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## Highlights at H1 2023 results

### Consistent strong delivery on strategic roadmap

#### **Financial results**

- H1 total-sales growth of 7.4%
- Growth platforms & newly acquired medicines now represent around two thirds of total sales
- Core operating margin of 34.0%

#### **Albireo**

- Albireo acquisition completed in March
- Integration progressing well



#### Pipeline update

- Onivyde: sNDA accepted (U.S.) 1L PDAC
- Bylvay: FDA approval (U.S.) ALGS
- Palovarotene: favorable outcome from Advisory Committee (U.S.) - FOP
- Elafibranor: met primary endpoint (ELATIVE) -2L PBC

#### 2023 guidance upgraded

- Total-sales growth greater than 6.0%<sup>1</sup>
- Core operating margin greater than 30.0%<sup>2</sup>

All growth rates are at constant exchange rates.



Growth platforms: Dysport, Decapeptyl, Cabometyx and Onivyde; sNDA: supplemental New Drug Application; 1L: first line; PDAC: pancreatic ductal adenocarcinoma; ALGS: Alaqille syndrome; FOP: fibrodysplasia ossificans progressiva; 2L: second line; PBC: primary biliary cholangitis.



## Sales performance

Growth platforms continuing to excel; contributions from newly acquired medicines

	H1 2023		Q2	2023
	€m	change	€m	change
Dysport	319	31.7%	165	38.3%
Decapeptyl	277	6.0%	147	11.0%
Cabometyx	266	26.3%	135	22.1%
Onivyde	78	-8.0%	41	-3.7%
<b>Growth platforms</b>	940	17.7%	488	20.6%
Bylvay	23	n/a	18	n/a
Tazverik	19	n/a	9	n/a
Newly acquired medicines	42	n/a	28	n/a
Somatuline	529	-12.0%	266	-14.1%
Other	27	-15.2%	14	-9.8%
Total sales	1,537	7.4%	795	9.0%



## Growth platforms: consistent strong performance



CABOMETYX® (cabozantinib) tablets



+31.7%

+26.3%

+6.0% +19.3%

Further aesthetics-market growth, accompanied by favorable baseline effect

Continued strong doubledigit therapeutics growth across regions Strong volume uptakes across most geographies

Momentum in first & second-line renal cell carcinoma

China sales recovery post-COVID in Q2

**Decapeptyl®** 

Growth in Europe offset by adverse pricing

Growth in the U.S. driven by market-share gains

1L PDAC pre-launch activities

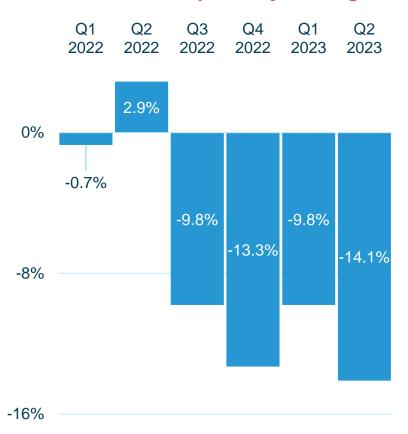


## Somatuline sales: continuing to decline gradually



#### Now around one third of total sales

#### Somatuline quarterly sales growth



### H1 2023 -12.0% sales growth

#### North America -9.6%

- Solid volume-demand growth
- Ongoing adverse pricing

#### **Europe -21.7%**

Generic competition continuing to impact

#### Rest of World +6.3%

- Solid underlying growth
- Several markets performing well, including Latin America



