



**Bring**  
The full potential of our innovative medicines to patients



**Build**  
A high-value sustainable pipeline



**Deliver**  
Efficiencies to enable targeted investment & growth



**Boost**  
A culture of collaboration & excellence

# FY 2022 results

9 February 2023



*Focus. Together.  
For patients & society*

# Disclaimer and safe harbor

- This presentation includes only summary information and does not purport to be comprehensive. Forward-looking statements, targets and estimates contained herein are for illustrative purposes only and are based on management’s current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated in the summary information. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably given that a new medicine can appear to be promising at a preparatory stage of development or after clinical trials but never be launched on the market or be launched on the market but fail to sell notably for regulatory or competitive reasons. Ipsen must deal with or may have to deal with competition from generic medicines that may result in market-share losses, which could affect its level of growth in sales or profitability. The Company expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this presentation to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law.
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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.
- In those countries in which public or private-health cover is provided, Ipsen is dependent on prices set for medicines, pricing and reimbursement-regime reforms and is vulnerable to the potential withdrawal of certain medicines from the list of reimbursable medicines by governments, and the relevant regulatory authorities in its locations. In light of the economic impact caused by the COVID-19 pandemic, there could be increased pressure on the pharmaceutical industry to lower medicine prices.
- Ipsen operates in certain geographical regions whose governmental finances, local currencies or inflation rates could erode the local competitiveness of Ipsen’s medicines relative to competitors operating in local currency, and/or could be detrimental to Ipsen’s margins in those regions where Ipsen’s sales are billed in local currencies.
- In a number of countries, Ipsen markets its medicines via distributors or agents; some of these partners’ financial strengths could be impacted by changing economic or market conditions, potentially subjecting Ipsen to difficulties in recovering its receivables. Furthermore, in certain countries whose financial equilibrium is threatened by changing economic or market conditions, and where Ipsen sells its medicines directly to hospitals, Ipsen could be forced to lengthen its payment terms or could experience difficulties in recovering its receivables in full.
- Ipsen also faces various risks and uncertainties inherent to its activities identified under the caption ‘Risk Factors’ in the Company’s Universal Registration Document.
- All of the above risks could affect Ipsen’s future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.

# Speakers



**David Loew**  
Chief Executive Officer



**Aymeric Le  
Chatelier**  
Chief Financial Officer



For Q&A  
**Howard Mayer**  
Head of Research &  
Development

# Agenda

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**Business  
overview**



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**Conclusion**



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**Questions**





# BUSINESS OVERVIEW

# Highlights

*Consistent strong delivery on strategic roadmap*

## Financial results

- Total-sales growth: +8.5% at CER
- Core operating margin: 36.9%<sup>1</sup>

## Acquisitions: Albireo<sup>2</sup> and Epizyme

- Expanding the scope in Rare Disease
- Strengthening the position in Oncology



## Pipeline update

- Onivyde 1L PDAC: primary endpoint met
- Palovarotene: U.S. FDA - CRL, E.U. CHMP - negative opinion

## 2023 guidance

- Total-sales growth greater than 4.0% at CER
- Core operating margin around 30%

# Sales highlights

*Growth platforms outweighing the gradual decline of Somatuline*

	FY 2022		Q4 2022	
	€m	change	€m	change
Dysport	594	29.4%	193	40.4%
Decapeptyl	530	12.4%	134	3.9%
Cabometyx	449	23.9%	121	23.1%
Onivyde	162	14.1%	40	5.9%
<b>Growth platforms</b>	<b>1,734</b>	<b>20.9%</b>	<b>488</b>	<b>21.1%</b>
Somatuline	1,218	-5.6%	306	-13.3%
Tazverik	13	n/a	10	n/a
Other	60	-10.8%	12	-28.8%
<b>Total</b>	<b>3,025</b>	<b>8.5%</b>	<b>816</b>	<b>5.8%</b>

All growth rates are at constant exchange rates. Due to rounding, the sum of euro values may not agree to totals.

