



# FY 2019 Results

February 13, 2020

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The implementation of the strategy has to be submitted to the relevant staff representation authorities in each country concerned, in compliance with the specific procedures, terms and conditions set forth by each national legislation.

The Group operates in certain geographical regions whose governmental finances, local currencies or inflation rates could be affected by the current crisis, which could in turn erode the local competitiveness of the Group's products relative to competitors operating in local currency, and/or could be detrimental to the Group's margins in those regions where the Group's drugs are billed in local currencies.

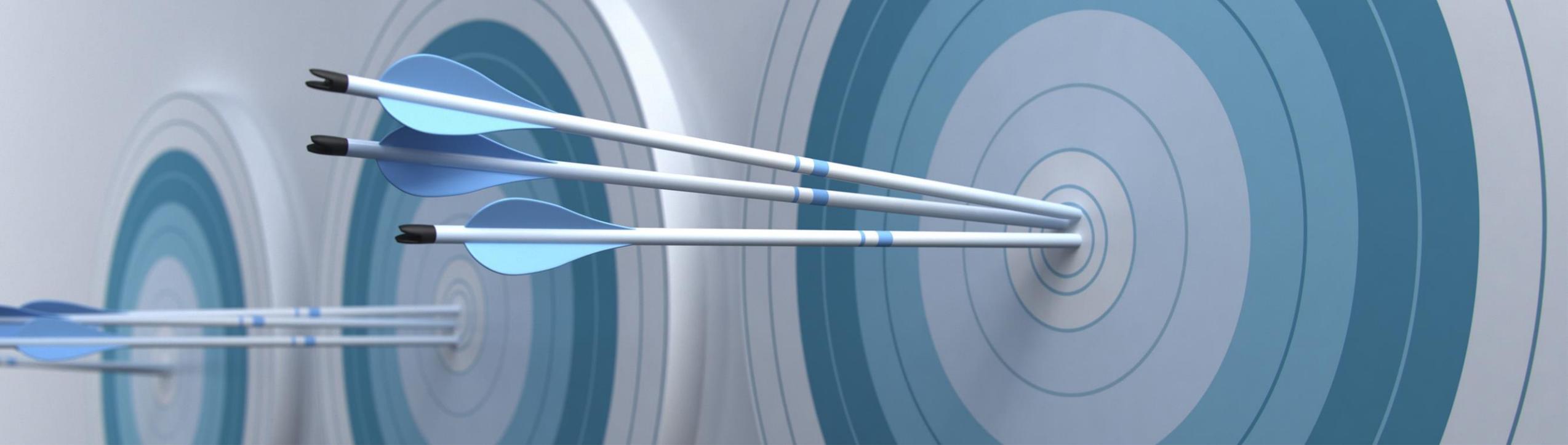
In a number of countries, the Group markets its drugs via distributors or agents: some of these partners' financial strength could be impacted by the crisis, potentially subjecting the Group to difficulties in recovering its receivables. Furthermore, in certain countries whose financial equilibrium is threatened by the crisis and where the Group sells its drugs directly to hospitals, the Group could be forced to lengthen its payment terms or could experience difficulties in recovering its receivables in full.

Finally, in those countries in which public or private health cover is provided, the impact of the financial crisis could cause medical insurance agencies to place added pressure on drug prices, increase financial contributions by patients or adopt a more selective approach to reimbursement criteria.

All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.

# Agenda

- 01 Excellent 2019 operating performance including sound financial structure
- 02 Setback in palovarotene development program
- 03 Strong business fundamentals and strategy
- 04 Solid 2020 guidance / Updated 2022 outlook
- 05 Conclusion/ Q&A



01

## FY 2019 Financial Performance

# Delivering strong 2019 operating performance and sound financial structure



## Top line



**Group sales exceeded €2.5bn**

**Double-digit Group sales growth of +14.8%<sup>1</sup>** driven by Specialty Care growth of +17.2%<sup>1</sup>

Strong performance across all major Specialty Care products and geographies

Somatuline exceeded €1.0 billion in sales

## Bottom line



Core Operating Income growth of +18.6% and **margin expansion to 30.4%**

Leveraging global commercial Oncology infrastructure

**Accelerated investment in R&D** (>15% of net sales), including palovarotene

## Financial structure



**Sound financial structure** with net debt at €1.1 billion after acquisition of Clementia

**Net leverage ratio<sup>2</sup> of 1.3x** allowing for additional investments in future growth

**Proposed distribution of €1.00 per share<sup>3</sup>**, consistent with the prior year

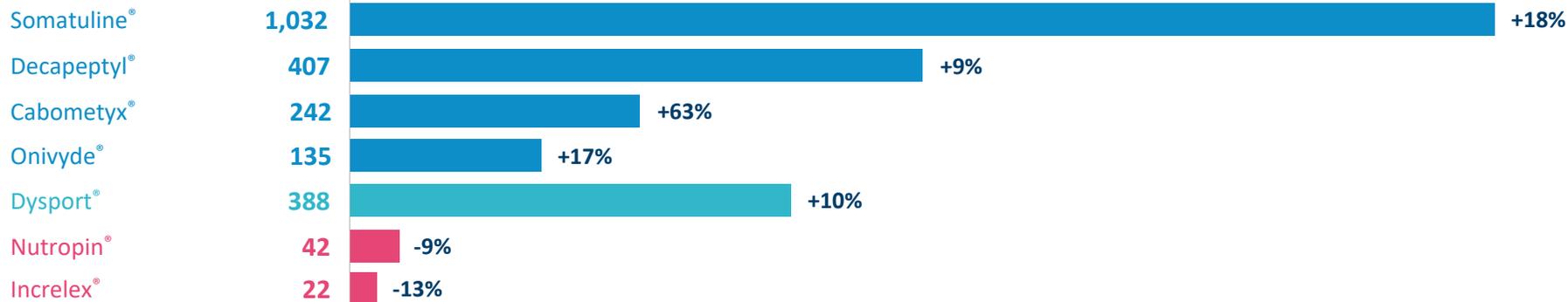
# FY 2019 sales growth driven by Specialty Care