## Recently acquired medicines



€23m

Growth of 140%<sup>1</sup>

Strong momentum in North America and Europe

Increasing number of treated PFIC patients



€19m

Growth of 18% in commercial sales<sup>2</sup>

Focus on all-comers, new-patient starts & duration of therapy

Increasing share of office-based patients



## Building high-value, sustainable pipeline

**IPN10200** 

Longer-acting neurotoxin

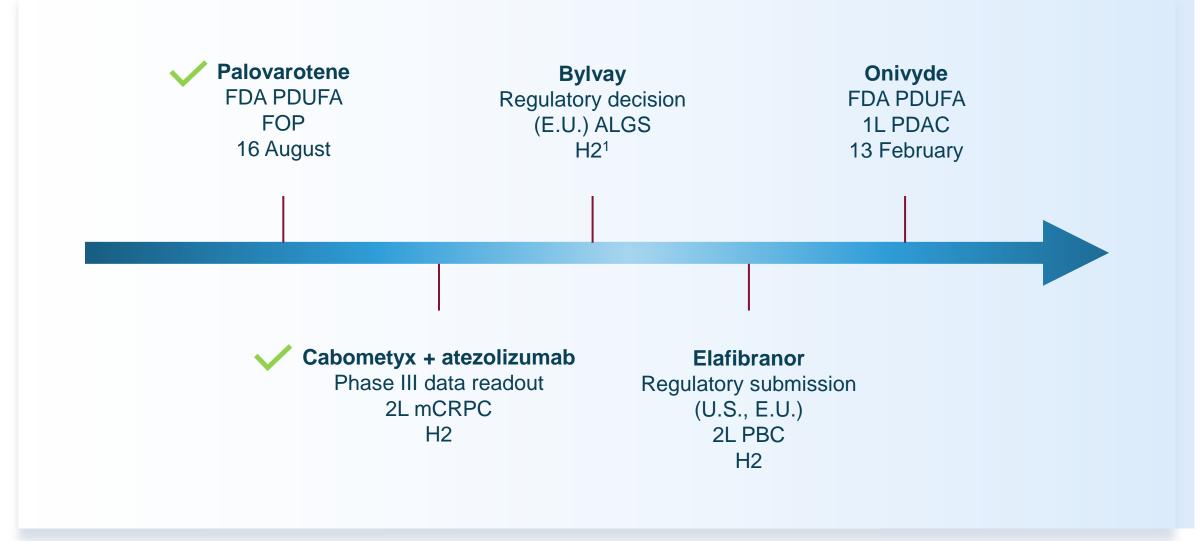
Tx

Registration Phase I Phase II Phase III CABOMETYX + **IPN60210 TAZVERIK** ONIVYDE + 5-FU/LV + R/R multiple myeloma **ATEZOLIZUMAB** (various combinations) **OXALIPLATIN** & R/R DLBCL 2L mCRPC R/R malignancies 1L PDAC **TAZVERIK IPN60260** TAZVERIK + R<sup>2</sup> **BYLVAY** (+ hormonotherapy) Viral cholestatic disease 2L FL Alagille syndrome **mCRPC PALOVAROTENE FIDRISERTIB ELAFIBRANOR FOP** 2L PBC **FOP ELAFIBRANOR BYLVAY PSC** Biliary atresia **IPN60250** Oncology **PSC** Rare Disease IPN10200 Information shown as at end of June 2023. Longer-acting neurotoxin Neuroscience Ax R/R: relapsed/refractory; DLBCL: diffuse large B-cell lymphoma; mCRPC: metastatic



castration-resistant prostate cancer; **FOP**: fibrodysplasia ossificans progressiva; **PSC**: primary sclerosing cholangitis; **Ax**: aesthetics; **Tx**: therapeutics; **2L**: second line; **1L**: first line; **R**<sup>2</sup>: lenalidomide + rituximab; **FL**: follicular lymphoma; **PBC**: primary biliary cholangitis; **PDAC**: pancreatic ductal adenocarcinoma.

## Pipeline: near-term milestones





## H1 2023 financial highlights

**Total sales** 

**Core operating income** 

Core operating margin<sup>1</sup>

Core EPS<sup>2</sup>

Free cash flow

€1,537m	+7.4%
€523m	-7.9%
34.0%	-5.6% pts
€4.73	-6.6%
€371m	+9.6%



### Core P&L

## Strong sales growth and significant investment for growth

€m
Total Sales
Other revenue
Cost of goods sold
Gross Profit
% of total sales
R&D expenses
% of total sales
SG&A expenses
% of total sales
Other operating income and expenses
Core Operating Income
% of total sales

H1 2023
1,536.6
86.5
(269.9)
1,353.3
88.1%
(290.2)
18.9%
(552.6)
36.0%
12.7
523.2
34.0%

H1 2022	Change
1,433.7	7.2%
64.2	34.8%
(242.1)	11.5%
1,255.8	7.8%
87.6%	0.5pts
(207.2)	40.1%
14.5%	4.4pts
(487.3)	13.4%
34.7%	13.0pts
6.5	94.9%
568.0	-7.9%
39.6%	-5.6pts