# Strong performance from growth platforms of +20.9%

**Dysport**<sup>®</sup>  
Clostridium botulinum Type A Toxin

**+29.4%**

Strong performances  
across  
Ax and Tx

Capacity increase  
meeting significant  
growing demand

**Decapeptyl**<sup>®</sup>  
triptorelin

**+12.4%**

Continued strong  
underlying growth,  
despite COVID-19 impact  
in China

Limited impact from  
new entrants in Europe

**CABOMETYX**<sup>®</sup>  
(cabozantinib) tablets

**+23.9%**

Launches of the  
combo in 1L RCC  
progressing well

Momentum in 2L RCC  
monotherapy across  
additional geographies

**onivyde**<sup>®</sup>  
(irinotecan liposome  
injection)

**+14.1%**

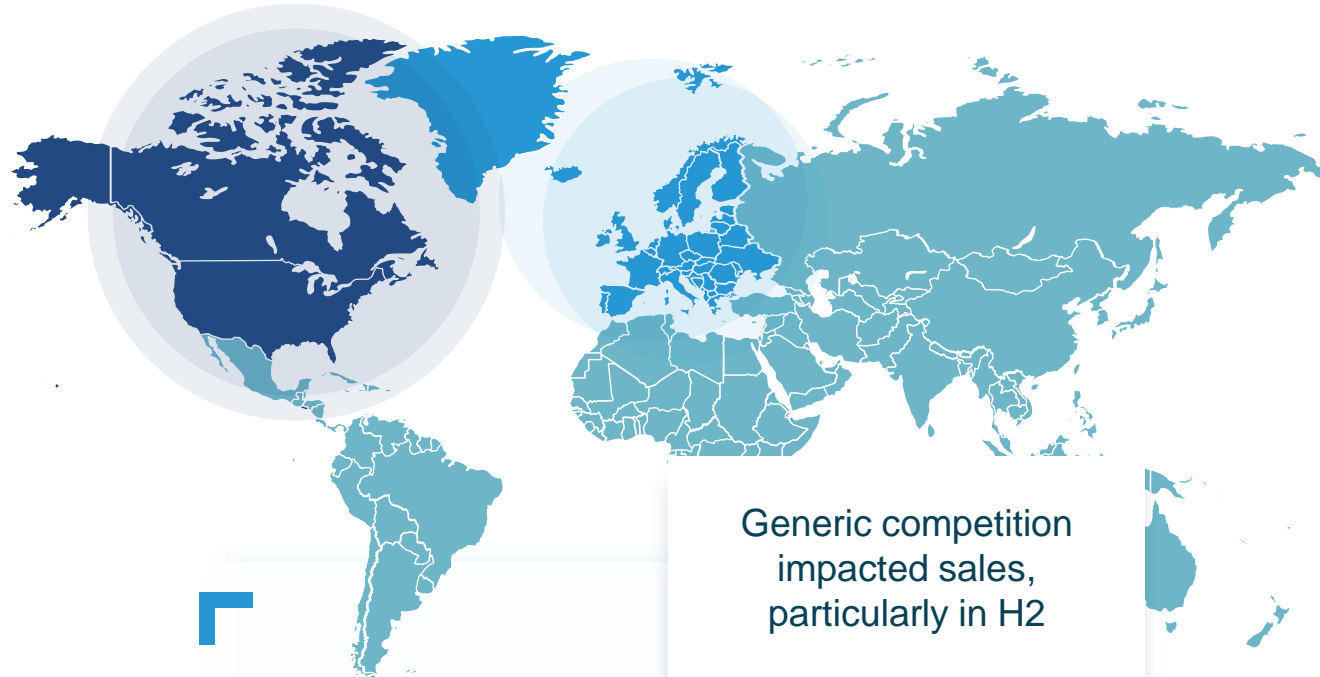
Solid U.S. share growth  
in the current setting

Good performance from  
ex-U.S. partner



# Somatuline sales gradually declining: FY 2022 -5.6%, Q4 2022 -13.3%

*A challenging environment in 2022 in the U.S. and Europe*



## NORTH AMERICA

FY 2022: -7.5%

Q4 2022: -17.6%

Direct and indirect impacts from competition

Pricing adversely impacted:

- commercial rebates
- channel mix

Reduced wholesaler inventories

## REST OF WORLD

FY 2022: +36.1%

Q4 2022: +40.3%

Strong performances in a number of markets, including Japan and Brazil

Solid volume growth

## EUROPE

FY 2022: -11.6%

Q4 2022: -18.7%

Generic competition impacted sales, particularly in H2

Largest sales declines:

- Germany
- France
- Spain

# Consistent execution of the external-innovation strategy

20 assets added in two years



## ONCOLOGY: 12 assets

**Tazverik**  
Epizyme<sup>1</sup>

Approved

**ERK-inhibitor**  
AGV Discovery

Preclinical

**METTL3**  
Accent  
Therapeutics

Preclinical

**BKX-001**  
BAKX  
Therapeutics

Preclinical

**FLIP-i**  
program  
Queen's  
University

Preclinical

**IO**  
Marengo

Preclinical



## RARE DISEASE: 5 assets

**Elafibranor**  
GENFIT

Phase III

**Bylvay**  
ALBIREO<sup>2</sup>

Approved



## NEUROSCIENCE: 3 assets

**Mesdopetam**  
IRLAB

Phase IIb

**SNAs**  
Exicure<sup>3</sup>



**BoNT/X**  
BCH/UOS

Preclinical

# Albireo<sup>1</sup>: expanding Ipsen's scope in Rare Disease

*Perfectly aligned to the external-innovation strategy*

## Global rights<sup>2</sup>

- Bylvay: a potentially best-in-class rare liver-disease medicine approved in the U.S. & E.U.

**Albireo** 

 **Bylvay**<sup>TM</sup>  
(odevixibat)

## Strategic fit

- Expanding the pipeline & portfolio in rare liver diseases

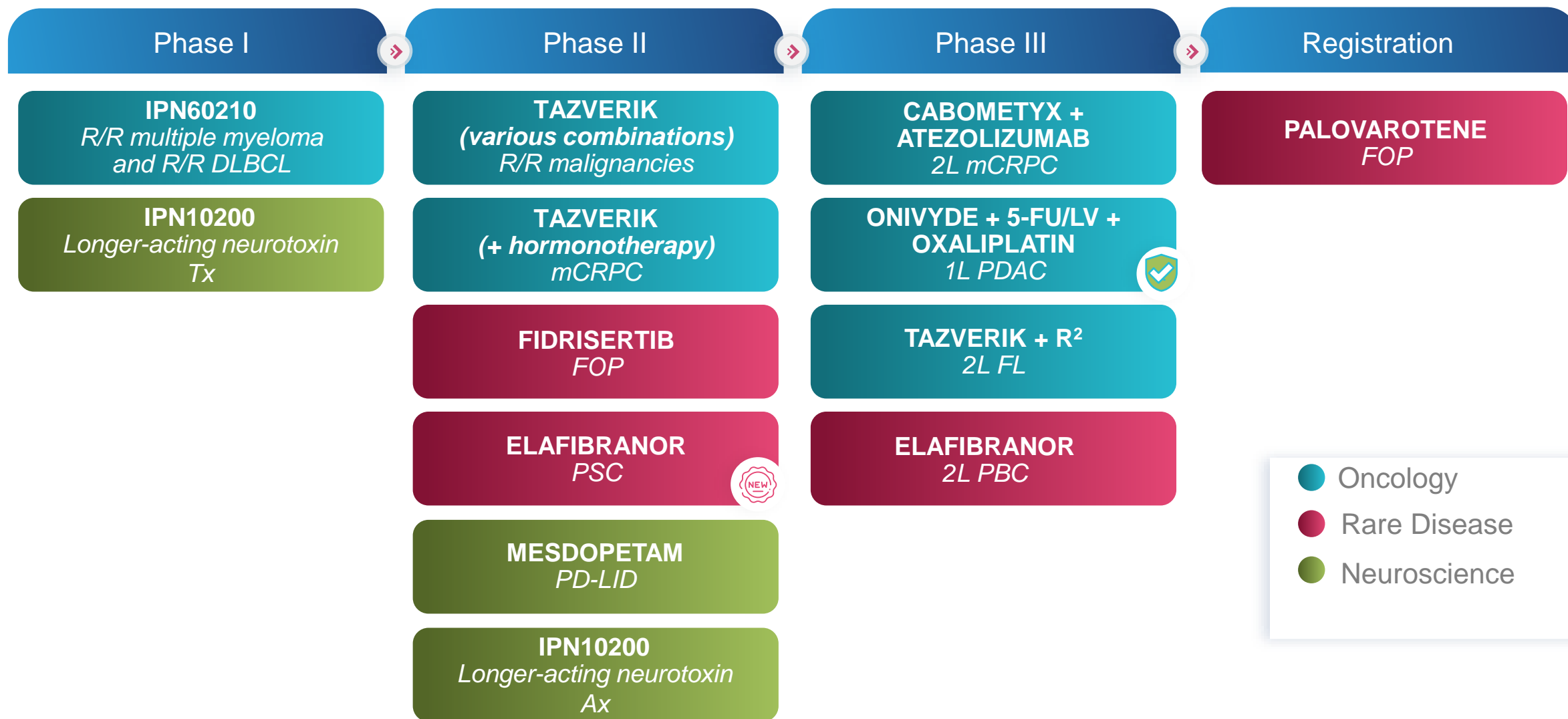
## Multiple opportunities

- Bylvay: progressive familial intrahepatic cholestasis, Alagille syndrome, biliary atresia
- Early-stage pipeline: adult cholestatic liver diseases

## Financial impact

- Peak sales ~\$800m
- Accretive to core operating income from 2025

# Building a high-value, sustainable pipeline



- Oncology
- Rare Disease
- Neuroscience

# Pipeline: near-term major milestones



## **Elafibranor: 2L PBC**

Phase III data readout



## **Palovarotene: FOP**

Information submission (U.S.)<sup>1</sup>

Request re-examination of CHMP opinion (E.U.)<sup>2</sup>



## **Onivyde: 1L PDAC**

Regulatory submission (U.S.)



## **Cabometyx + atezolizumab: 2L mCRPC**

Phase III data readout (PFS)



## **Bylvay<sup>3</sup>: Alagille syndrome**

Regulatory decisions (U.S., E.U.)