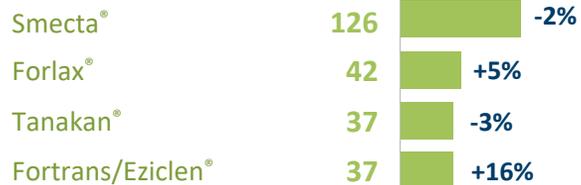
Janice  
Living with cervical dystonia  
Tennessee, USA

Net sales of key products in FY 2019 in million euros – % excluding foreign exchange impact

## Specialty Care sales



## Consumer Healthcare sales



**Group sales**  
€2,576.2m  
**+14.8%<sup>1</sup>**

**Specialty Care**  
€2,299.4m  
**+17.2%<sup>1</sup>**

**Consumer Healthcare**  
€276,8m  
**-1.2%<sup>1</sup>**

Specialty Care growth driven across all major products and geographies

# FY 2019 Commercial highlights



Wade  
Living with acromegaly,  
Salt Lake City, USA

## Oncology

**+20% growth** driven by strong performance across all major products and geographies

**Somatuline sales > €1bn, +18%** including +21% in North America

**Cabometyx sales +63%** reflecting continued steady launch across geographies and indications

**Onivyde sales +17%** in the U.S. and through ex-U.S. partner

**Decapeptyl sales +9%** driven by double-digit growth in China

## Neuroscience

**+10% growth** of strong sustainable neurotoxin franchise

**Dysport brand total sales > €600m**

**U.S.**  
Good performance in the U.S. in the therapeutics and aesthetics markets

**Rest of World**  
Solid performance in the aesthetics market in Brazil, as well as higher sales in Russia and in the Middle East

## Consumer Healthcare

**Sales down -1.2%** with sales growth +0.9% in H2 2019

**Smecta sales -1.8%** mainly due to the new hospital competitive environment in China and lower sales in Algeria

**Fortrans/Eziclen sales up +16.0%** driven by China

**Tanakan sales were down 3.2%** due to lower demand in China

# Investments focused on pipeline and commercial support

In €m	FY 2019	FY 2018	% Change
<b>Net sales</b>	<b>2,576.2</b>	<b>2,224.8</b>	<b>+15.8%</b>
Other Revenues	116.5	123.6	-5.7%
<b>COGS</b>	<b>(488.0)</b>	<b>(454.2)</b>	<b>+7.4%</b>
<i>as % of net sales</i>	<i>18.9%</i>	<i>20.4%</i>	
<b>Selling expenses</b>	<b>(838.6)</b>	<b>(787.4)</b>	<b>+6.5%</b>
<i>as % of net sales</i>	<i>32.6%</i>	<i>35.4%</i>	
<b>R&amp;D Expenses</b>	<b>(388.8)</b>	<b>(302.1)</b>	<b>+28.7%</b>
<i>as % of net sales</i>	<i>15.1%</i>	<i>13.6%</i>	
<b>G&amp;A Expenses</b>	<b>(181.4)</b>	<b>(165.7)</b>	<b>+9.5%</b>
<i>as % of net sales</i>	<i>7.0%</i>	<i>7.4%</i>	
Other core operating income and expenses	(13.2)	(20.8)	
<b>Core Operating Income</b>	<b>782.6</b>	<b>659.9</b>	<b>+18.6%</b>
<b>Core Operating Margin</b>	<b>30.4%</b>	<b>29.7%</b>	<b>+0.7 pts</b>

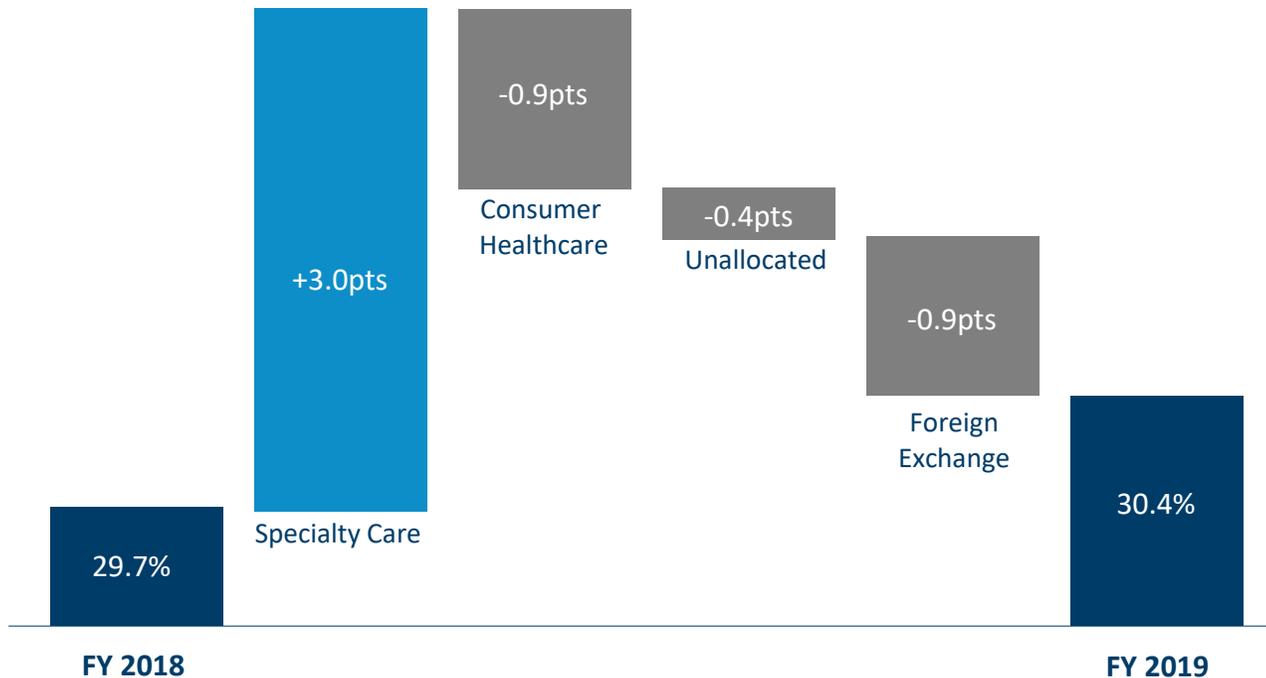
**COGS:** Improvement from positive mix effect of growing Specialty Care business offset by higher Cabometyx royalties