#### **Total sales**

Limited impact of currencies

#### Other revenue

Favorable impact from license rights to Onivyde

#### Cost of goods sold

Adverse mix of royalties paid

#### **R&D** expenses

Investment from pipeline assets of Epizyme & Albireo

#### **SG&A** expenses

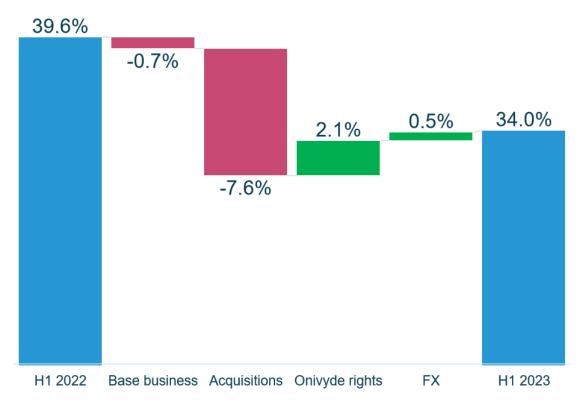
Commercial investment for growth including Tazverik & Bylvay launch activity



## H1 core operating margin evolution

### Reflected dilutive impact from recent acquisitions

#### Core Operating margin (as a % of total sales)



#### **Base business**

- Contribution of growth platforms
- Pre-launch & RoW commercial activities & existing pipeline investment
- Gradual decline of Somatuline

#### **Acquisitions**

- Epizyme & Albireo dilutive impact based on commercial & R&D investments
- Limited synergies to date

#### **Onivyde rights**

 Upfront fee from licence rights with ex-U.S. partner for 1L PDAC

Strong underlying level of core operating margin at 34% of total sales



## Core operating income to consolidated net profit

€m	H1 2
Core Operating Income	52
Amortization of intangible assets	(90
Restructuring and other operating expense	(12
Impairment losses	(11
IFRS Operating Income	29
Net financing expenses	(12
Other financial income	(22
Income taxes and other	(60
Net profit from discontinued operations	0
IFRS Consolidated Net Profit	19
Core earnings per share	€4

H1 2023	H1 2022	Change
523.2	568.0	-7.9%
(90.7)	(46.6)	94.6%
(125.0)	(20.0)	n/a
(11.9)	0.0	n/a
295.6	501.3	-42.2%
(12.0)	(9.5)	-27.0%
(22.1)	(0.5)	n/a
(66.4)	(109.1)	-39.2%
0.0	12.1	n/a
195.1	394.3	-50.5%
€4.73	€5.06	-6.6%

## **Amortization of intangible assets**

Increase mainly from Bylvay & Tazverik

## Restructuring & other operating expense

Mainly related to Albireo integration & transaction costs, other transformation programs and discontinuation of clinical trials

#### **Core earnings per share**

In line with core operating income with core effective tax rate at 20.4%



## Cash flow & net debt

€m	H1 2023	H1 2022		
Opening Net Cash/(Debt) <sup>1</sup>	398.8	28.0		
Free cash flow	371.5	339.0	*	Solid free cash flow: growing by 9.6%
Dividend	(99.6)	(100.2)		
Net investments	(945.9)	(101.9)	*	Strong balance sheet:
Change in cash from discontinued activities	13.9	6.1		closing net debt of €0.3bn
Other (share buyback, FX, discontinued)	(10.9)	(2.8)		
Change in net cash	(671.0)	140.3	*	Significant firepower <sup>2</sup> for external innovation:
Closing Net Cash/(Debt) <sup>1</sup>	(272.2)	168.2		€1.7bn at end of H1 2023



## **Upgraded FY 2023 guidance**



**Total-sales growth** 

greater than 6.0% at constant exchange rates



Expected adverse impact of around 3% from currencies, based on average level of exchange rates in June 2023