# Onivyde



## Potential in 1L PDAC

### 1L data presented at ASCO GI, San Francisco

**Potential to expand Onivyde's peak-sales potential**

Current label: post gemcitabine-based therapy

**Onivyde regimen**

Statistically significant & clinically meaningful improvement in overall survival

**Trial met key secondary endpoint of progression-free survival**

A safety profile consistent with the previous trial

**A potential advance in an aggressive and difficult-to-treat cancer**

Forthcoming regulatory submission in the U.S.

**Leveraging Ipsen's existing in-market presence & building on the commitment to Oncology**

1L: first line; PDAC: pancreatic ductal adenocarcinoma.

## Environment

- » **Emissions**  
GHG emission-reduction trajectory: officially certified by the Science Based Targets initiative<sup>1</sup>
- » **Renewables**  
90% renewable electricity for all global operations
- » **Fleet**  
Launched *Fleet for Future* programs

## Patients

- » **Access**  
Partnership with *Access Accelerated*: continued to support communities that lack sufficient access to healthcare
- » **Ukraine**  
€1.5m donation to the Red Cross and Tulipe, plus medicine donations

## People

- » **Diversity**  
Females: 48% of the Global Leadership Team
- » **Employer of choice**  
in 23 countries
- » **Community**  
44% of colleagues participated in Ipsen's *Community Day*

## Governance

- » **Certification**  
ISO 37001 certification for anti-corruption management systems
- » **Compliance**  
Continued rigorous compliance with highest ethics and compliance standards



**FINANCIALS**



# FY 2022 financial highlights

<b>Total sales</b>	» €3,025m	» <b>+8.5%</b>
<b>Core operating income</b>	» €1,115m	» <b>+13.5%</b>
<b>Core operating margin<sup>1</sup></b>	» 36.9%	» <b>-0.3 pts</b>
<b>Core EPS<sup>2</sup></b>	» €10.51	» <b>+18.4%</b>
<b>Free cash flow</b>	» €817m	» <b>+4.7%</b>

