

# Ipsen delivers solid sales growth in the first nine months of 2023 and confirms its full-year guidance

# Paris (France), 26 October 2023

Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical company, today presents its sales performance for the year to date and the third quarter of 2023.

	YTD 2023	YTD 2022	% ch	Q 202		Q3 2022	% change		
	€m	€m	Actual CER <sup>1</sup>		€r	n	€m	Actual	CER <sup>1</sup>
Oncology	1,744.1	1,767.2	-1.3%	0.8%	574	.5	603.1	-4.7%	0.8%
Neuroscience	489.0	407.7	19.9%	24.5%	164	.8	160.7	2.5%	13.7%
Rare Disease	76.0	33.6	n/a	n/a	33	.2	11.0	n/a	n/a
Total Sales	2,309.1	2,208.5	4.6%	7.1%	772	2.4	774.8	-0.3%	6.5%

## Sales and pipeline highlights

- Total-sales growth in the year to date of 7.1% at CER<sup>1</sup>, or 4.6% as reported, driven by the performance of the growth platforms<sup>2</sup>, up by 16.1%<sup>1</sup>, with Dysport<sup>®</sup> (abobotulinumtoxinA) up by 24.7%<sup>1</sup> and Cabometyx<sup>®</sup> (cabozantinib) up by 24.4%<sup>1</sup>, respectively. The performance included contributions from new medicines Bylvay<sup>®</sup> (odevixibat), Tazverik<sup>®</sup> (tazemetostat) and Sohonos<sup>®</sup> (palovarotene)
- Further pipeline progress, including the regulatory approval and launch in the U.S. of Sohonos in Rare Disease and initial results from the CONTACT-02 Phase III trial of Cabometyx plus atezolizumab in Oncology

# David Loew, Chief Executive Officer, commented:

"Ipsen's strategic success has been reflected in further sales and pipeline progress so far this year. Our portfolio has performed well across the three therapy areas, driven by strengthened commercial execution and the results of our external-innovation strategy. Based on the solid sales momentum, today we are confirming our guidance for the full year.

Further good news from the pipeline, including the regulatory approval of Sohonos in the U.S., continue to provide additional options for patients with real unmet medical needs. In the final quarter of the year, we look forward to regulatory steps for elafibranor in primary biliary cholangitis, as well as sharing further details on sustainable growth opportunities across our portfolio and pipeline at our forthcoming capital-markets day."

<sup>&</sup>lt;sup>1</sup> At constant exchange rates (CER), which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

<sup>&</sup>lt;sup>2</sup> Dysport, Decapeptyl<sup>®</sup> (triptorelin), Cabometyx and Onivyde<sup>®</sup> (irinotecan).



# Full-year 2023 guidance

Ipsen has confirmed its financial guidance for FY 2023:

- Total-sales growth greater than 6.0%, at constant exchange rates. Based on the average level of exchange rates in September 2023, an adverse impact on total sales of around 3.5% from currencies is expected
- Core operating margin greater than 30% of total sales

## **Pipeline development**

In August 2023, it was announced that the U.S. Food and Drug Administration (FDA) had approved Sohonos, the first and only treatment for people with fibrodysplasia ossificans progressiva.

It was also announced that the global CONTACT-02 pivotal Phase III trial of Cabometyx plus atezolizumab in metastatic castration-resistant prostate cancer met one of two primary endpoints, demonstrating a statistically significant improvement in progression-free survival at the primary analysis.

In October 2023, the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products confirmed its negative opinion recommending not to maintain the orphan designation for Bylvay in Alagille syndrome (ALGS). This was despite a positive opinion from the Committee for Medicinal Products for Human Use in July 2023. To maintain Bylvay's orphan designation in the approved treatment of progressive familial intrahepatic cholestasis, Ipsen is planning to resubmit to the EMA under a new brand name for the treatment of ALGS by the end of 2023.

## Galderma partnership

In September 2023, the Arbitral Tribunal of the International Chamber of Commerce issued a final decision following a difference of opinion on the regulatory-submission strategy for the liquid botulinum toxin type A, QM1114. In October 2023, Ipsen announced that its partner, Galderma, had received a Complete Response Letter from the U.S. FDA related to its Biologics License Application for QM1114.

A second arbitration proceeding, related to the territorial scope of the Dysport/Azzalure<sup>®</sup> aesthetics' partnership, is anticipated to conclude next year.