Core operating margin

greater than 30.0% of total sales



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



## Conclusion

Strategic roadmap driving growth story





## DELIVERING FURTHER STRONG RESULTS



Growth platforms & newly acquired medicines driving sales growth

A strong core operating margin

Cash generation supporting a robust balance sheet



## ADVANCING PIPELINE



Favorable developments in first half of year

Anticipated regulatory decisions in near term

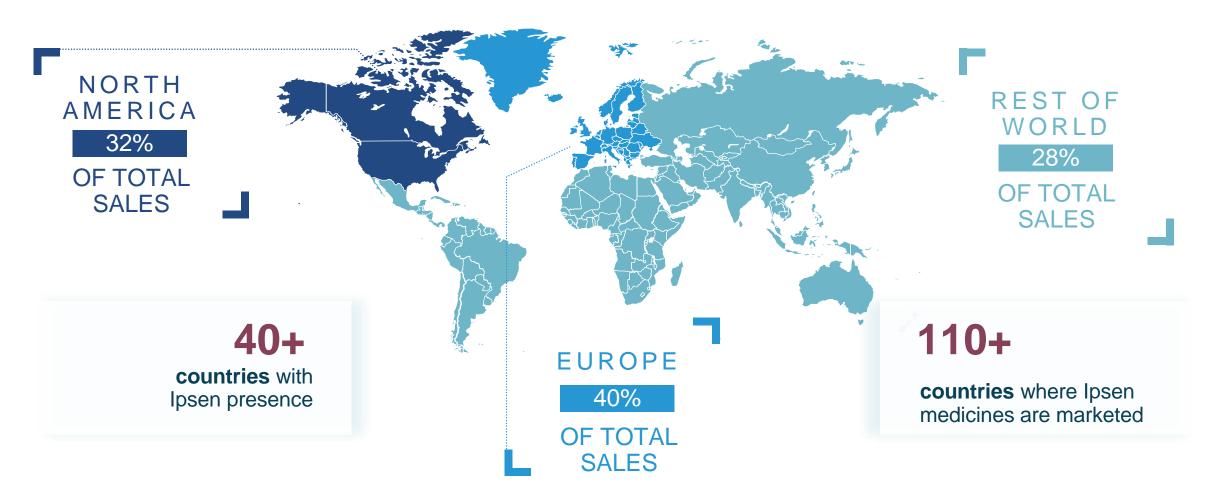
Capital-markets day: 7 December 2023, London



# **APPENDIX**

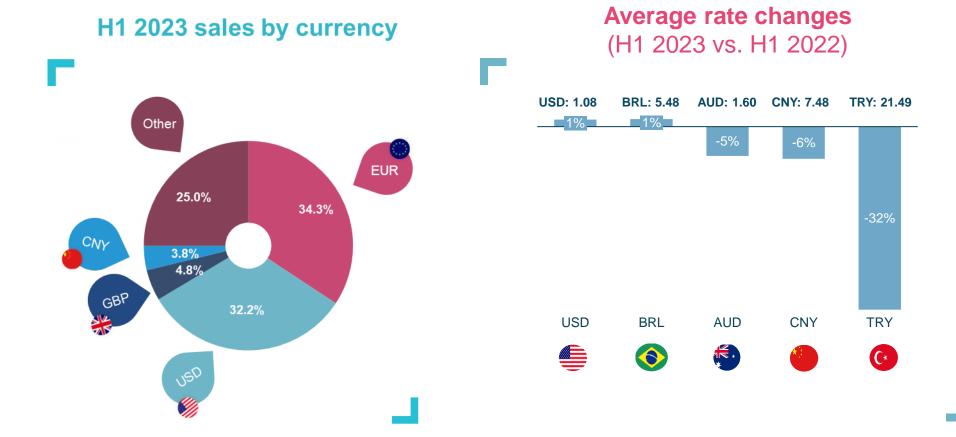


## A strong global footprint





### H1 2023 total sales: fx rates





## Oncology

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
Cabometyx CONTACT-02 Phase III NCT04446117	2L mCRPC	580	Second novel hormonal therapy (abiraterone & prednisone or enzalutamide) or Cabometyx + atezolizumab	PFS, OS	Recruiting <sup>1</sup> PFS primary endpoint met
Onivyde NAPOLI-3 Phase III NCT04083235	1L PDAC	770	Nab-paclitaxel + gemcitabine or Onivyde + 5-FU/LV + oxaliplatin	OS	U.S. PDUFA date 13 February 2024
Tazverik SYMPHONY-1 Phase III NCT04224493	R/R FL: following at least one prior systemic chemotherapy, immunotherapy, or chemo- immunotherapy	540	Placebo + R <sup>2</sup> or Tazverik + R <sup>2</sup>	PFS	Recruiting <sup>1</sup>



