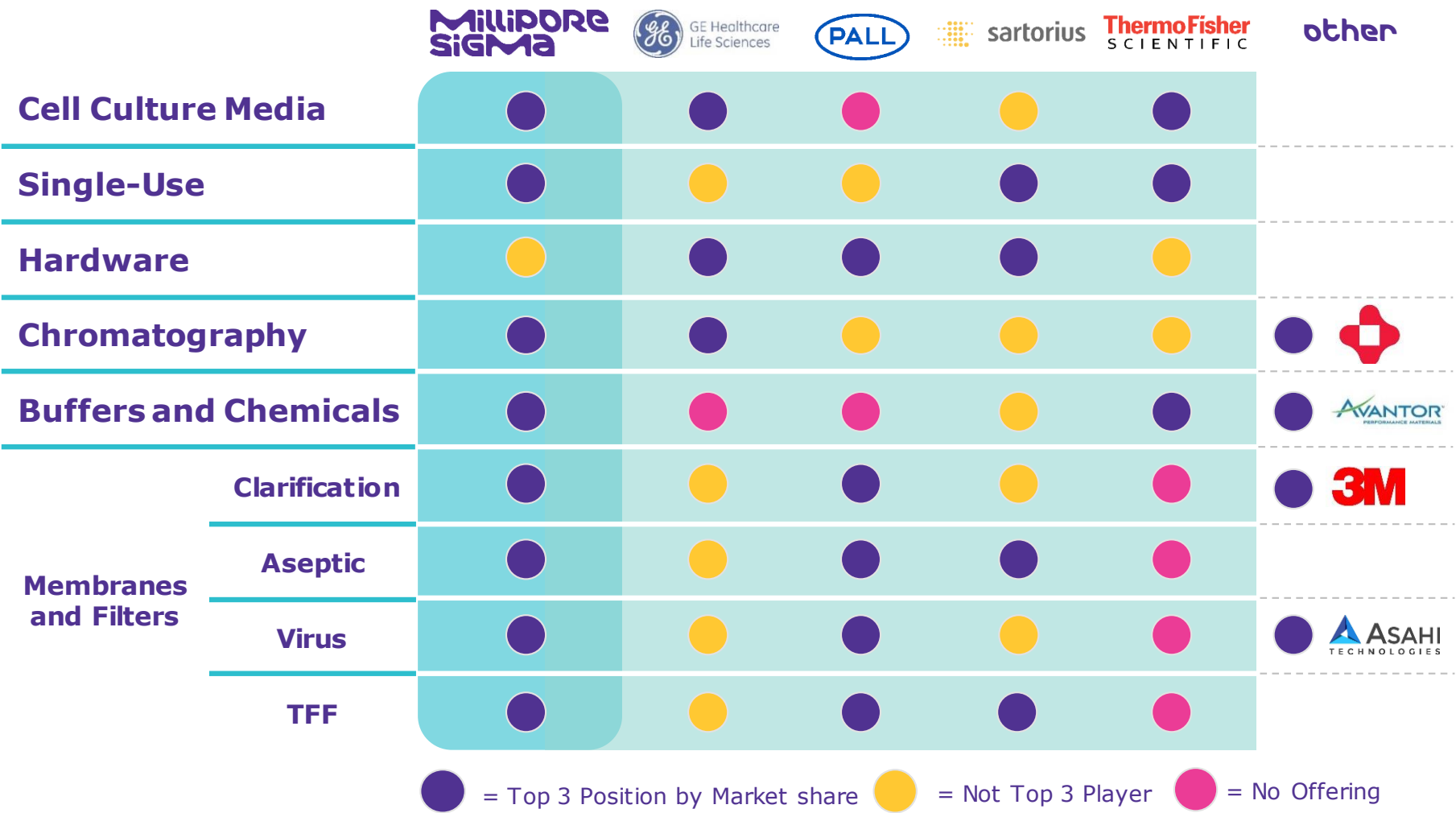


All timelines are event-driven and may be subject to change.

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

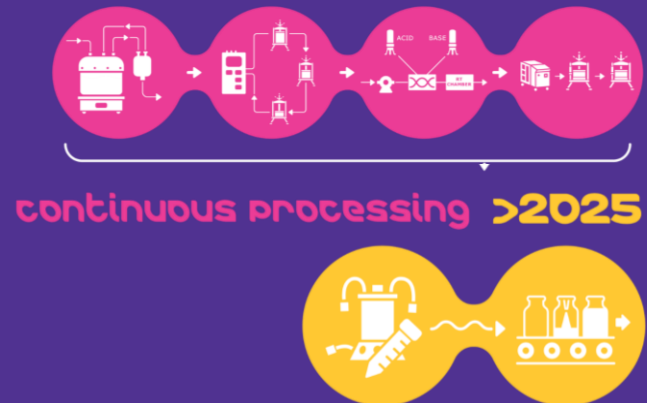
# Process Solutions

## Next-generation bioprocessing on the cards

Today's  
process & portfolio



### MAb process intensification 2017 - 2020+



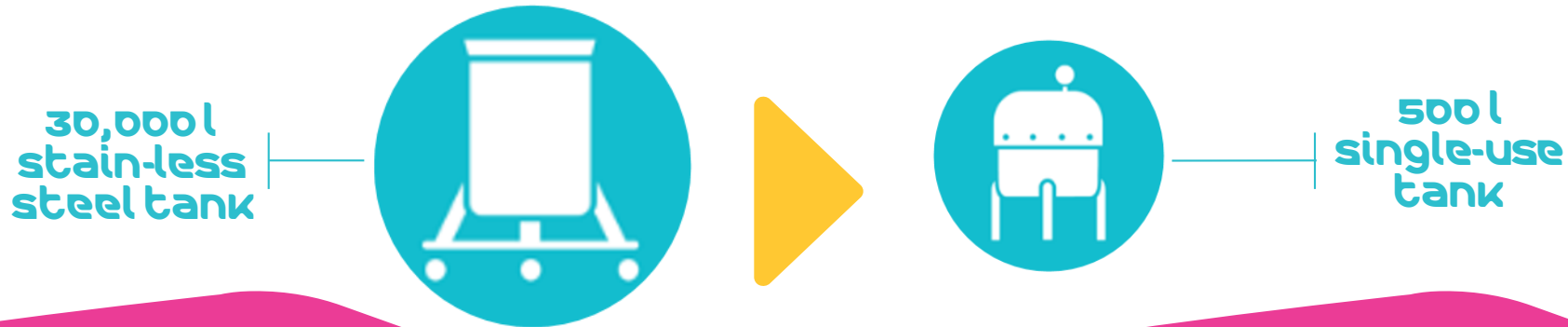
### Continuous bioprocessing will ...

- 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

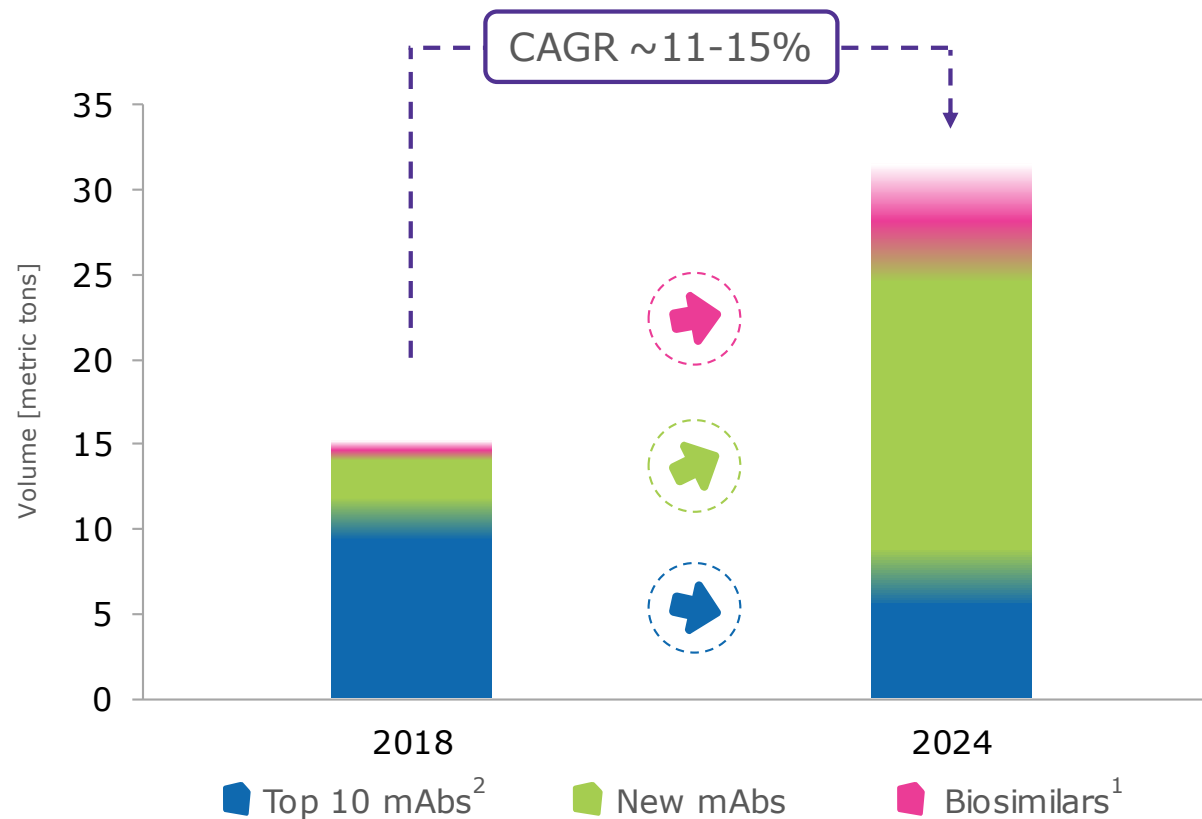
CAPEX required	\$20 m to \$100 m
Time to construct	1.5 years
Change over time	0.5 days
Footprint	~11,000 m <sup>2</sup>