**Selling expenses:** Limited growth in commercial investments to support Specialty Care product growth thanks to disciplined and smart allocation of resources

**R&D investments:** Significant increase to support advancement of internal pipeline programs in oncology and neurotoxins and for palovarotene

**G&A expenses:** Increase resulting from the impact of increased corporate structure and new rare disease infrastructure

# Operating leverage driving core operating margin expansion



Further Core Operating Income margin expansion **exceeding 30.0%** of net sales

Group margin expansion **driven by Specialty Care growth** despite dilutive impact of palovarotene development costs

**Consumer Healthcare** lower profitability as compared to the Group margin with selected investments based on limited top-line growth

Negative limited impact of currencies on profitability

# Core Operating Income to Consolidated Net Profit



In €m	FY 2019	FY 2018	Change
<b>Core Operating Income</b>	<b>782.6</b>	<b>659.9</b>	<b>+122.8</b>
<i>Core operating margin</i>	<i>30.4%</i>	<i>29.7%</i>	<i>+0.7pts</i>
Amortization of intangible assets	(83.8)	(73.1)	-10.7
Restructuring/ Other operating income and expense	(63.4)	(52.3)	-11.1
Impairment gain / (loss)	(668.8)	(15.0)	-653.8
<b>Operating Income / (loss)</b>	<b>(33.4)</b>	<b>519.4</b>	<b>-552.8</b>
Net financing costs	(28.0)	(5.3)	-22.7
Other financial income / expense	22.8	(20.1)	+42.9
Income taxes and other	(11.7)	(105.0)	+93.3
<b>Consolidated net profit / (loss)</b>	<b>(50.2)</b>	<b>389.1</b>	<b>-439.3</b>

## Operating Income

Impairment loss of €669 million before tax related to the recent setbacks in the palovarotene development program

Restructuring and Other Operating costs mainly from the Group's transformation programs and the Clementia acquisition and integration costs

## Consolidated net profit

Other financial income/ expense including the Clementia CVR revaluation, partly offset by the Onivyde earnout revaluation

Income taxes including the write-off of deferred tax assets related to Clementia, offset by the positive impact of the palovarotene intangible asset impairment on deferred tax

# Strong cash flow generation and sound financial structure

## 2019 Free Cash Flow at €468m (+2.2% vs. 2018)

with an EBITDA of €873m (+22%), limited increase in working capital and increased capital expenditure

*Strong Free Cash Flow conversion to support business development strategy*

## Net Debt at €1.1bn at the end of 2019

after acquisition of Clementia for €1.0bn and dividend paid for €83m

## Net debt to EBITDA at 1.3x in 2019,

below industry average

## Full refinancing in 2019

to increase debt capacity for future business development, extend the maturity horizon and diversify sources of financing:

*€1.5 billion 5-year revolving credit facility (RCF)*

*\$300 million dual-tranche issuance of notes on the U.S. market (U.S. Private Placement)*

## Significant financing capacity

to leverage balance sheet up to **2.0x net debt to EBITDA**

*>€1bn business development fire power by end of 2020*



02

## Palovarotene Update

# Setback in palovarotene development program

## What happened

- **FDA partial clinical hold** for patients below 14 years in FOP and MO studies
  - *Dosing discontinued in this population; FDA letter received by end of December*
- IDMC informed Ipsen that Phase 3 MOVE trial reached pre-specified second interim futility analysis criteria
  - *Ipsen **paused dosing of patients ( $\geq 14$  years) in FOP trials**; IDMC recommended to not discontinue trials based on **encouraging therapeutic activity** observed in post-hoc analyses*

## Next steps

- Expeditious assessment of Phase 3 MOVE dataset
- Questions being addressed from FDA and other health authorities
- **Next steps of the program to be decided as soon as possible** in close collaboration with patients, investigators, ethics committees and regulatory authorities

## Financial implications

- Partial impairment of **€668.8m** before tax based on risk-adjusted scenarios (non cash)
- Discounted accounting value of CVR and earnout related to MO reducing net debt by **€114.6m**

# Commitment to FOP and to build successful Rare Diseases franchise



Marin  
Living with fibrodysplasia ossificans progressiva  
Hamilton, Canada

## FOP: Ultra-rare and severely-disabling bone disorder with no therapeutic treatment options

### Palovarotene

- Most advanced clinical program for the treatment of FOP
- Ipsen remains highly committed and motivated to bring the first therapeutic treatment option to the FOP patient community

### BLU-782

- Most advanced ALK2 inhibitor in development for FOP - Different mechanism of action addressing the underlying cause of FOP
- Phase 1 showed BLU-782 is well-tolerated; expect to initiate Phase 2 in 2020