<sup>&</sup>lt;sup>1.</sup> Recruitment status as per ct.gov, June 2023. **2L**: second line; **mCRPC**: metastatic castration-resistant prostate cancer; **PFS**: progression-free survival; **OS**: overall survival; **1L**: first line; **PDAC**: pancreatic ductal adenocarcinoma; **R/R**: relapsed/refractory; **FL**: follicular lymphoma; **R**<sup>2</sup>: lenalidomide + rituximab.

## Oncology

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
Tazverik ARIA Phase lb/II NCT05205252	R/R hematologic malignancies	156	Tazverik in various combinations: multi-cohort	Phase Ib: dosing, safety Phase II: ORR	Recruiting <sup>1</sup>
IPN60210 Phase I/Ib NCT05121103	R/R multiple myeloma & R/R DLBCL	96	IPN60210	Treatment-emergent adverse events, dosing & ORR	Recruiting <sup>1</sup>
Tazverik CELLO-1 Phase lb/II NCT04179864	mCRPC: patients who have not received chemotherapy	104	Enzalutamide + Tazverik or abiraterone/prednisone + Tazverik	Phase Ib: dosing, safety  Phase II: rPFS  Tazverik + enzalutamide	Active, not recruiting <sup>1</sup>



<sup>1.</sup> Recruitment status as per ct.gov, June 2023. R/R: relapsed/refractory; ORR: objective response rate; DLBCL: diffuse large B-cell lymphoma; mCRPC: metastatic castration-resistant prostate cancer; rPFS: radiographic progression-free survival.

## **Rare Disease**

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT	STATUS
Elafibranor ELATIVE 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	Primary endpoint met
Bylvay ASSERT Phase III NCT04674761	Alagille syndrome	63	Placebo or Bylvay	Change from baseline in scratching score	U.S. regulatory approval June 2023
Bylvay BOLD Phase III NCT04336722	Biliary atresia	205	Placebo or Bylvay	Proportion of patients who are alive and have not undergone a liver transplant after 104 weeks of study treatment	Recruiting <sup>1</sup>



<sup>&</sup>lt;sup>1.</sup> Recruitment status as per ct.gov, June 2023. **2L**: second line; **PBC**: primary biliary cholangitis; **ALP**: alkaline phosphatase; **ULN**: upper limit normal; **PDUFA**: Prescription Drug User Fee Act.

## **Rare Disease**

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
Palovarotene MOVE 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. regulatory approval August 2023
Fidrisertib FALKON 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



## **Rare Disease**

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT(S)	STATUS
<b>IPN60250</b> Phase II NCT05642468	Primary sclerosing cholangitis	12	10mg IPN60250 tablet QD for 12 weeks 30mg (3x10 mg) IPN60250 tablets QD for 12 weeks	Treatment-related adverse events	Recruiting <sup>1</sup>
Elafibranor ELMWOOD Phase II NCT05627362	Primary sclerosing cholangitis	60	Placebo or elafibranor	Safety, significant changes in physical examination findings, laboratory parameters, vital signs, electrocardiogram readings	Recruiting <sup>1</sup>
IPN60260 Phase I ISRCTN13265717	Viral cholestatic disease	108	Interventional	To be confirmed	Recruiting <sup>1</sup>



<sup>&</sup>lt;sup>1.</sup> Recruitment status as per ct.gov, June 2023. **QD**: once a day.

## **Neuroscience**

TRIAL	POPULATION	PATIENTS	DESIGN	PRIMARY ENDPOINT	STATUS
IPN10200 Ax LANTIC Phase II NCT04821089	Moderate to severe upper facial lines	424	Dose escalation & dose finding versus Dysport or placebo	Safety	First patient commenced dosing Q1 2023
IPN10200 Tx LANTIMA Phase II NCT04752774	Adult patients with upper-limb spasticity	209	Dose escalation & dose finding versus Dysport or placebo	Safety	First patient commenced dosing Q2 2023





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