**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

## 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

**Merck KGaA**  
Darmstadt, Germany

## Research Solutions

# Leading e-Commerce and operational excellence to serve customers

### unique customer experience



SEARCH

Hundreds of  
thousands of products



Articles, protocols  
and peer reviewed  
papers



SCIENTIFIC  
CONTENT



ORDER

Real-time pricing  
and availability

### 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

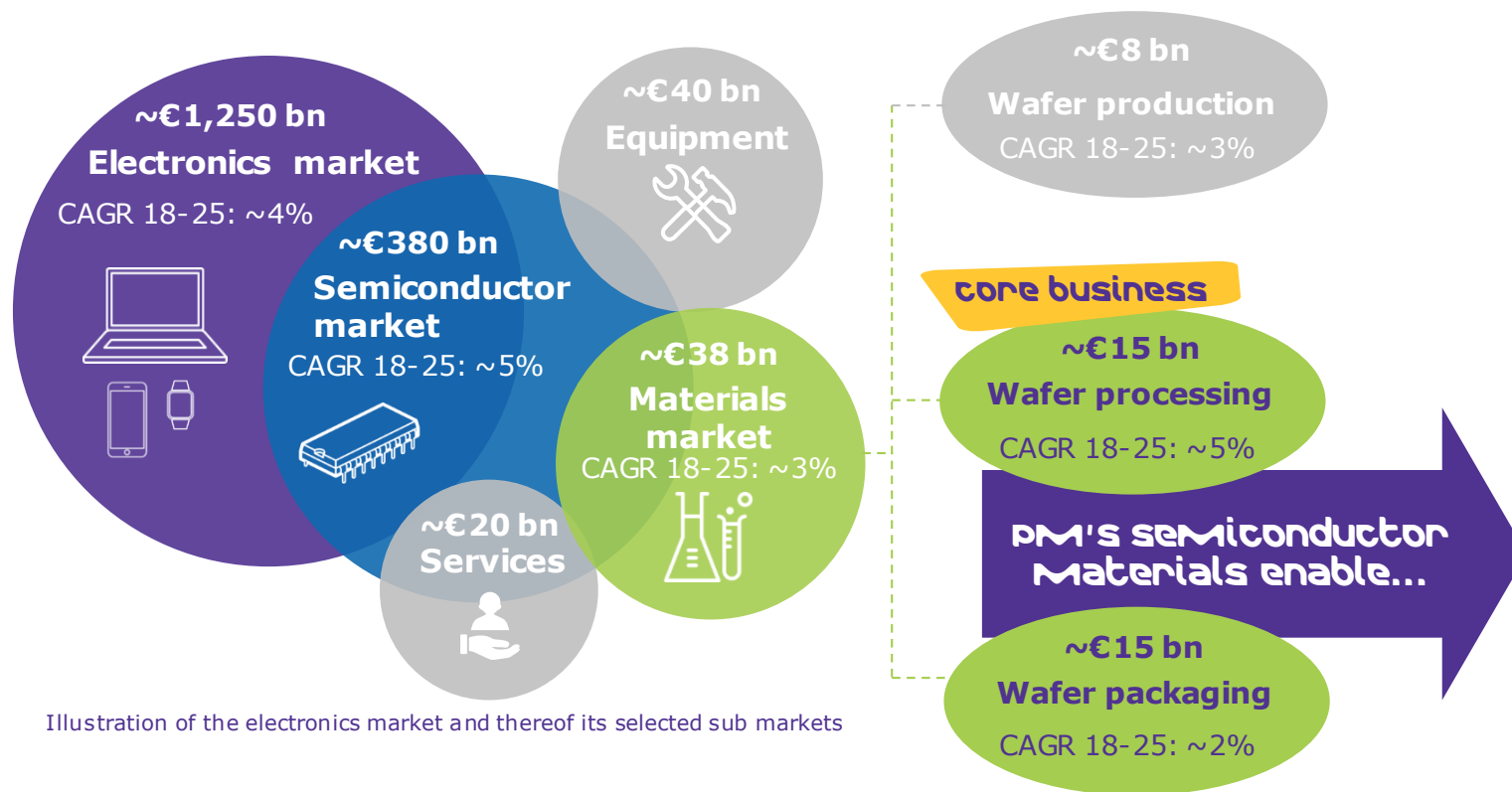
**~90%** fill rate globally

**>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

# Semiconductor Solutions

## Key enabler for digital trends



### ...customer needs

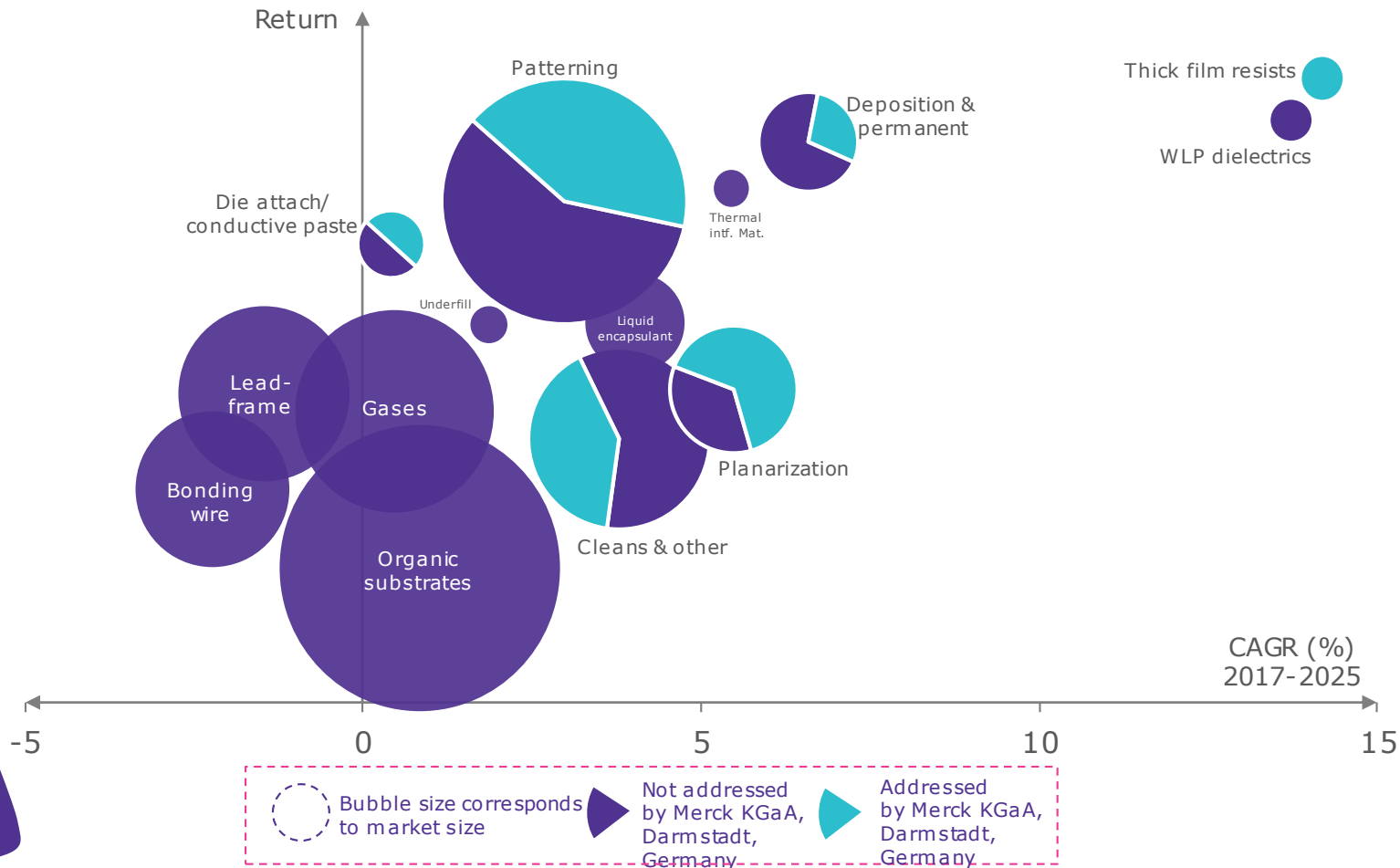
- Smaller structures beyond limitations of existing technologies
- Higher memory capacity, faster processing speed, less power consumption
- Improved yield and lower processing costs

**Performance enhancing materials will benefit over-proportionately from attractive semiconductor growth rate of 5% CAGR**

# Semiconductor Solutions

## Well positioned in highly attractive market segments

Market landscape of wafer processing and packaging materials

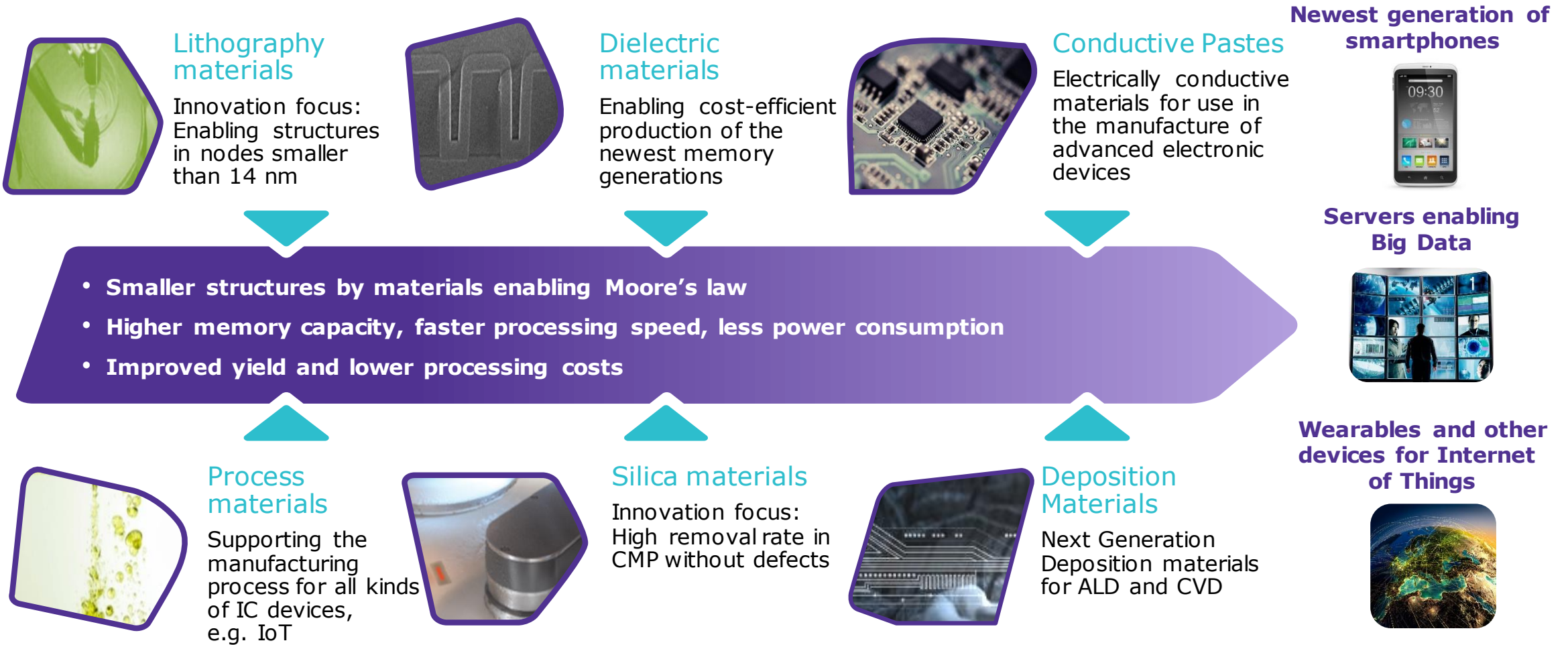


### Market positioning

- Positioned in attractive sub-segments
- Focus on enabling material solutions with small part in bill of materials
- Address innovative technologies through collaborative R&D
- Above-market growth
- Opportunities to increase footprint

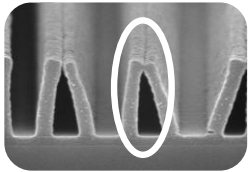
# Semiconductor Solutions

## Enabler of key technology trends

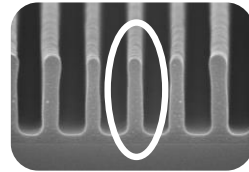


# Expanding the limits of how small you can go

## Pattern collapse

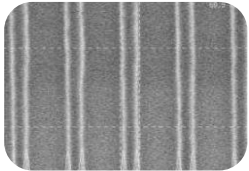


## AZ FIRM® rinse materials



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

## Lithography limitation

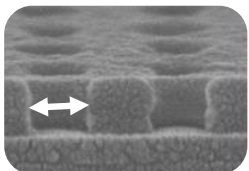


## Directed self-assembly (DSA)

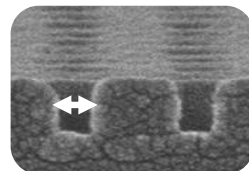


Block copolymer can generate small lines or contact holes by self-assembly. This allows miniaturization without expensive new equipment.