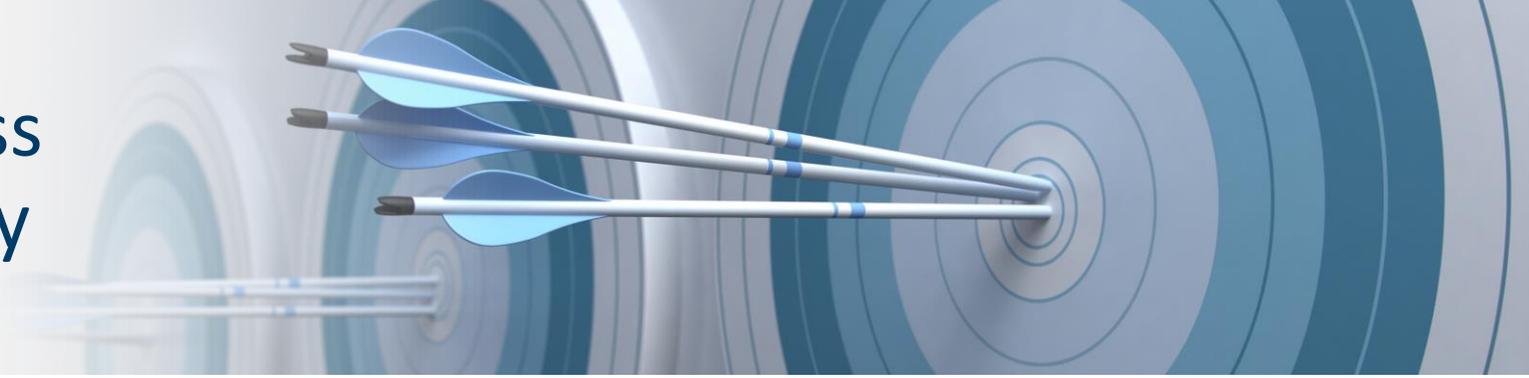




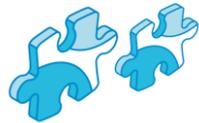
03

## Strong Business Fundamentals and Strategy

# Confirming strong business fundamentals and strategy



Diversified geographical footprint



Strong Specialty Care franchise built over the years



Sound financial structure and attractive cash flow conversion



Advancing R&D pipeline

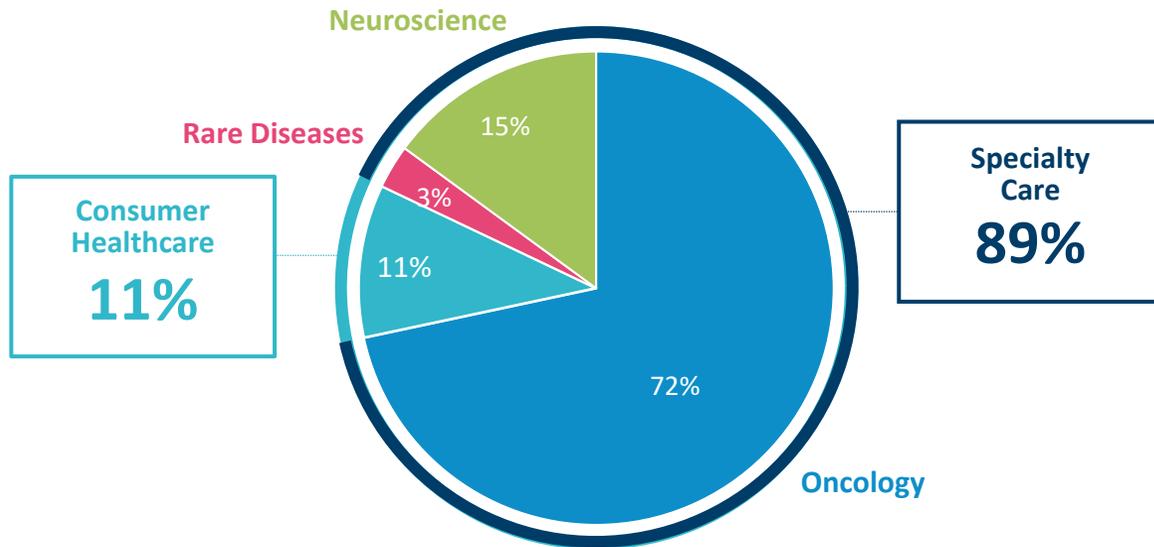


Disciplined business development strategy

# Leading global biopharma focused on innovation and Specialty Care

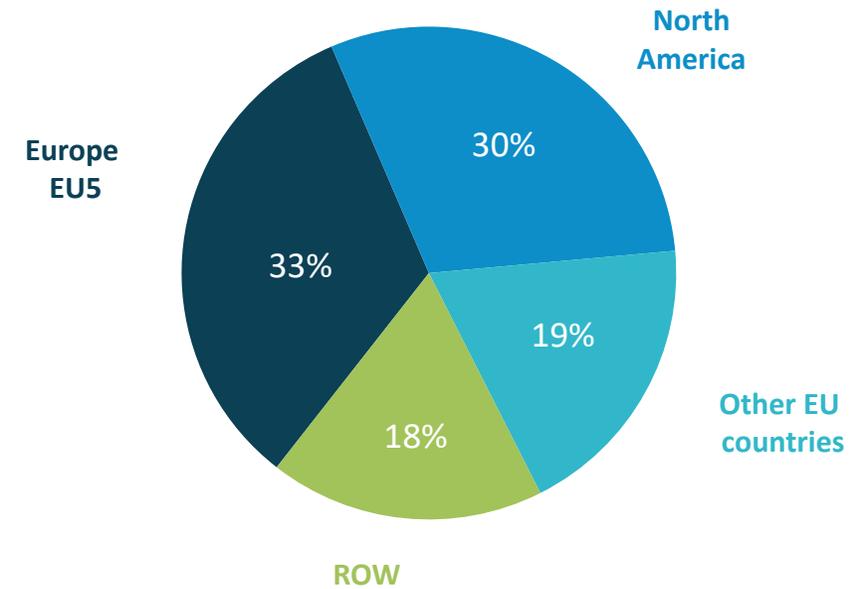
## Sales by therapeutic area

FY 2019 sales by therapeutic area



## Sales by geography

FY 2019 sales by geographical area



# Strong Specialty Care franchise built over the years



**Ronny**  
Living with neuroendocrine tumors  
Ringwood, UK

## Oncology

Established niche presence

**Somatuline: Best-in-class SSA** with superior clinical profile, positive real-world evidence, new delivery system

**Decapeptyl: Recommended backbone therapy** in prostate cancer with expanded use in other indications

**Cabometyx: TKI of choice in 2L RCC;** significant 2L RCC opportunity as IO combinations move into 1L RCC

**Onivyde: Strong synergies** with U.S. commercial oncology team

**Significant LCM programs** in additional indications to expand benefits and market potential (Cabometyx, Onivyde)

## Neuroscience

Leading player

**Leading neurotoxin Dysport**

Expertise in research, development, manufacturing, commercialization

**R&D programs for additional indications**  
– Phase 2 trials for hallux valgus and vulvodynia

**Recombinant neurotoxins** to provide innovative solutions along treatment paradigm - Fast acting neurotoxin entering in Phase 2 and long-acting program in preclinical