# Core P&L: strong sales growth; stable core operating margin

€m	FY 2022	FY 2021	change
<b>Total Sales</b>	<b>3,025.0</b>	<b>2,643.3</b>	<b>14.4%</b>
Other revenue	131.5	105.4	24.7%
Cost of goods sold	(527.7)	(438.6)	20.3%
<b>Gross Profit</b>	<b>2,628.7</b>	<b>2,310.0</b>	<b>13.8%</b>
<i>% of total sales</i>	86.9%	87.4%	-0.5 pts
R&D expenses	(445.3)	(424.4)	4.9%
<i>% of total sales</i>	14.7%	16.1%	-1.3 pts
SG&A expenses	(1,039.2)	(916.3)	13.4%
<i>% of total sales</i>	34.4%	34.7%	-0.3 pts
Other operating income and expenses	(28.8)	13.8	n/a
<b>Core Operating Income</b>	<b>1,115.4</b>	<b>983.1</b>	<b>13.5%</b>
<i>% of total sales</i>	36.9%	37.2%	-0.3 pts

- Total sales**  
Positive impact from currencies
- Other revenue**  
Increased Dysport royalties received from Galderma
- Cost of goods sold**  
Unfavorable mix of sales
- R&D expenses**  
Investment re: Epizyme in the second half
- SG&A expenses**  
Commercial investment for growth including Tazverik and focus on efficiencies

All growth rates are at actual exchange rates.

# Cash flow and net debt



	FY 2022 €m	FY 2021 €m	change
<b>Opening Net Cash/(Debt)<sup>1</sup></b>	<b>28.0</b>	<b>(388.0)</b>	<b>n/a</b>
Free cash flow	817.2	780.7	4.7%
Dividend	(100.2)	(83.1)	-20.6%
Net investments	(564.5)	(240.4)	n/a
Change in cash from discontinued activities	249.0	25.7	n/a
Other (share buyback, FX, discontinued)	(30.7)	(66.9)	54.1%
<b>Change in net cash</b>	<b>370.8</b>	<b>416.0</b>	<b>-10.9%</b>
<b>Closing Net Cash</b>	<b>398.8</b>	<b>28.0</b>	<b>n/a</b>

- » **Solid free cash flow:**  
growing by 5%
- » **Fully deleveraged balance sheet:**  
closing net cash of €0.4bn
- » **Significant firepower<sup>2</sup>  
for external innovation:**  
€1.5bn at the end of 2022

# FY 2023 guidance

*Reflecting sustained top-line growth and enhanced pipeline investment*



**Total-sales growth**  
greater than 4.0% at  
constant exchange rates



Expected adverse impact of  
around 2% from currencies,  
based on average level of  
exchange rates  
in January 2023



**Core operating margin**  
around 30%  
of total sales



Excludes any potential impact  
of incremental investments  
from external-innovation  
transactions



**Guidance  
assumptions**



Closing of the Albireo  
acquisition in Q1 2023<sup>1</sup>

<sup>1</sup> The acquisition of Albireo is anticipated to close in Q1 2023, is subject to satisfaction of customary deal closing conditions.