## 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

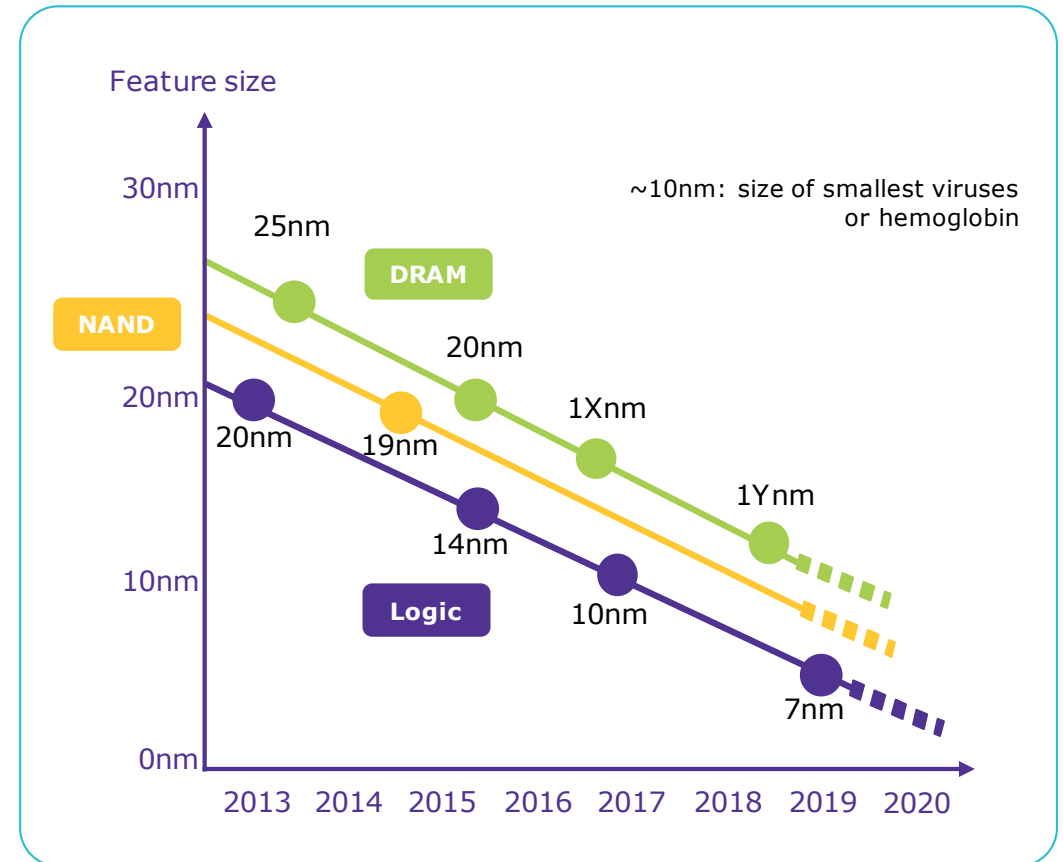
**Big Data:** Increasing need for intelligent data storage

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

### Selected competitors

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

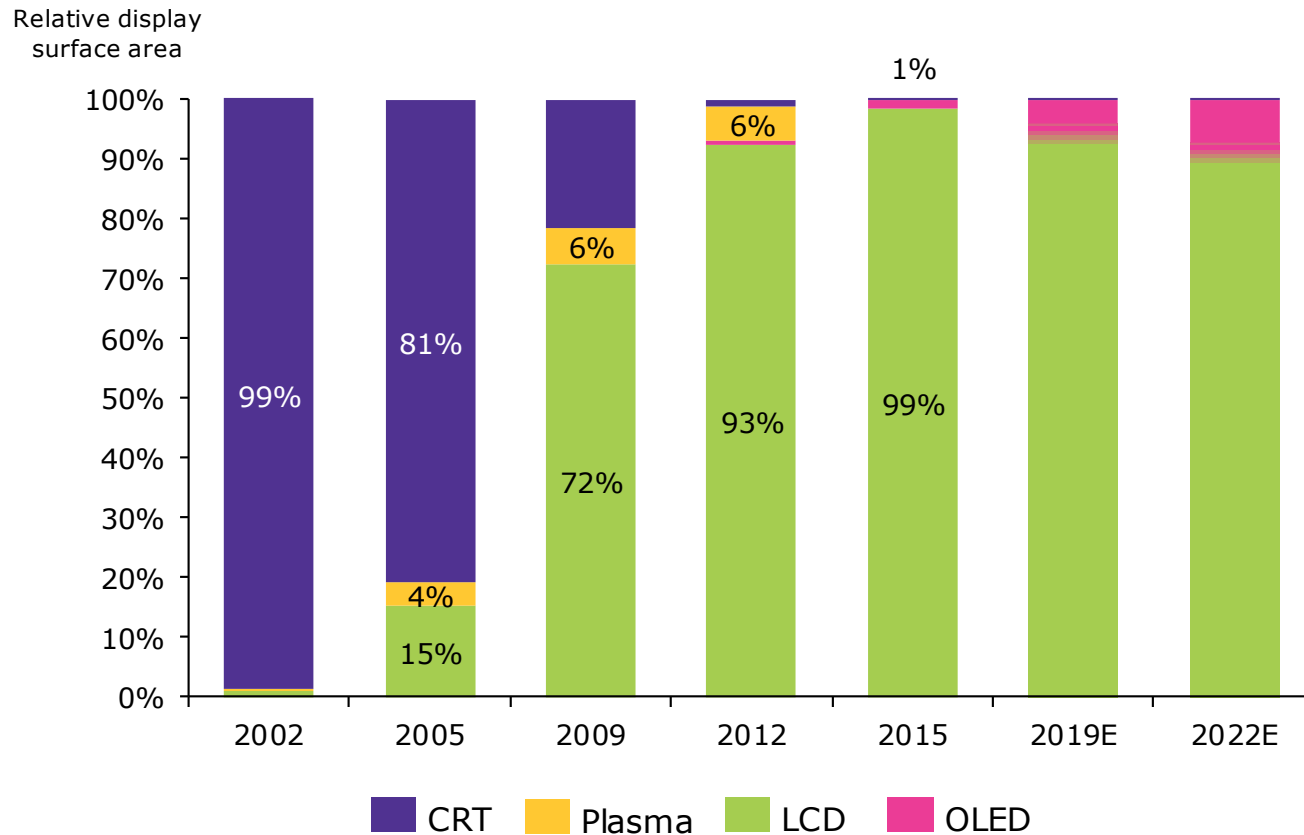
Feature sizes in memory market develop as predicted by Moore's law<sup>1</sup>



# Display Solutions

## Liquid crystals are clearly the dominant display technology

### Market share by display technology



### Rationale for LCD leadership

#### For consumers:

- Price
- Thinner frames
- Higher resolution in all sizes
- Proven track record of extreme reliability

#### For manufacturers:

- Price and scalability
- Production costs and capacities

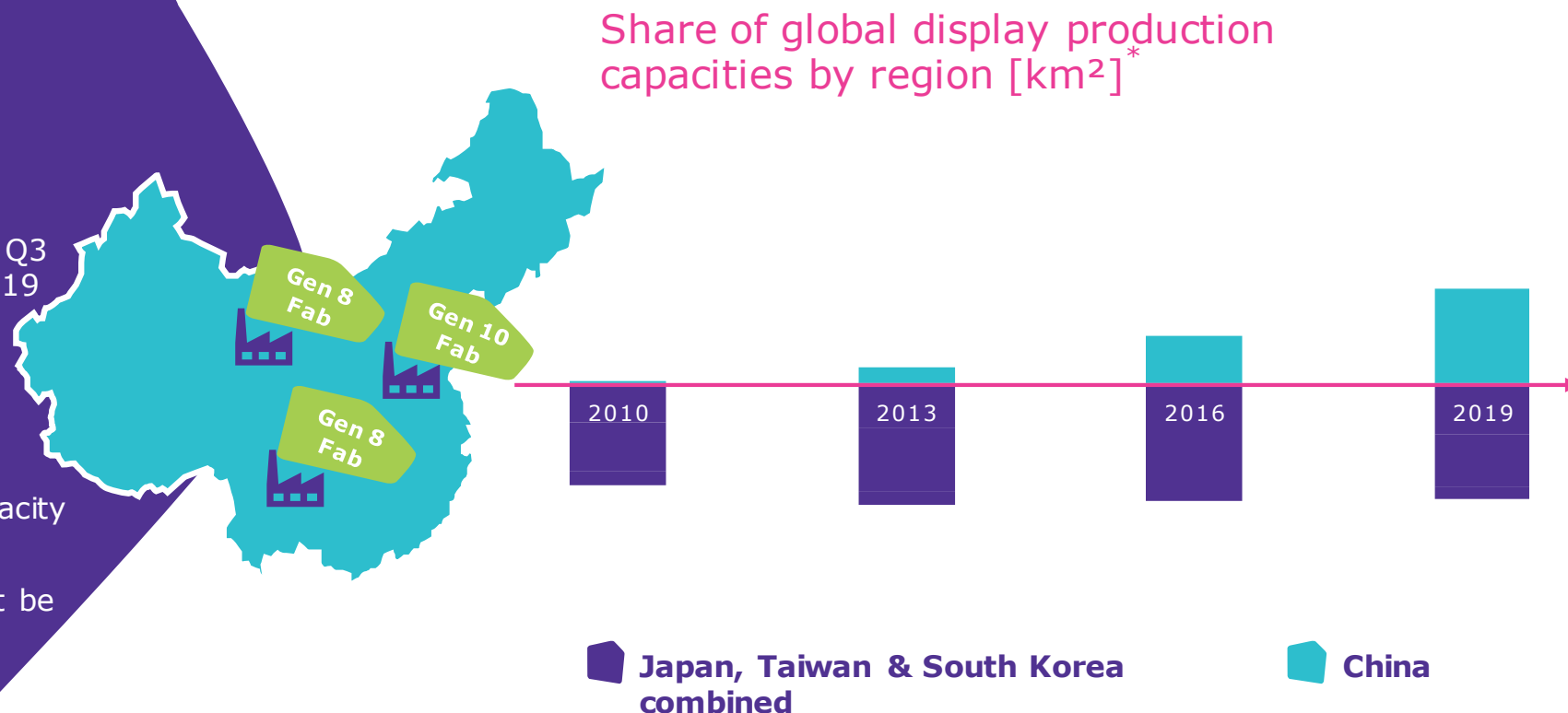
**LCD progress creates higher technological and commercial entry barriers**