## Rare Diseases

Establishing niche presence

Proven capabilities and patient-centric model to serve unmet medical needs

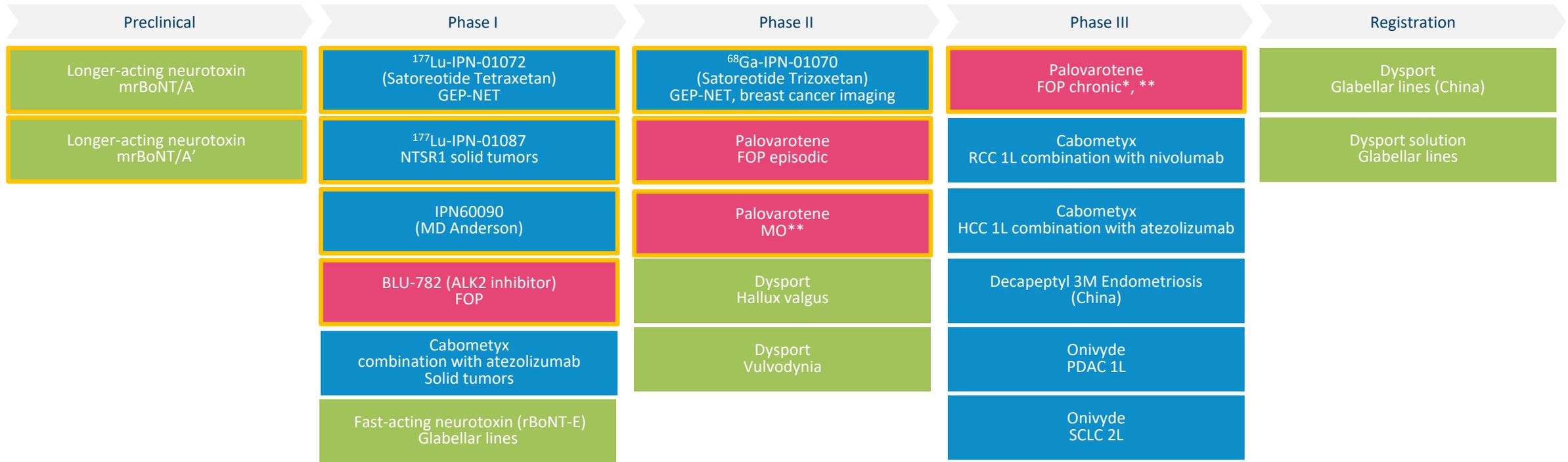
**Established Rare Disease assets** in endocrinology (Increlex, Nutropin)

**Establishing leadership position in FOP** with anchor asset palovarotene and additional licensing of BLU-782

Remain committed to developing the first therapeutic treatment option for the FOP patient community

**Searching for additional assets** in selected rare disease space with unmet medical needs and well-defined patient population

# Advancing solid pipeline across 3 strategic TAs with several significant Phase 3 / registrational trials



# Delivering key R&D milestones in 2020



## Program advancements

Long-acting neurotoxin (A)  
Phase 1/2  
Spasticity and aesthetics

Fast-acting neurotoxin  
Phase 2  
Glabellar lines

BLU-782  
Phase 2  
FOP

## Top-line results

Cabometyx  
Phase 3 CheckMate 9ER  
1L RCC combo w/Opdivo

Dysport  
Phase 2  
Hallux Valgus

Decapeptyl  
Phase 3  
3M Endometriosis

## Regulatory decisions

Dysport  
Glabellar Lines  
(China)

Dysport solution  
Glabellar Lines  
(EU)

# Driving disciplined business development strategy for long-term sustainability

## Core therapeutic areas targeted

### Oncology

Differentiated, best-in-class assets in specialized niche markets

### Neuroscience

Expertise in research, development, manufacturing, commercialization

### Rare Diseases

Proven capabilities and patient-centric model to serve unmet medical needs

## Type of investments

### Full maturity spectrum:

Early and mid-stage assets to low-risk late-stage investments

### All types of transactions:

licensing, partnership, co-development, M&A transactions

### Deal structuring of transactions to minimize risk

## Funding and management of investments

Strong Free Cash Flow generation to replenish **firepower to >€1bn by end of 2020, growing beyond**

**Focus on capital discipline** and risk/return profile of transactions



04

## 2020 Guidance Updated 2022 Outlook

# 2020 guidance



## Sales growth

**>+6.0%** at constant currency

- Assuming no impact of currencies based on the current level of exchange rates
- Assuming no impact in 2020 of new SSA generic entry

## Core Operating margin

**~30.0%** of net sales

- Assuming no impact in 2020 of new SSA generic entry
- Excluding the impact of incremental investments in pipeline expansion initiatives

**High single-digit sales growth for Specialty Care** Including impact of octreotide generic on Somatuline in EU and lower sales for Onivyde

**Mid single-digit sales decline for Consumer Healthcare** Considering challenging competitive environment in China hospital channel and in France