**CONCLUSION**

# Conclusion

*Successfully executing on our strategy*



## DELIVERING STRONG RESULTS



Strong progress on the four strategic pillars

Growth platforms outpacing Somatuline's gradual decline

New medicines set to drive further growth



## ADVANCING THE PIPELINE



Increased number of assets and trials

Opportunities across the three therapy areas

Several milestones in the near term



## FOCUSING ON EXTERNAL INNOVATION



20 assets added to the pipeline in two years

Significant firepower underpinned by a strong balance sheet

Strategic momentum for further external innovation



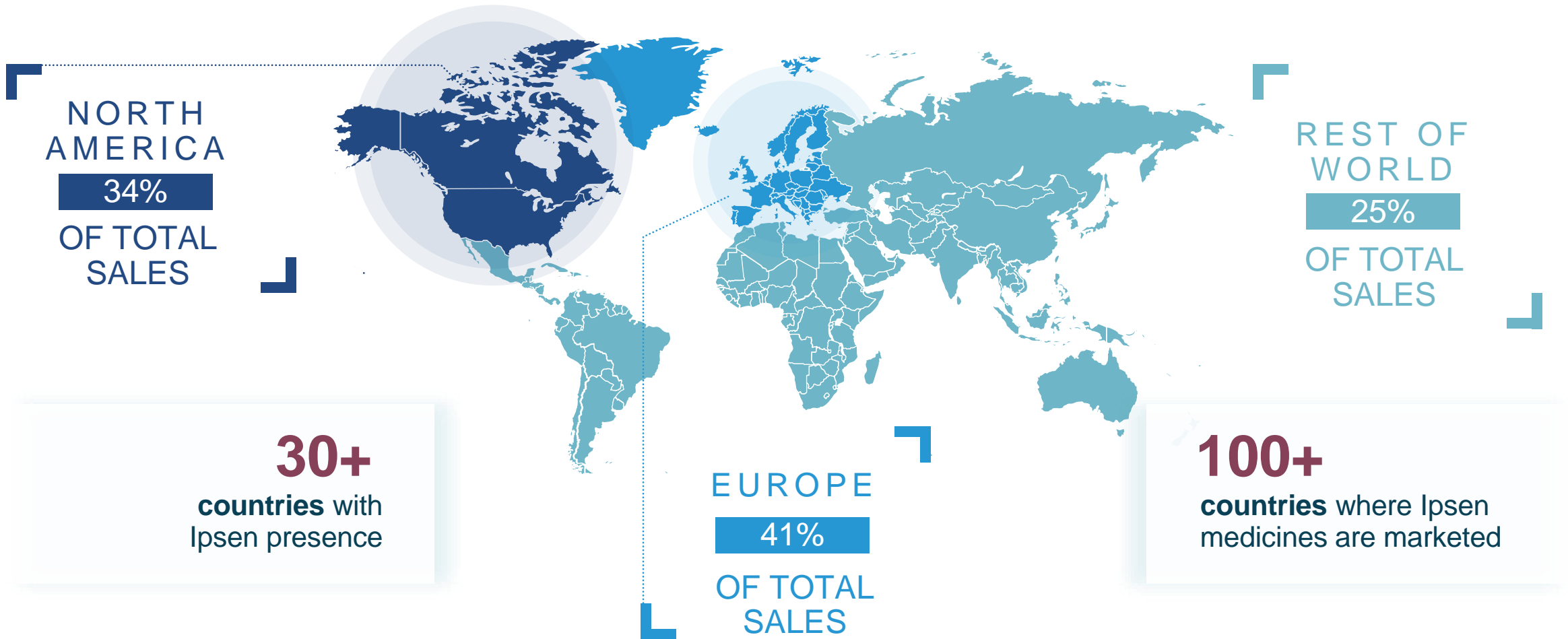
**QUESTIONS**



# APPENDIX

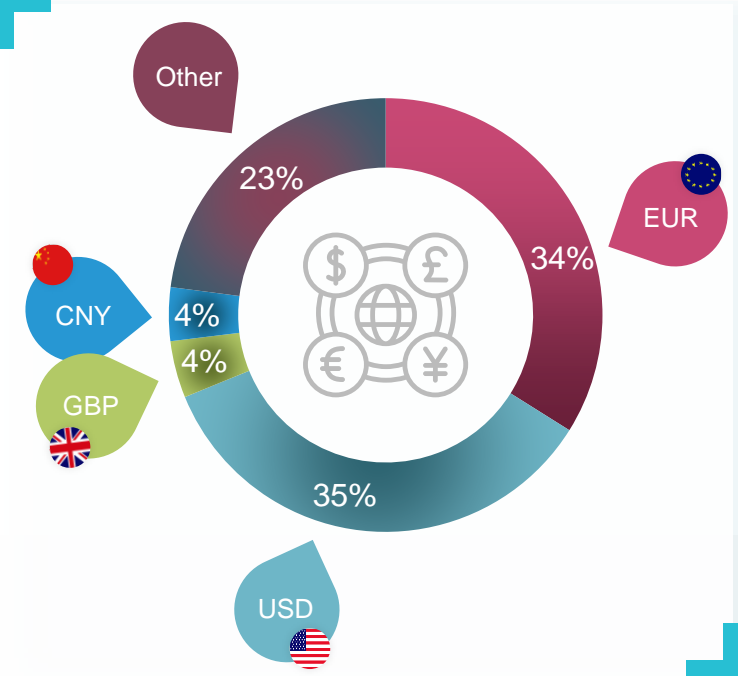


# A strong and expanded global footprint

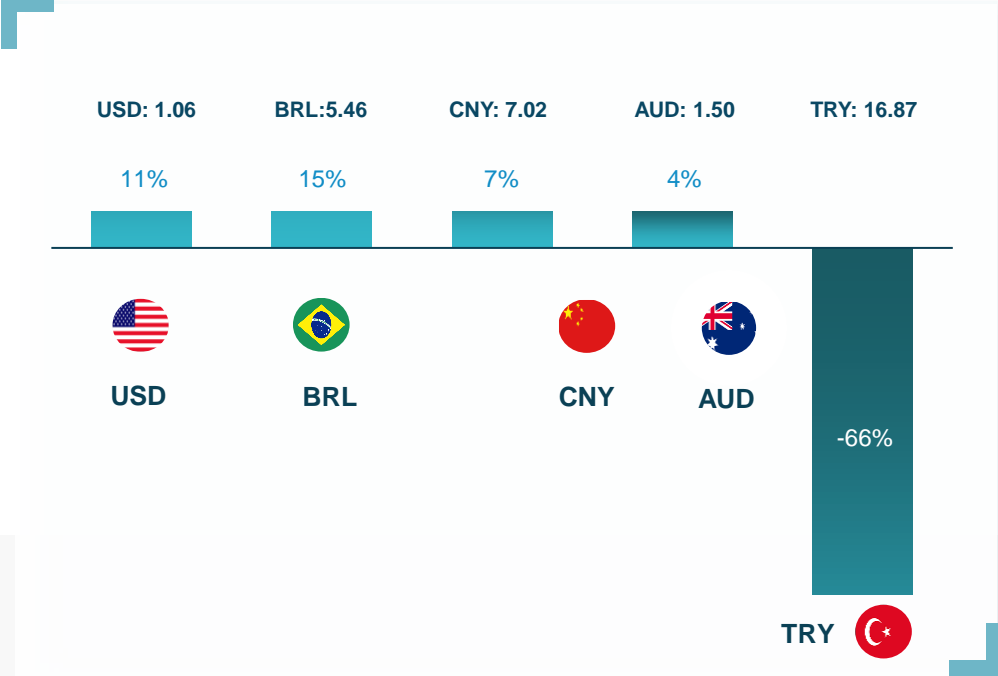


# FY 2022 total sales: favorable impact of fx rates

FY 2022 sales by currency



Average rate changes (FY 2022 vs. FY 2021)



Favorable 6.0% impact






# Core operating income to consolidated net profit

	FY 2022 €m	FY 2021 €m	change
<b>Core Operating Income</b>	<b>1,115.4</b>	<b>983.1</b>	<b>13.5%</b>
Amortization of intangible assets	(103.6)	(79.4)	30.6%
Restructuring and other operating expense	(167.5)	(69.9)	n/a