**OLED share will increase in mobile applications**

# Performance Materials: Liquid crystals currently benefitting from new display-panel plant capacity ramp up projects

## Temporary nature

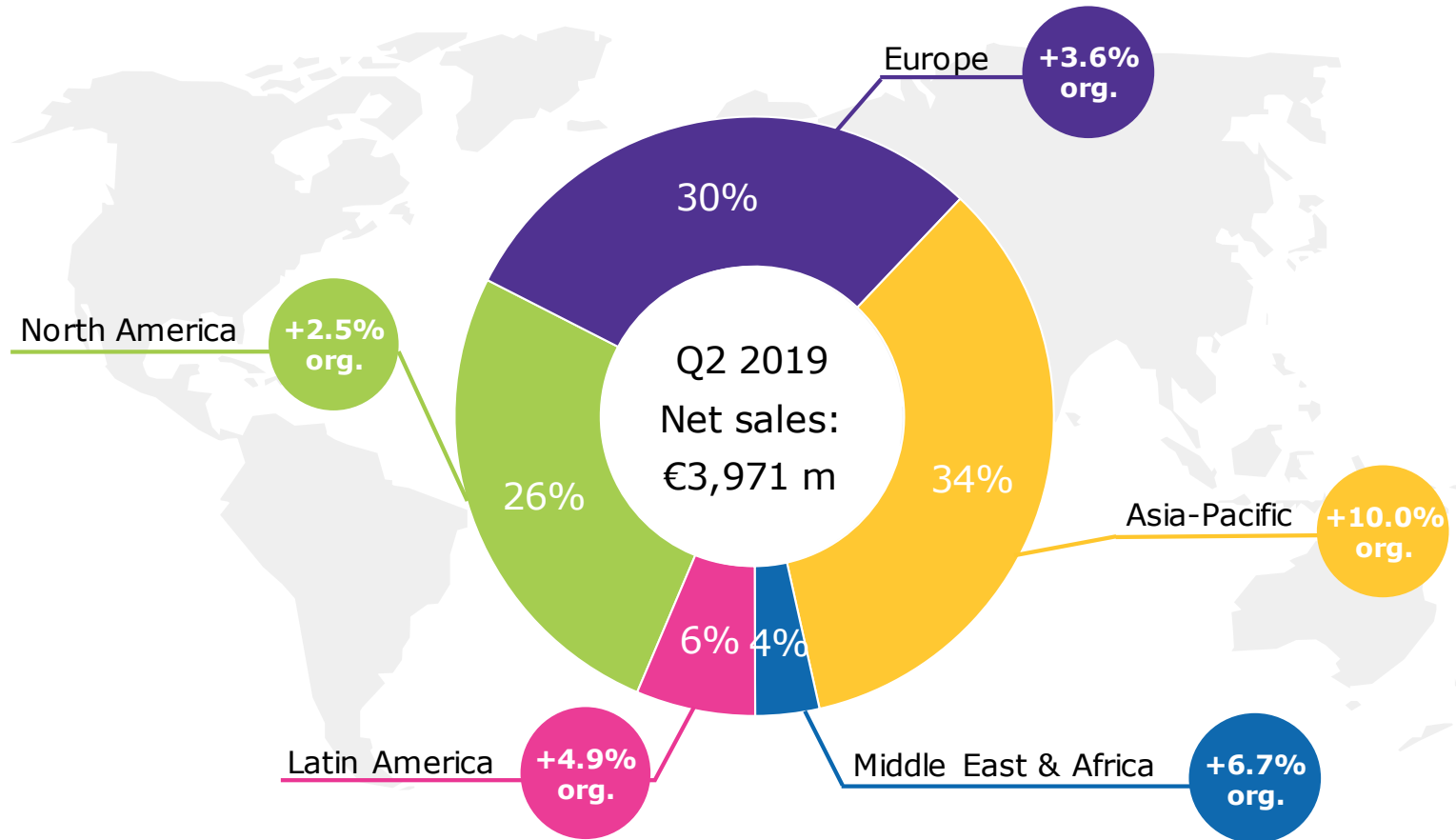
- Accelerated ramp up of Chinese panel production facilities
- Projects supporting LC business since Q3 2018 and expected to last until H1 2019
- Increased market share during ramp up phase, but dual sourcing afterwards highly probable
- Overcapacity in 2018 due to massive capacity ramp up in China, global capacity is expected to consolidate in 2019
  - Some manufacturing capacity might be converted to OLED or might be taken off



**Overall LC materials market decline in value with mid- to high-single digit CAGR until 2025 confirmed**

# Organic growth driven by all regions

## Regional breakdown of net sales [€m]



## Regional organic development

- Strong APAC due to double-digit growth of Glucophage<sup>®</sup>, Erbitux<sup>®</sup> and OLED; Life Science with ongoing strong demand
- Europe driven by strong demand in Life Science; strong Mavendad<sup>®</sup> ramp-up overcompensates Rebif<sup>®</sup> decline
- North America reflects double-digit growth of Process Solutions, Fertility and Mavendad<sup>®</sup> ram-up, outweighing double-digit decline of Rebif<sup>®</sup>
- Solid performance in LATAM due to strong Life Science, Erbitux and N&I franchise
- Middle East and Africa driven by strong Rebif<sup>®</sup> and Glucophage<sup>®</sup>

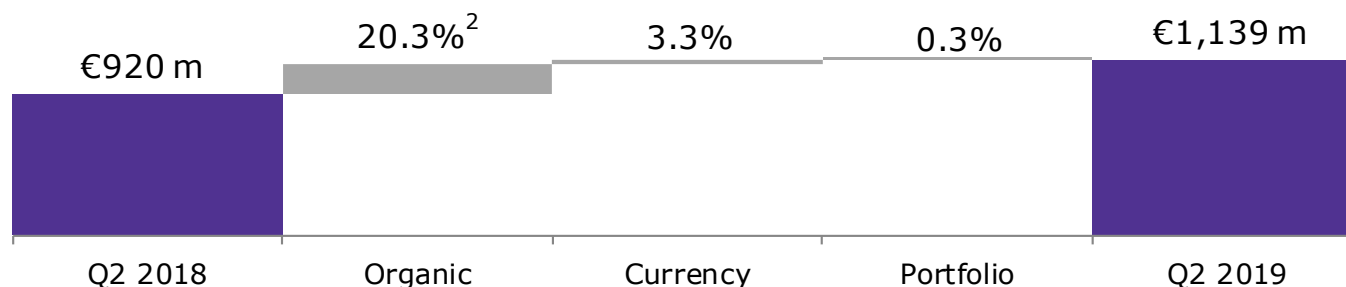
## Life Science and Healthcare drive organic growth supported by FX tailwinds

### Q2 2019 YoY net sales

	Organic	Currency	Portfolio	Total
Healthcare	5.2%	0.7%	0.0%	<b>5.9%</b>
Life Science	9.0%	2.1%	-0.6%	<b>10.5%</b>
Performance Materials	-2.0%	2.4%	0.0%	<b>0.4%</b>
Group	5.6%	1.5%	-0.2%	<b>6.9%</b>

- Solid growth in Healthcare reflects stable core business and increasing contributions from Mavenclad<sup>®</sup> and Bavencio<sup>®</sup>
- Above-market organic growth in Life Science due to strong demand across all businesses and regions
- Performance Materials reflects lower LC due to reduced China ramp-up support and softer market demand in Semiconductor and Surface Solutions; OLED again strong

### Q2 YoY EBITDA pre



- Increased organic EBITDA pre driven by milestone payments and deferred income in HC as well as ongoing strong performance of LS
- Positive FX impact on EBITDA pre due to EUR/USD development and last years' ARS<sup>1</sup> devaluation burdened by hedging losses

<sup>1</sup>ARS – Argentine peso; <sup>2</sup>Thereof IFRS 16 effect with +3.5% (+€32 m); Totals may not add up due to rounding

## Q2 2019: Overview

### Key figures

[€m]	Q2 2018	Q2 2019	Δ
Net sales	3,714	<b>3,971</b>	6.9%
EBITDA pre	920	<b>1,139</b>	23.8%
Margin (in % of net sales)	24.8%	28.7%	
EPS pre	1.23	<b>1.54</b>	25.2%
Operating cash flow	367	<b>743</b>	102.2%

[€m]	Dec. 31, 2018	June 30, 2019	Δ
Net financial debt	6,701	<b>7,829</b>	16.8%
Working capital	3,486	<b>3,866</b>	10.9%
Employees	51,749	<b>53,051</b>	2.5%

### Comments

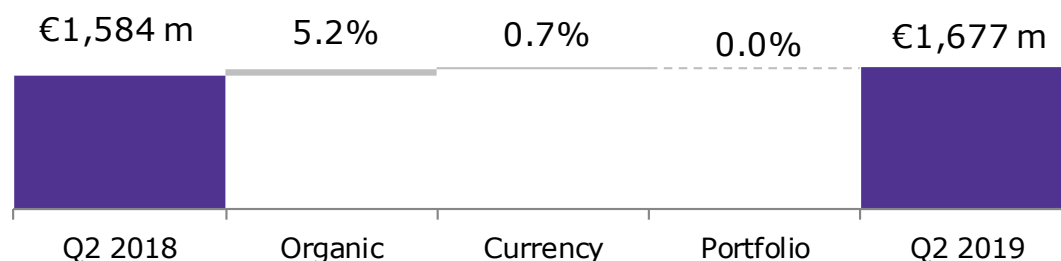
- Net sales growth driven by Life Science and Healthcare
- EBITDA pre & margin reflect Peg-Pal (~€75 m) and Bavencio<sup>®</sup> (~€35 m) milestones, GSK deferred income (~€30 m) and strong performance of LS
- Strong operating cash flow due to higher profit after tax and GSK upfront payment
- Working capital reflects increased business activity and FX
- Higher net financial debt mainly due to IFRS 16 adoption, dividends and temporary investment of cash proceeds from CH divestment

# Healthcare: Underlying profitability increases vs. Q1 driven by organic performance and cost discipline, further boosted by non-recurring business-related income

## Healthcare P&L

[€m]	Q2 2018 <sup>1</sup>	Q2 2019
Net sales	1,584	<b>1,677</b>
Marketing and selling	-592	<b>-599</b>
Administration	-82	<b>-84</b>
Research and development	-407	<b>-395</b>
EBIT	155	<b>345</b>
EBITDA	338	<b>523</b>
EBITDA pre	379	<b>528</b>
Margin (in % of net sales)	23.9%	<b>31.5%</b>