**Increasing investment in R&D** to support internal pipeline in Oncology, Neuroscience and Rare Diseases

**Leveraging global Specialty Care** commercial infrastructure

**Protecting Consumer Healthcare** profitability through cost optimization

# Updated 2022 financial outlook



**Group Net Sales >€2.8bn**  
(assuming current level of exchange rates)

**Core Operating Margin >28.0%**  
(as % of net sales)

2019

2020

2021

2022

- **Existing portfolio**, assumes no approval of additional meaningful products or indications
  - *No sales assumed for palovarotene*
- **Assuming progressive entry** of additional octreotide and lanreotide generics globally from 2021
- **Excluding the impact of incremental investments in pipeline expansion initiatives**
  - *Early and mid-stage pipeline transactions could negatively impact short-term margins*

# Solid product portfolio

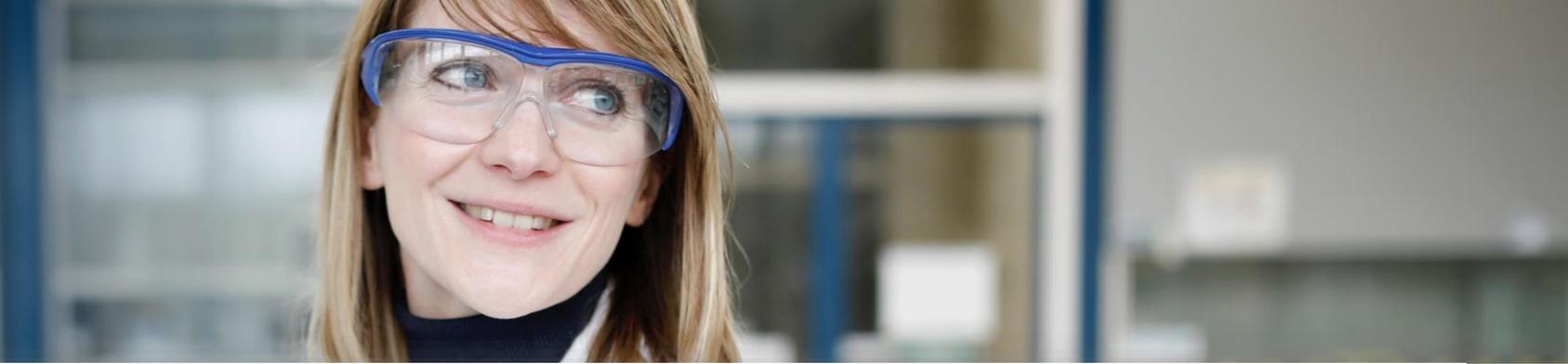
	Brand/ asset	Geographies	Major indications	Growth / Peak sales
Specialty Care	 Somatuline autogel	Global	Neuroendocrine Tumors (NET) Acromegaly	Double-digit volume growth until potential impact of lanreotide generic
	 Decapeptyl <sup>®</sup> SR triptorelin	Ex-U.S. and Japan	Prostate Cancer	Mid single-digit growth in all territories (assuming no generic impact in China)
	 CABOMETYX <sup>®</sup> (cabozantinib) tablets	Ex-U.S. and Japan	Renal Cell Carcinoma (RCC) Hepatocellular Carcinoma (HCC)	Expected peak sales of €400m on current approved indications
	 onivyde <sup>™</sup> (irinotecan liposome injection)	U.S. only	Pancreatic cancer	Expected peak sales of \$175m <sup>1</sup> for current indication in 2L PDAC post gemcitabine
	 Dysport <sup>®</sup> (abobotulinumtoxinA)	Global	Spasticity (Tx) Glabellar lines (Ax)	Double-digit growth in line with market growth in both therapeutic and aesthetic markets
CHC	 smecta <sup>®</sup>  tanakan  forlax <sup>®</sup> 10g Macrogol 4000	Mainly France, Russia and China	Gastro Intestinal (GI)	Expected to grow in line with Consumer Healthcare market



05

Conclusion  
Q&A

# 2020 Objectives



## Growth

- Maximize growth, value and market share worldwide for differentiated best-in-class Specialty Care products
- Continue Consumer Healthcare transformation and autonomy
- Leverage current organization and optimize cost base for growth



## Pipeline

- Increase value of internal pipeline by transforming R&D organization and prioritizing key internal R&D programs
- Foster disciplined business development strategy to bring new assets or products and build innovative and sustainable pipeline



## Culture

- **People:** Continue transformation through leadership and people
- **Patients:** Bring innovative therapies to patients with unmet medical needs
- **Environment:** Minimize impact by ensuring activities are safe and sustainable

Deliver long-term superior value to patients and shareholders



# Q&A



**Marin**  
Living with fibrodysplasia ossificans progressiva  
Hamilton, Canada

Thank You



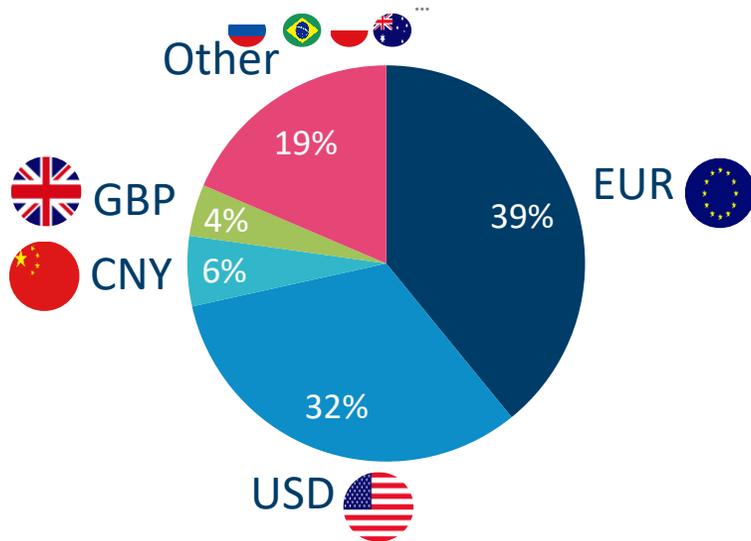
# From consolidated net profit to core net profit