Impairment losses	(114.3)	(9.1)	n/a
<b>IFRS Operating Income</b>	<b>729.9</b>	<b>824.7</b>	<b>-11.5%</b>
Net financing expenses	(18.5)	(21.8)	-15.2%
Other financial income	(5.5)	(13.8)	n/a
Income taxes and other	(113.8)	(157.9)	-28.0%
<i>Net profit from discontinued operations</i>	<i>55.4</i>	<i>15.5</i>	<i>n/a</i>
<b>IFRS consolidated net profit</b>	<b>647.5</b>	<b>646.7</b>	<b>0.1%</b>

# Oncology





## Key ongoing clinical-trial highlights

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
<b>Cabometyx CONTACT-01</b> Phase III NCT04471428	2L NSCLC	<b>366</b> 	Docetaxel or Cabometyx + atezolizumab	OS	Primary endpoint not met
<b>Cabometyx CONTACT-02</b> Phase III NCT04446117	2L mCRPC	<b>580</b> 	Second novel hormonal therapy (abiraterone & prednisone or enzalutamide) or Cabometyx + atezolizumab	OS, PFS	Recruiting
<b>Onivyde NAPOLI-3</b> Phase III NCT04083235	1L PDAC	<b>770</b> 	Nab-paclitaxel + gemcitabine or Onivyde + 5-FU/LV + oxaliplatin	OS	Primary endpoint met

2L: second line; **NSCLC**: non-small cell lung cancer; **OS**: overall survival; **mCRPC**: metastatic castration-resistant prostate cancer; **PFS**: progression-free survival; **1L**: first line; **PDAC**: pancreatic ductal adenocarcinoma.