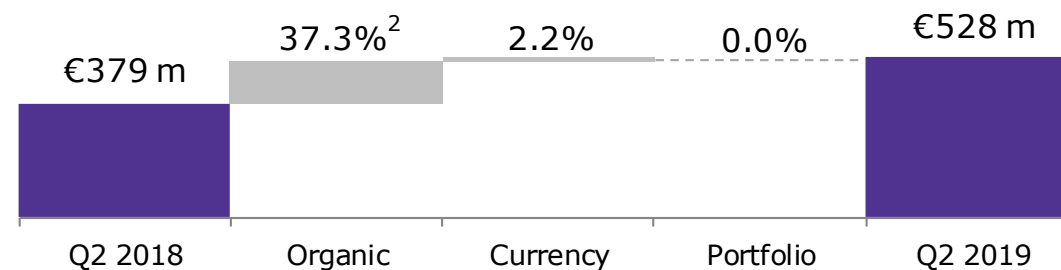
## Net sales bridge



## Comments

- Solid growth in Healthcare driven by General Medicine, Mavenclad<sup>®</sup>, Erbitux<sup>®</sup>, Fertility and Bavencio<sup>®</sup>, more than offset strong Rebif<sup>®</sup> decline
- Mavenclad<sup>®</sup> with continued strong uptake supported by initial U.S. sales following approval (+41% vs. Q1)
- Bavencio<sup>®</sup> on track; Erbitux<sup>®</sup> benefiting from China reimbursement, still facing ongoing competition and price pressure in major markets
- R&D below prior year due to stringent project prioritization
- Higher EBITDA pre driven by Peg-Pal (~€75 m) and Bavencio<sup>®</sup> (~€35 m) milestone as well as GSK deferred income (~€30 m), sequential underlying<sup>3</sup> margin increase

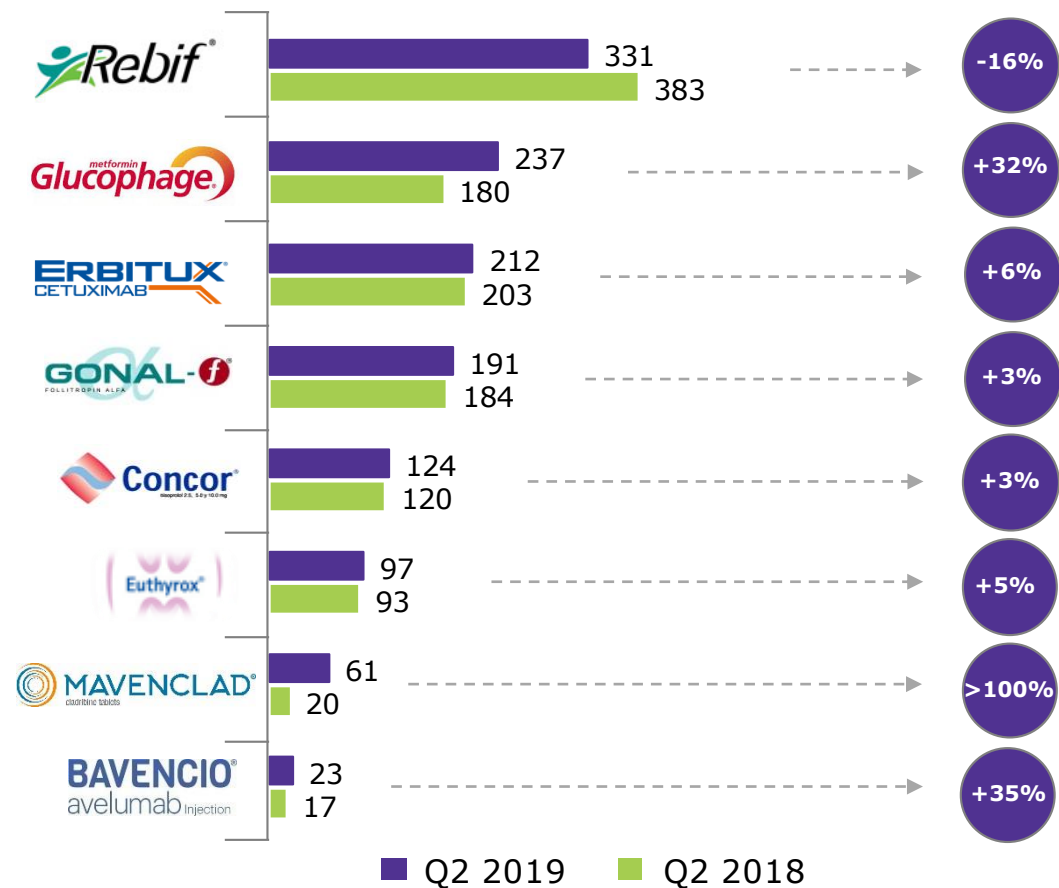
## EBITDA pre bridge



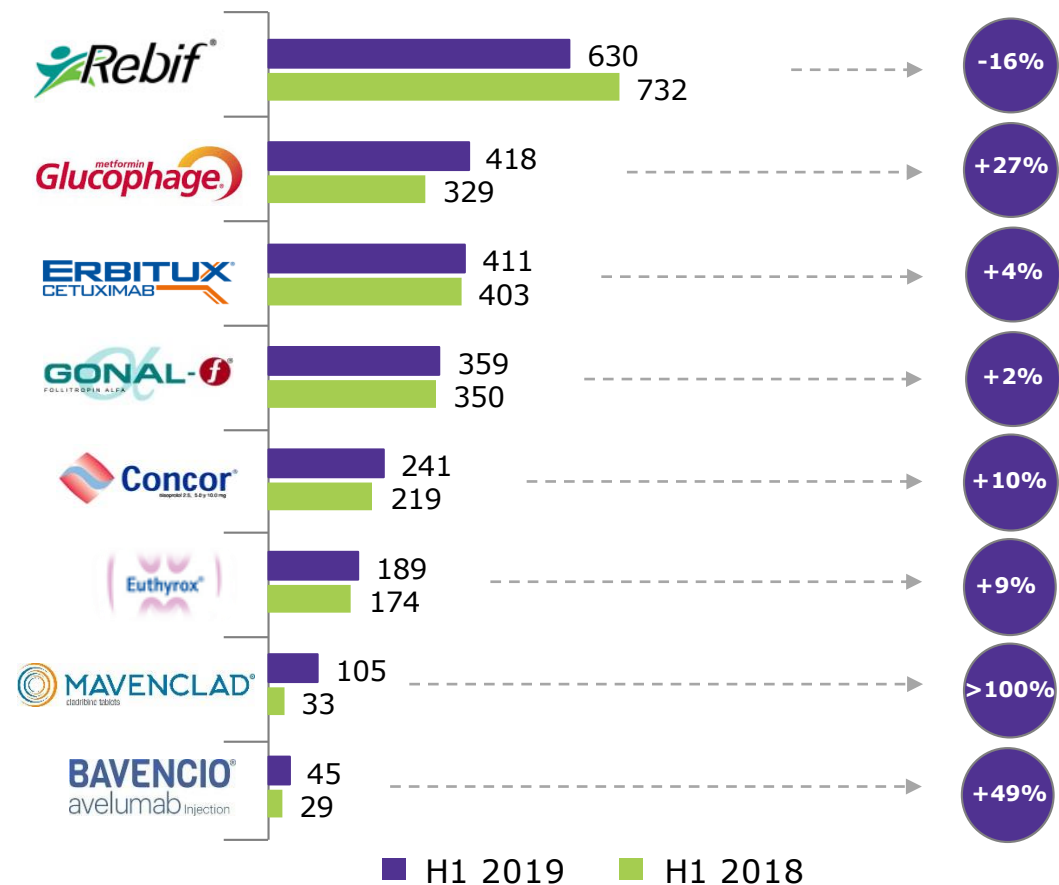
<sup>1</sup>LY numbers have been modified, due to disclosure changes of adjustments; <sup>2</sup>Thereof IFRS 16 effect with +3.2% (+€12 m); <sup>3</sup>EBITDA pre adjusted for €140 m non-recurring income; Totals may not add up due to rounding

# Healthcare organic growth by franchise/product

Q2 2019 organic sales growth [%]  
by key product [€m]

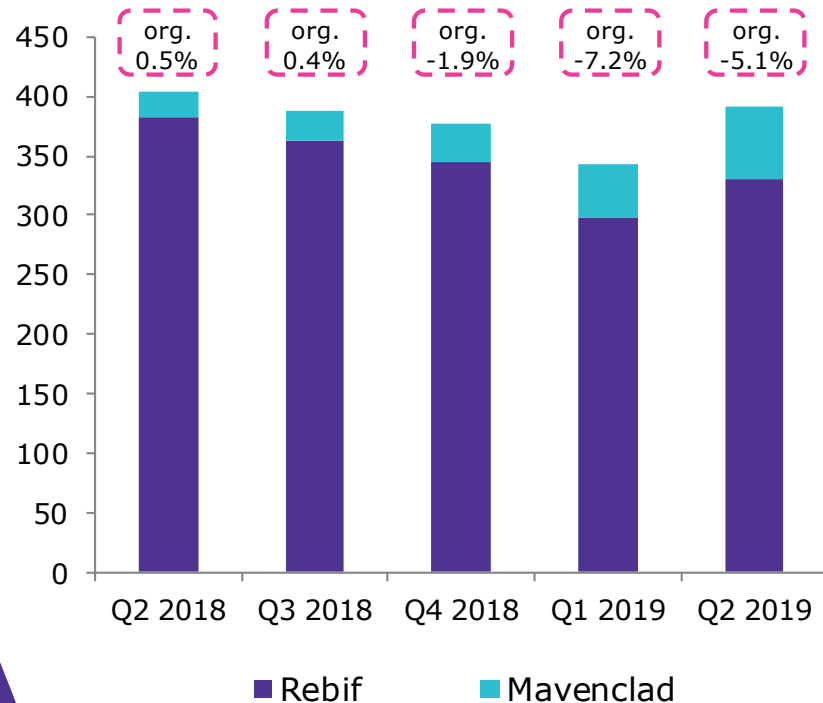


H1 2019 organic sales growth [%]  
by key product [€m]

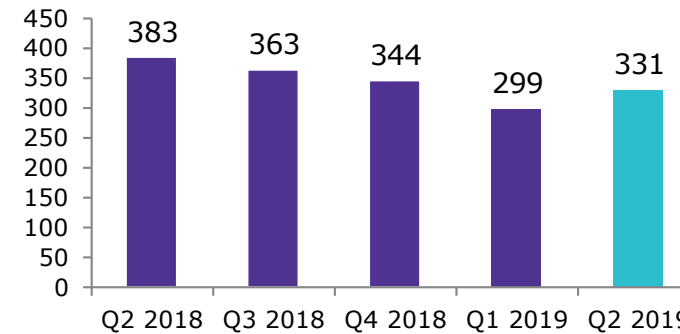


# Neurodegenerative Diseases: Strong growth of Mavenclad<sup>®</sup> still overcompensated by Rebif<sup>®</sup> decline

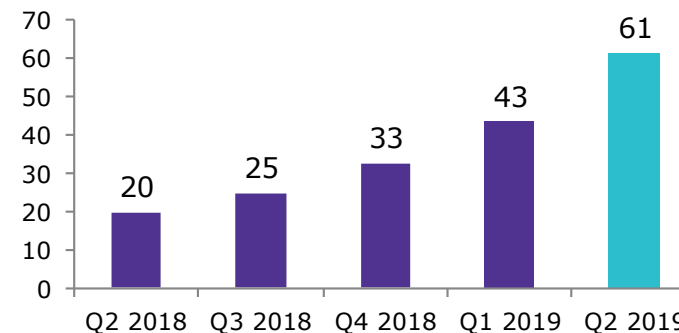
Sales development NDI, [€m]