<i>In €m</i>	Actual 2019 Reported	Palovarotene impairment impacts	Actual 2019 Before Impairment
<b>Consolidated net profit</b>	<b>-50.2</b>	<b>448.8</b>	<b>398.6</b>
Amortization of intangible assets (excl. software)	83.8	-	83.8
Other operating income and expenses	35.8	-	35.8
Restructuring costs	27.7	-	27.7
Impairment losses	668.8	-668.8	-
Financial result	-51.6	114.6	63.0
Net profit/(loss) from disc. operations	-4.2	-	-4.2
Tax effects on non current items	-146.6	105.4	-41.2
<b>Core net profit</b>	<b>563.4</b>	<b>-</b>	<b>563.4</b>

# Positive impact of foreign exchange in FY 2019

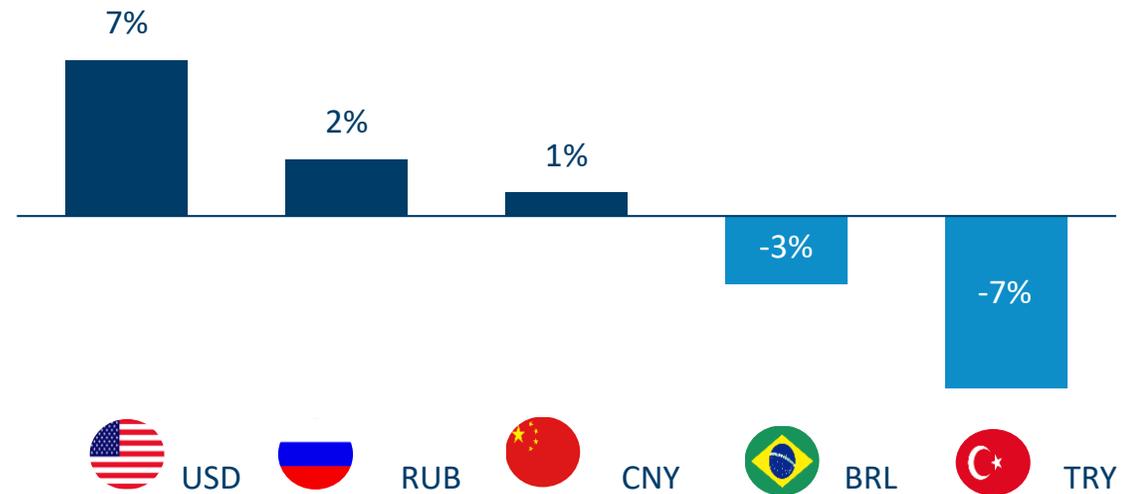
**61% of sales in non-EUR currencies**  
**USD now 32% of sales**

2019 sales by currency<sup>1</sup>



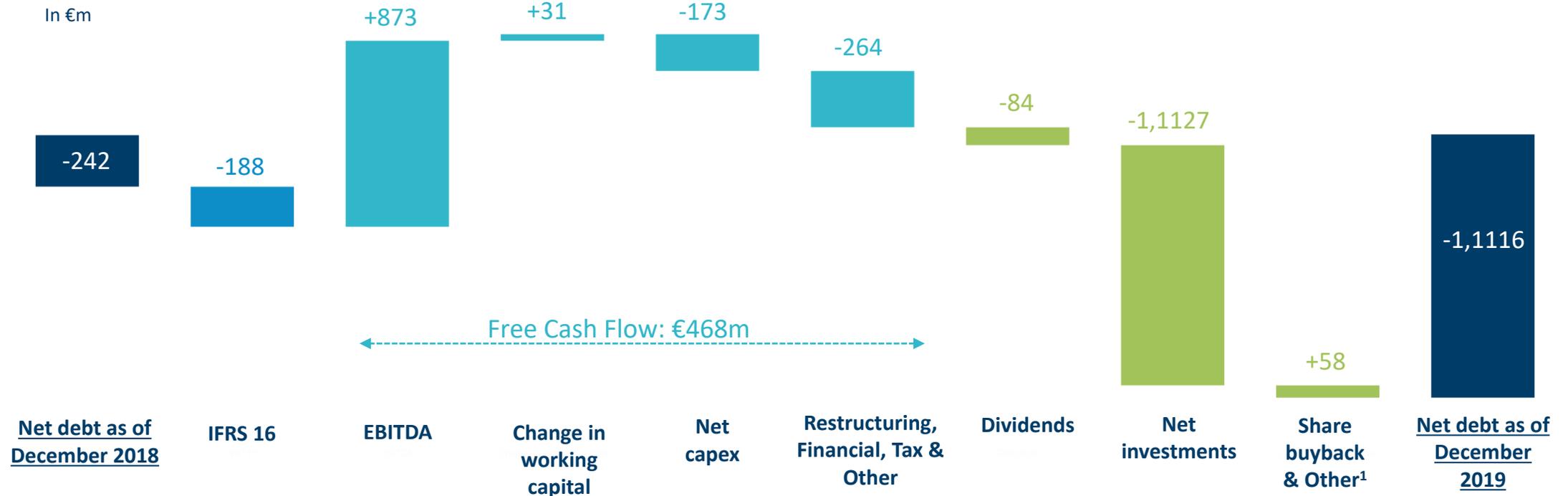
## Sales by geography

Average rates change (2019 vs. 2018)



Positive impact on Sales of +2.1% mainly from higher USD

# Free Cash Flow generation of €468mn strengthening Balance Sheet



Strong Free Cash Flow of €468 million  
 impact of application of IFRS16 (leases) as of January 1, 2019 amounted to €188 million