# Oncology





## Key ongoing clinical-trial highlights

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
<b>Tazverik SYMPHONY-1</b> Phase III NCT04224493	R/R FL: following at least one prior systemic chemotherapy, immunotherapy, or chemoimmunotherapy	<b>540</b> 	Placebo + R <sup>2</sup> or Tazverik + R <sup>2</sup>	PFS	Recruiting
<b>Tazverik ARIA</b> Phase Ib/II NCT05205252	R/R hematologic malignancies	<b>156</b> 	Tazverik in various combinations: multi-cohort	Phase Ib: dosing, safety Phase II: ORR	Recruiting
<b>IPN60210</b> Phase I/Ib NCT05121103	R/R multiple myeloma and R/R DLBCL	<b>96</b> 	IPN60210	Treatment-emergent adverse events, dosing & ORR	Recruiting
<b>Tazverik CELLO-1</b> Phase Ib/II NCT04179864	mCRPC: patients who have not received chemotherapy	<b>104</b> 	Enzalutamide + Tazverik or abiraterone/prednisone + Tazverik	Phase Ib: dosing, safety  Phase II: rPFS Tazverik + enzalutamide	Recruiting

R/R: relapsed/refractory; FL: follicular lymphoma; R<sup>2</sup>: lenalidomide + rituximab; PFS: progression-free survival; ORR: objective response rate; DLBCL: diffuse large B-cell lymphoma; mCRPC: metastatic castration-resistant prostate cancer; rPFS: radiographic progression-free survival.





# Rare Disease

## Key ongoing clinical-trial highlights

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
<b>Palovarotene</b> <b>MOVE</b> Phase III NCT03312634	FOP (chronic)	107 	Palovarotene - 5mg QD and upon flare-up, 20mg QD for 28 days, followed by 10mg for 56 days	Annualized change in new HO volume	U.S.: CRL December 2022  E.U. CHMP: negative opinion January 2023
<b>Fidrisertib</b> <b>FALKON</b> Phase II NCT05039515	FOP (chronic)	~90 	Placebo or two dosing regimens of fidrisertib	Annualized change in new HO volume and safety	First patient commenced dosing Q1 2022
<b>Elafibranor</b> <b>ELATIVE</b> Phase III NCT04526665	2L PBC	161 	Placebo or elafibranor	Response to treatment defined as ALP < 1.67 x ULN and total bilirubin ≤ ULN and ALP decrease ≥ 15 percent	Recruitment completed  Data anticipated H1 2023
<b>Elafibranor</b> <b>ELMWOOD</b> Phase II NCT05627362	PSC	60 	Placebo or elafibranor	Safety, significant changes in physical examination findings, laboratory parameters, vital signs, electrocardiogram readings	Initiating

# Neuroscience

## Key ongoing clinical-trial highlights

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
<b>Mesdopetam</b> Phase IIb NCT04435431	Levodopa-induced dyskinesia in Parkinson's disease	<b>156</b> 	Mesdopetam or placebo	Change in average daily hours of ON-time <sup>1</sup> without troublesome dyskinesia	Primary endpoint not met
<b>IPN59011 Ax LONG-SET</b> Phase I/II NCT04736745	Moderate to severe upper facial lines	<b>424</b> 	Dose escalation & dose finding versus Dysport or placebo	Safety	Terminated
<b>IPN10200 Ax LANTIC</b> Phase II NCT04821089	Moderate to severe upper facial lines	<b>424</b> 	Dose escalation & dose finding versus Dysport or placebo	Safety	First patient commenced dosing Q1 2023
<b>IPN10200 Tx LANTIMA</b> Phase I/II NCT04752774	Adult patients with upper limb spasticity	<b>209</b> 	Dose escalation & dose finding versus Dysport or placebo	Safety	Recruiting

<sup>1</sup>. Good 'ON-time' is the time that people living with Parkinson's disease experience improved Parkinsonian symptoms and no dyskinesia.



**THANK  
YOU**



# Investor Relations



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