Rebif<sup>®</sup> net sales, [€m]



Mavenclad<sup>®</sup> net sales, [€m]



- Rebif<sup>®</sup> sales of €331 m in Q2 2019 reflects organic decline of -16.1% mitigated by FX effect of +2.5%
- U.S. and European volume decline mainly due to competition
- U.S. decline in line with IFN market dynamics

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

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

# 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

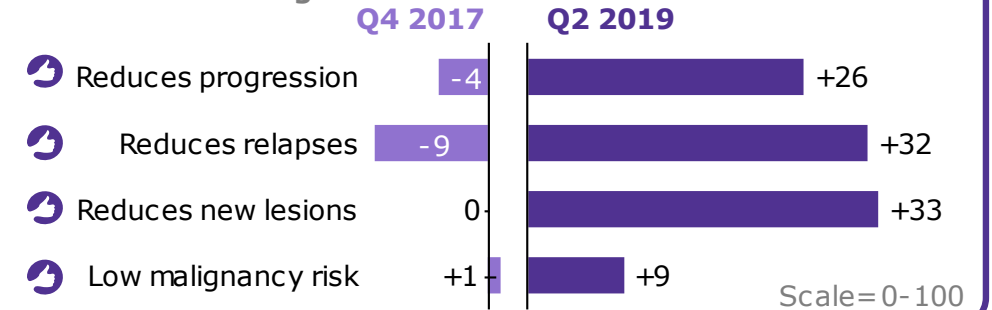


**On track for up to mid-triple digit m€ sales in 2019**

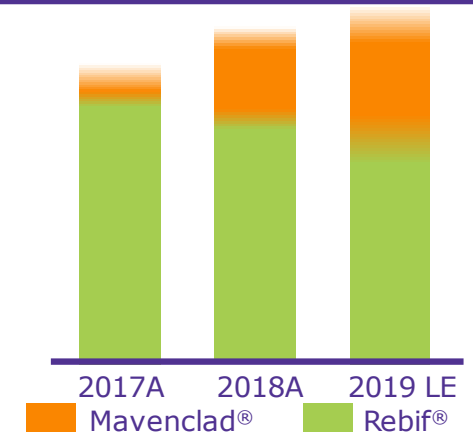


## Improved clinical perception versus leading HE oral (Germany)<sup>4</sup>

### 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

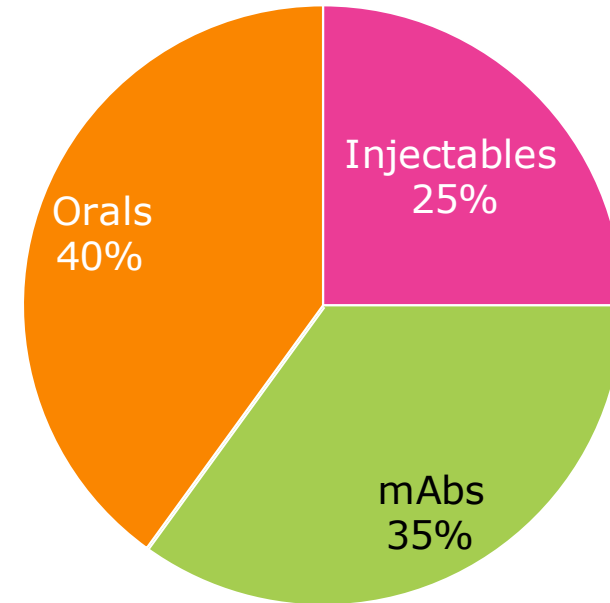
- **Positive, early payer acceptance:**



- **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>



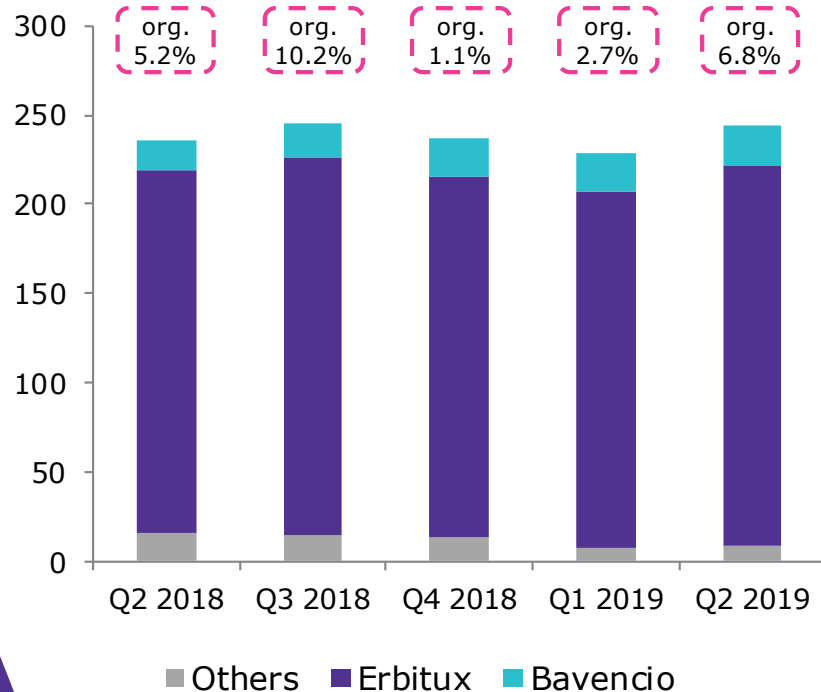
<sup>1</sup>Appropriate USA patients as per MAVENCLAD FDA label; <sup>2</sup>The NDC (National Drug Code) is a unique product identifier code for all drugs in the USA;

<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;

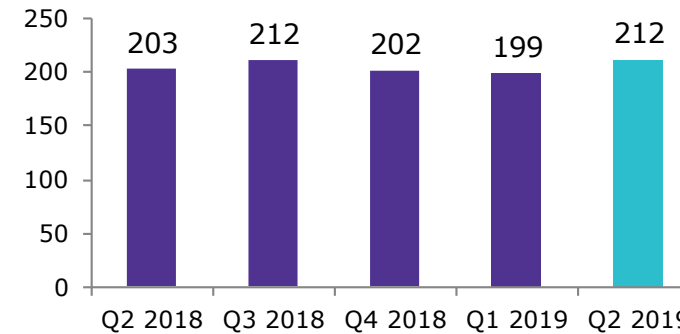
<sup>4</sup>Spherix Global Insights RealTime Dynamix – MS Q2/19; <sup>5</sup>Company data based on MAVENCLAD patient support program "MS Life Lines"

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

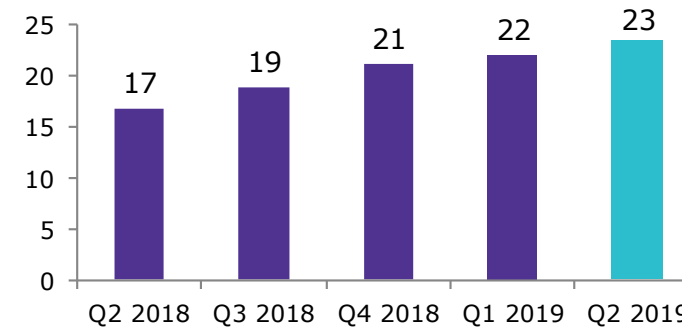
Sales development Oncology, [€m]



Erbitux<sup>®</sup> net sales, [€m]



Bavencio<sup>®</sup> net sales, [€m]



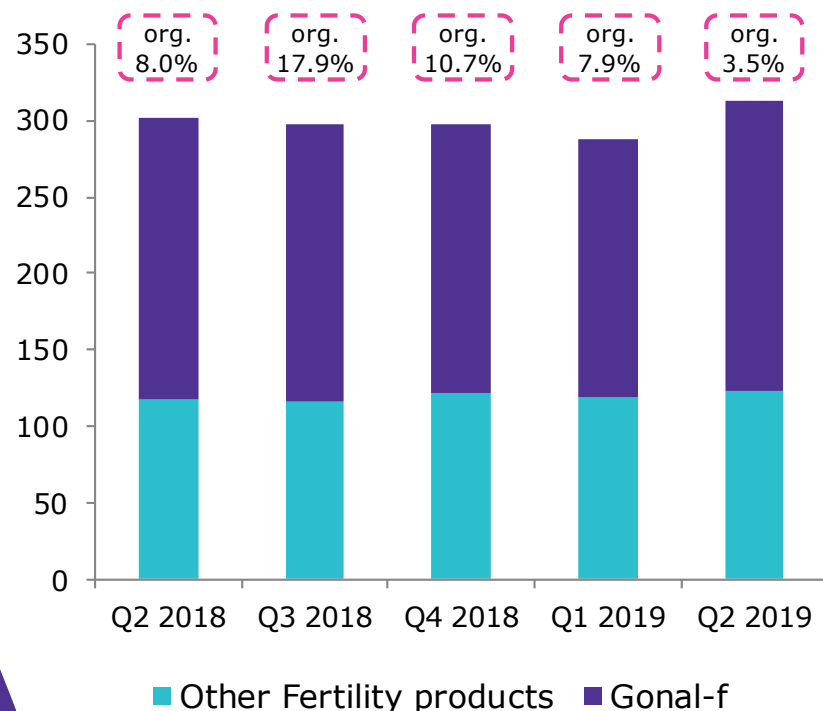
- Absolute sales of €212 m reflect solid growth (org. 5.7%; FX -1.5%)
- Decline in Europe reflects ongoing competition, price reductions and shrinking market size
- LATAM strong, while MEA affected by tender phasing due to import permit
- Strong APAC driven by China reimbursement recognition

**Bavencio<sup>®</sup> approved for RCC in US mid May 2019**

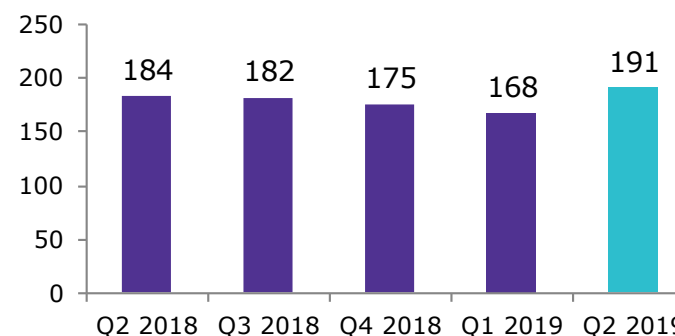
**FY 2019 guidance of high double-digit €m**

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

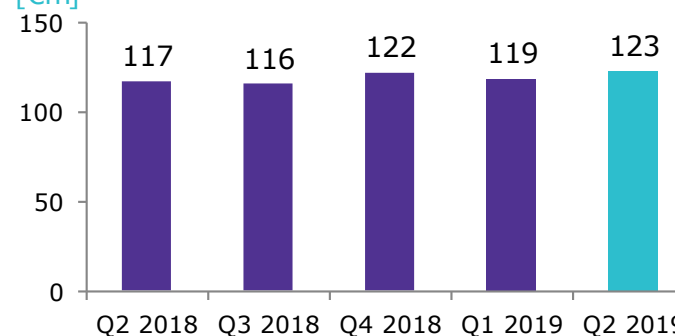
Sales development Fertility, [€m]