# Oncology ongoing clinical trial highlights

Trial	Population	Patients	Design	Endpoints	Status	Addressable population in Ipsen territories
Cabometyx Phase 3 CheckMate 9ER NCT03141177	1L RCC	638	<ul style="list-style-type: none"> <li>Arm 1: cabozantinib + nivolumab</li> <li>Arm 2: sunitinib</li> </ul>	<ul style="list-style-type: none"> <li>Primary: PFS</li> <li>Secondary: OS, ORR, safety</li> </ul>	Data expected early 2020	~30K patients
Cabometyx Phase 3 COSMIC 312 NCT03755791	1L HCC	740	<ul style="list-style-type: none"> <li>cabozantinib 40 mg oral, qd + atezolizumab 1200 mg infusion, q3w</li> <li>sorafenib 400 mg bid</li> </ul>	<ul style="list-style-type: none"> <li>Primary: PFS, OS</li> </ul>	Recruiting	~26K patients (ex-China)
Cabometyx Phase 1b NCT03170960	Solid tumors	1732	<ul style="list-style-type: none"> <li>cabozantinib (20 mg, 40 mg, or 60 mg qd) + atezolizumab 1200 mg infusion q3w</li> </ul>	<ul style="list-style-type: none"> <li>Primary: MTD, ORR</li> <li>Secondary: safety</li> </ul>	Recruiting	
Cabometyx Phase 1b NCT03299946	1L HCC	15	<ul style="list-style-type: none"> <li>cabozantinib 40mg daily for 8 weeks + nivolumab 240mg intravenously every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>Primary: safety</li> </ul>	Recruiting	~26K patients (ex-China)
Onivyde Phase 3 NCT03487016	1L PDAC	270	<ul style="list-style-type: none"> <li>Arm 1: Onivyde (nanoliposomal irinotecan) + 5-FU/LV + oxaliplatin</li> <li>Arm 2: Gem-Abraxane</li> </ul>	<ul style="list-style-type: none"> <li>Primary: PFS</li> </ul>	Recruiting	~28K patients
Onivyde Phase 2/3 NCT03088813	2L SCLC	486	<ul style="list-style-type: none"> <li>Onivyde (nanoliposomal irinotecan)</li> <li>Topotecan</li> </ul>	<ul style="list-style-type: none"> <li>Primary: OS</li> <li>Secondary: PFS, ORR, safety</li> </ul>	Recruiting	~14K drug-treated patients
Onivyde Phase 1 NCT01770353	Breast cancer (ER/PR positive, TNBC, active brain metastasis)	45	<ul style="list-style-type: none"> <li>Onivyde (nanoliposomal irinotecan) IV on Days 1 and 15 every 4 weeks + ferumoxytol 5 mg/kg IV once on Day 1</li> </ul>	<ul style="list-style-type: none"> <li>Primary: tumor levels of irinotecan and SN-38</li> <li>Secondary: safety, tumor response rate</li> </ul>	Ongoing	

# Oncology ongoing clinical trial highlights

Trial	Population	Patients	Design	Endpoints	Status
Satoreotide trizoxetan <sup>68</sup> Ga-IPN-01070 Phase 2 NCT03220217	GEP-NET	25	<ul style="list-style-type: none"> <li>Satoreotide trizoxetan</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Difference in relative lesion counts</li> <li>Secondary: Difference in image quality</li> </ul>	Recruiting
IPN01087 Phase 1 NCT03525392	NTSR1 solid tumors	320	<ul style="list-style-type: none"> <li>IPN01087</li> </ul>	<ul style="list-style-type: none"> <li>Incidence DLT and organ exposure to radiation</li> </ul>	Recruiting
IPN 60090 Phase 1 NCT03894540	Solid tumors	236	<ul style="list-style-type: none"> <li>IPN 60090</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Rate of DLT, MTD, RD</li> </ul>	Recruiting

# Neuroscience ongoing clinical trial highlights

Trial	Population	Patients	Design	Endpoints	Status	Addressable population in Ipsen territories
Dysport Phase 2 NCT03569098	Hallux valgus (foot bunions)	165	<ul style="list-style-type: none"> <li>Dysport (AbobotulinumtoxinA)</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Change from baseline in daily Numeric Pain Rating Scale (NPRS) score</li> </ul>	Recruiting	<ul style="list-style-type: none"> <li>High prevalence worldwide: 23%<sup>1</sup></li> <li>15% consult specialist</li> <li>10%<sup>2</sup> moderate to severe patients</li> </ul>
Dysport Phase 2 NCT03598777	Vulvodynia	93	<ul style="list-style-type: none"> <li>Dysport (AbobotulinumtoxinA)</li> <li>Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Safety, change from baseline in vaginal pain on Numeric Rating Scale</li> </ul>	Recruiting	<ul style="list-style-type: none"> <li>6.5%<sup>3</sup> of female population</li> <li>69%<sup>4</sup> consult specialist</li> <li>40% vulvodynia diagnosis</li> <li>60%<sup>5</sup> provoked vulvodynia</li> </ul>

# Rare Diseases ongoing clinical trial highlights

Trial	Population	Patients	Design	Endpoints	Status	Addressable population in Ipsen territories
Palovarotene Phase 3 MOVE NCT03312634	FOP (chronic)	90	<ul style="list-style-type: none"> <li>Palovarotene - 5 mg once daily and upon flare-up, 20 mg once daily for 28 days followed by 10 mg for 56 days</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Change in HO volume</li> </ul>	Dosing paused after reaching pre-specified second interim analysis futility criteria / partial clinical hold on patients <14 years of age	~9K WW
Palovarotene Phase 2	MO	240	<ul style="list-style-type: none"> <li>Palovarotene 2.5 mg daily</li> <li>Palovarotene 5.0 mg daily</li> <li>Placebo</li> </ul>	<ul style="list-style-type: none"> <li>Primary: Annualized rate of new osteochondromas</li> </ul>	Partial clinical hold on patients <14 years of age	~150K WW, ~24K pediatric, moderate to severe