Gonal-f<sup>®</sup> net sales, [€m]



Other Fertility products net sales, [€m]

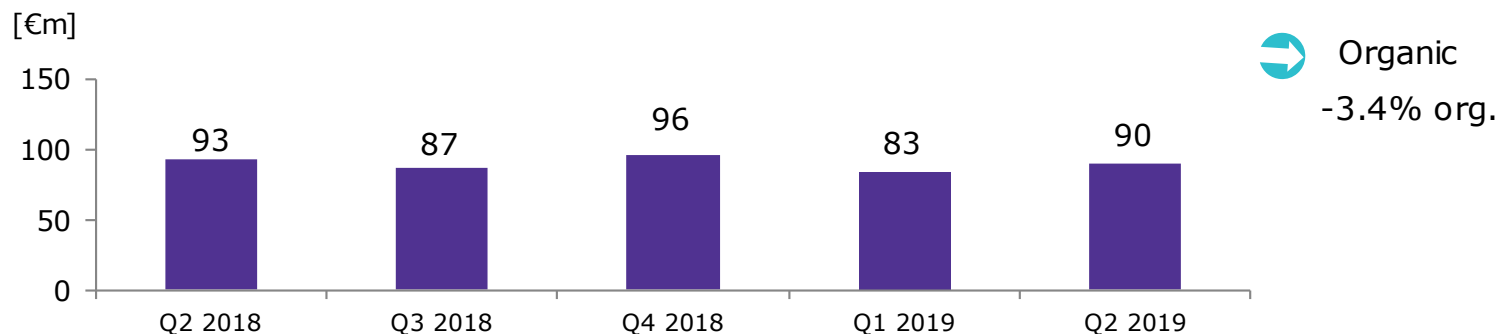


- Fertility franchise posts moderate organic growth driven by North America and APAC
- Gonal-f<sup>®</sup> absolute sales reflect moderate growth posting €191 m (org. 2.8%; FX 0.9%)
- Gonal-f<sup>®</sup> driven by ongoing strong demand in the U.S. despite tough comps last year
- Other Fertility products with solid growth driven by APAC and Europe

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

## Sales evolution

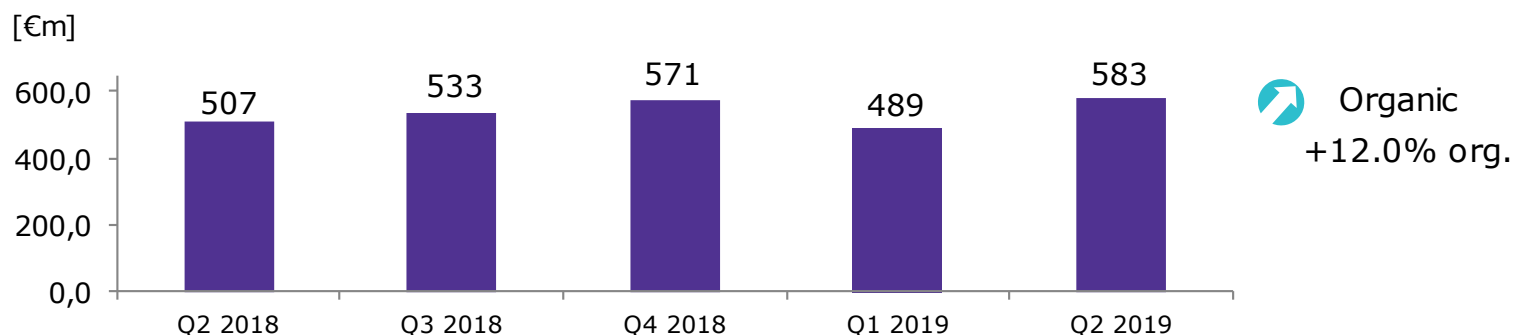
### Endocrinology



## Q2 2019 organic drivers

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

### General Medicine\*



- General Medicine reflects double digit growth of Glucophage<sup>®</sup>, ongoing strong demand for Concor<sup>®</sup> and Euthyrox<sup>®</sup> driven by China and LATAM

\*includes CardioMetabolic Care & General Medicine and Others

# Life Science: Strong organic growth fueled by all businesses

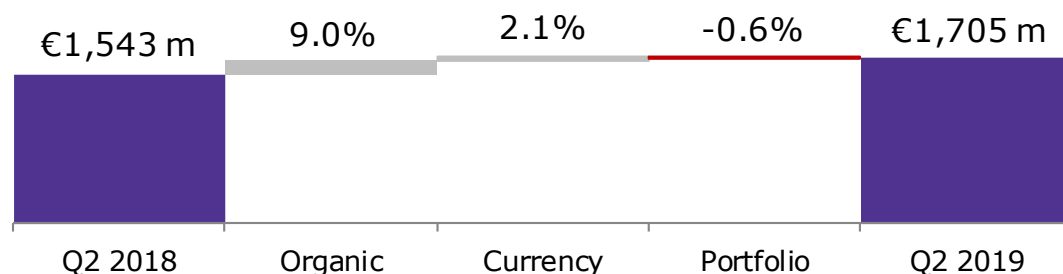
## Life Science P&L

[€m]	Q2 2018 <sup>1</sup>	Q2 2019
Net sales	1,543	<b>1,705</b>
Marketing and selling	-452	<b>-490</b>
Administration	-65	<b>-68</b>
Research and development	-61	<b>-69</b>
EBIT	254	<b>322</b>
EBITDA	442	<b>518</b>
EBITDA pre	452	<b>533</b>
Margin (in % of net sales)	29.3%	<b>31.3%</b>

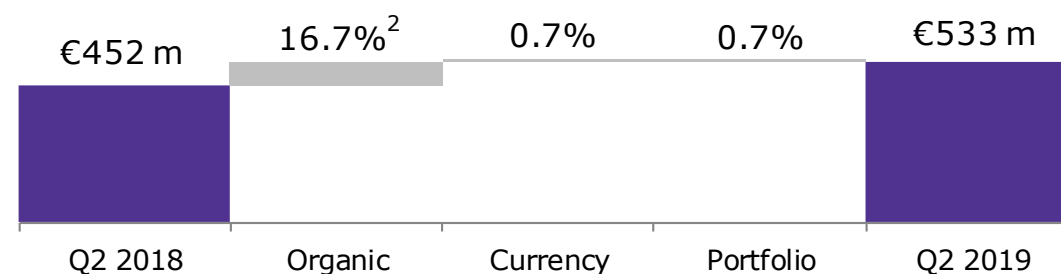
## Comments

- Process Solutions with continued strong demand: double-digit growth in all major business fields, especially single-use
- Advanced Analytical and Lab Water main contributor to Applied Solutions solid organic growth, all business segments and regions contributing
- Moderate organic growth of Research Solutions due to ongoing strong demand for lab chemicals and workflow tools, especially in APAC and NA
- M&S increase reflects volume growth and investments in eCommerce
- EBITDA pre and margin increase driven by strong top-line

## Net sales bridge



## EBITDA pre bridge



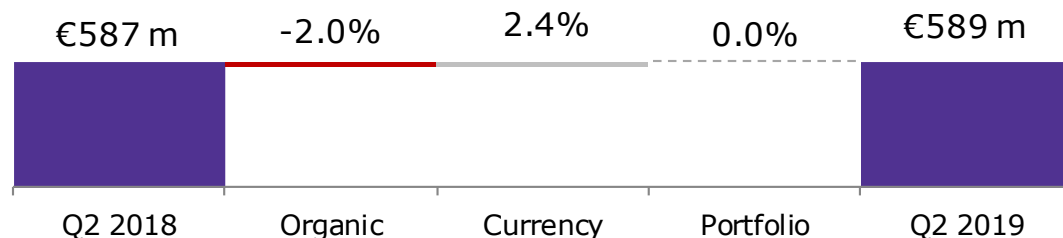
<sup>1</sup>LY numbers have been modified, due to disclosure changes of adjustments; <sup>2</sup>Thereof IFRS 16 effect with +2.8% (+€12 m); Totals may not add up due to rounding

# Performance Materials: Reduced China support for Liquid Crystals mitigated by strong demand for OLED, amid market slowdown in Semiconductor and Surface

## Performance Materials P&L

[€m]	Q2 2018 <sup>1</sup>	Q2 2019
Net sales	587	<b>589</b>
Marketing and selling	-61	<b>-66</b>
Administration	-27	<b>-25</b>
Research and development	-59	<b>-74</b>
EBIT	131	<b>100</b>
EBITDA	192	<b>161</b>
EBITDA pre	196	<b>190</b>
Margin (in % of net sales)	33.4%	<b>32.3%</b>

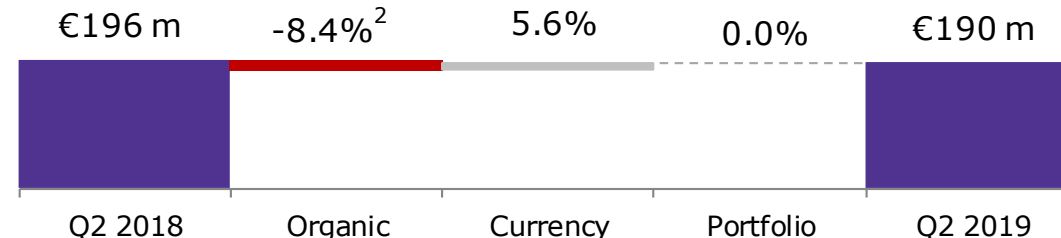
## Net sales bridge



## Comments

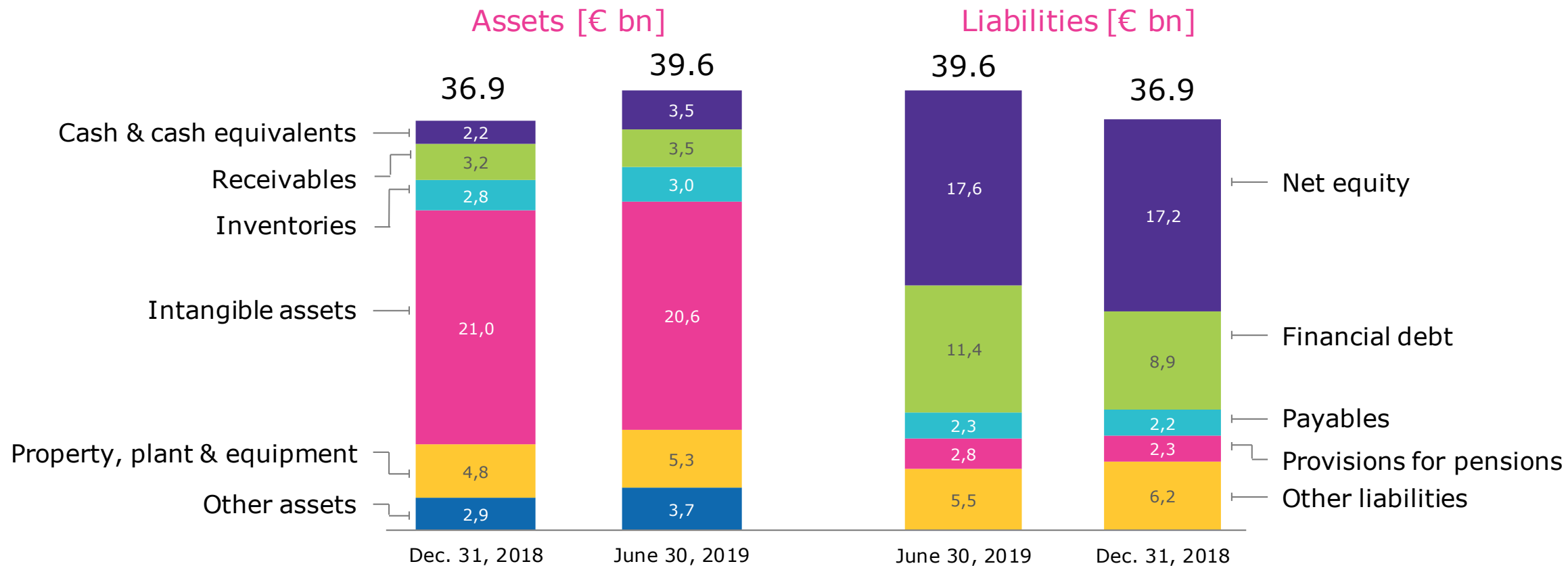
- About stable Display Solutions sales driven by strong demand for OLED, almost offset by decline in LC due to deceleration of China ramp-up support
- Softness of Semiconductor Solutions reflects market slowdown
- Surface Solutions below prior year due to weak automotive market
- Provisions related to Bright Future program drive M&S and R&D increase; adjusted for EBITDA pre - decrease in R&D reflecting cost control
- EBITDA pre impacted by ongoing liquid crystal price decline and slowing China ramp up contribution as well as reduced fixed cost leverage due to softness in Surface Solutions and Semiconductor Solutions

## EBITDA pre bridge



<sup>1</sup>LY numbers have been modified, due to disclosure changes of adjustments; <sup>2</sup>Thereof IFRS 16 effect with +1.3% (+€3 m); Totals may not add up due to rounding

## Balance sheet – Reflecting bond placements and IFRS 16 adoption



- Higher cash & cash equivalents driven by bond placements (€1.5 bn)
- Property, plant and equipment increase mainly due to IFRS 16 adoption
- Other assets reflect temporary investment of cash proceeds from Consumer Health divestment

- Increase in equity reflects profit after tax (equity ratio of 44.4%)
- Higher financial debt due to bond placements (€1.5 bn) and IFRS 16 reclassification of lease liabilities
- Increase of provisions for pensions reflects decline in interest rate

Totals may not add up due to rounding

# Reported figures

## Reported results

[€m]	Q2 2018	Q2 2019	Δ
EBIT	392	<b>618</b>	57.6%
Financial result	-65	<b>-61</b>	-5.4%
Profit before tax	328	<b>557</b>	70.0%
Income tax	-84	<b>-136</b>	62.8%
<i>Effective tax rate (%)</i>	25.5%	<b>24.4%</b>	
Net income <sup>*</sup>	247	<b>471</b>	90.8%
EPS (€)	0.57	<b>1.08</b>	89.5%

## Comments

- Increased EBIT due to Peg-Pal and Bavencio<sup>®</sup> milestones, GSK deferred income as well as strong top-line contribution from Life Science
- Effective tax rate within guidance range of ~24-26%
- Higher net income and EPS reflect higher EBIT

\*From continuing and discontinued operations;  
Totals may not add up due to rounding

# Cash flow statement

## Q2 2019 – cash flow statement

[€m]	Q2 2018	Q2 2019	Δ
Profit after tax	251	<b>471</b>	220
D&A	448	<b>453</b>	5
Changes in provisions	34	<b>-47</b>	-80
Changes in other assets/liabilities	-243	<b>-26</b>	217
Other operating activities	25	<b>-51</b>	-76
Changes in working capital	-148	<b>-58</b>	90
Operating cash flow	367	<b>743</b>	375
Investing cash flow	-200	<b>-870</b>	-671
thereof Capex on PPE	-168	<b>-165</b>	3
Financing cash flow	-295	<b>1,244</b>	1,539

## Cash flow drivers

- Profit after tax in line with higher EBIT
- Changes in provisions driven by LTIP\* adjustment
- Changes in other assets/liabilities reflects GSK upfront and Peg-Pal milestone payment
- Changes in working capital driven by increased trade accounts payable
- Increased investing cash flow due to temporary investment of cash proceeds from Consumer Health divestment
- Higher financing cash flow reflects the issuance of new hybrid bonds (€1.5 bn)

\*LTIP – long-term incentive plan;  
Totals may not add up due to rounding

# Adjustments in Q2 2019

## Adjustments in EBIT

[€m]	Q2 2018		Q2 2019	
	Adjustments	thereof D&A	Adjustments	thereof D&A
Healthcare	40	0	5	0
Life Science	26	16	15	0
Performance Materials	5	1	29	0
Corporate & Other	26	0	16	0
Total	97	17	65	0

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.

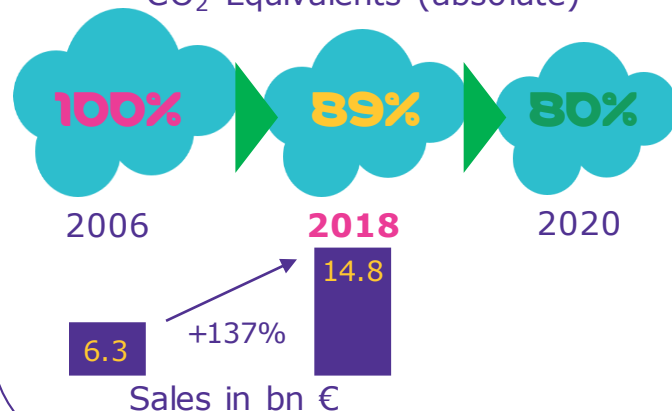


# Emissions, Water, Waste reduced despite growing business

## 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

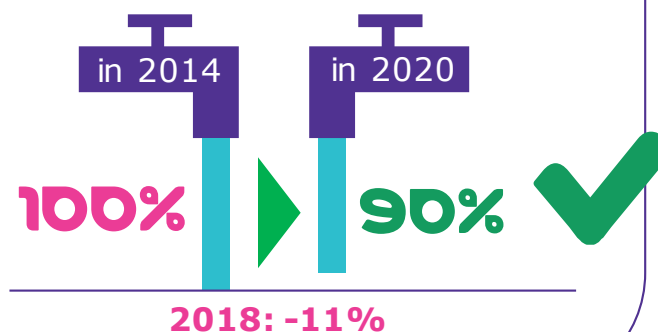
CO<sub>2</sub>-Equivalents (absolute)



## 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



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).

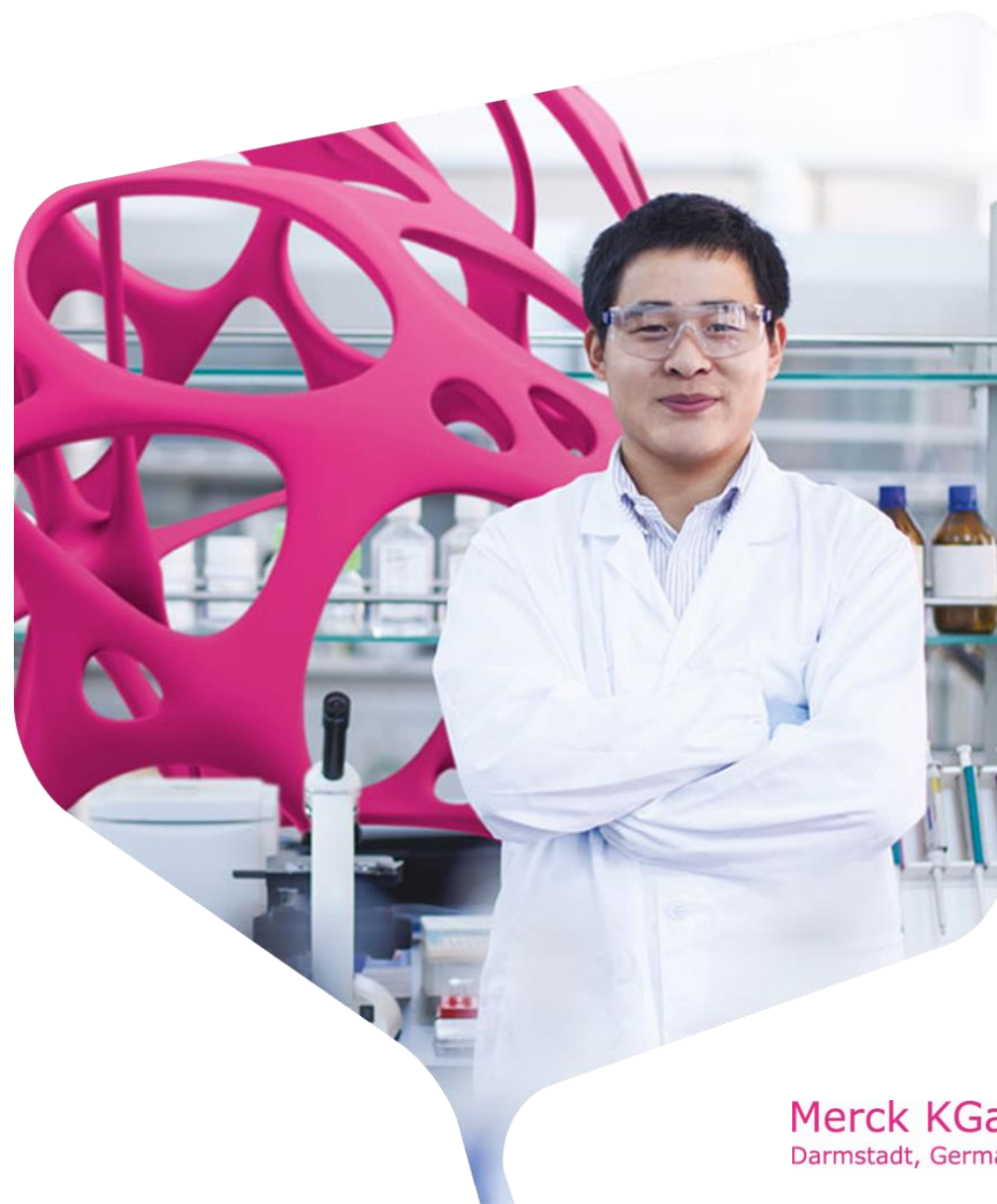
**CDP Water:** In 2018 we received a "B-" (2017: B).

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
November 14, 2019	Q3 2019 Earnings release
March 5, 2020	FY 2019 Earnings release
April 24, 2020	Annual General Meeting
May 14, 2020	Q1 2020 Earnings release



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