## AASLD call

To accompany the presentation of the ELATIVE Phase III trial results at the American Association for the Study of Liver Diseases (AASLD) 2023 Annual World Congress, Ipsen plans to host a conference call for analysts and investors on 14 November 2023, at 4.30pm CET. Participants can access the call and its details by registering <u>here</u>; webcast details can be found <u>here</u>. A recording will be available on <u>ipsen.com</u>.

#### Capital-markets day

The Company is planning to host a capital-markets event, starting at 12.30pm GMT on 7 December 2023 in London. The event will be webcast live and details will be available on ipsen.com in due course. In-person attendance will be by invitation only.

#### Calendar

Ipsen intends to publish its full-year and fourth-quarter results on 8 February 2024.



# Conference call: YTD 2023

A conference call and webcast for investors and analysts will begin today at 2pm CET. Participants can access the call and its details by registering <u>here</u>; webcast details can be found <u>here</u>. A recording will be available on <u>ipsen.com</u>.

# Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the nine-month period to 30 September 2023 (YTD 2023) and the three-month period to 30 September 2023 (Q3 2023), compared to nine-month period to 30 September 2022 (YTD 2022) and the three-month period to 30 September 2022 (Q3 2022), respectively, unless stated otherwise. Commentary is based on the performance in YTD 2023, unless stated otherwise.

## Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With total sales of €3.0bn in FY 2022, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, the Company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and lifescience hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has around 5,300 colleagues worldwide and is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit <u>ipsen.com</u>.

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# Total sales by therapy area and medicine

A breakdown of medicine sales by geographical area is shown in the appendix.

	YTD 2023	YTD 2022	% change		Q 20		Q3 2022	% change		
	€m	€m	Actual	CER <sup>3</sup>	€r	n	€m	Actual	CER <sup>3</sup>	
Oncology	1,744.1	1,767.2	-1.3%	0.8%	574	1.5	603.1	-4.7%	0.8%	
Somatuline®	787.9	911.9	-13.6%	-12.0%	259	9.2	311.9	-16.9%	-12.0%	
Decapeptyl®	407.1	396.0	2.8%	5.5%	130	).3	131.4	-0.9%	4.5%	
Cabometyx®	397.7	327.7	21.4%	24.4%	131	9.9	115.5	14.1%	20.8%	
Onivyde®	120.2	122.0	-1.4%	-0.3%	42	.6	38.8	9.8%	17.5%	
Tazverik®	28.1	2.8	n/a	n/a	9.	4	2.8	n/a	n/a	
Other Oncology	3.1	6.9	-54.7%	-54.5%	1.	0	2.6	-60.9%	-60.9%	
Neuroscience	489.0	407.7	19.9%	24.5%	164	1.8	160.7	2.5%	13.7%	
Dysport®	482.0	400.3	20.4%	24.7%	162	2.6	158.0	2.9%	13.4%	
Other Neuroscience	7.0	7.3	-4.4%	10.8%	2.	2	2.7	-21.4%	29.5%	
Rare Disease	76.0	33.6	n/a	n/a	33	.2	11.0	n/a	n/a	
Bylvay®	45.7	-	n/a	n/a	22	.5	-	n/a	n/a	
Sohonos®	2.8	0.1	n/a	n/a	2.	3	0.0	n/a	n/a	
NutropinAq®	14.8	20.8	-28.7%	-28.5%	4.	0	6.3	-36.1%	-35.8%	
Increlex®	12.7	12.8	-0.1%	1.3%	4.	3	4.8	-9.3%	-5.0%	
Total Sales	2,309.1	2,208.5	4.6%	7.1%	772	2.4	774.8	-0.3%	6.5%	

- Somatuline: in North America, sales declined by 12.6%<sup>3</sup> in the year to date, primarily reflecting adverse U.S. pricing; volumes remained robust. In Europe, sales fell by 17.9%<sup>3</sup>, driven by the penetration of generic lanreotide in many markets, including France, Spain and Italy. In the Rest of World region, sales grew by 9.6%<sup>3</sup>, a result of solid performances in several geographies, including Latin America
- Decapeptyl: growth driven by the performance in China, despite adverse pricing and moderate market recovery, in other Asia-Pacific markets, and in the Middle East and North Africa
- Cabometyx: strong volume uptakes across most geographies in the second-line renal cell carcinoma indication, and the first-line combination with nivolumab
- Onivyde: sustained growth in the U.S., offset by lower sales to Ipsen's ex-U.S. partner, driven by a new manufacturing set-up

<sup>&</sup>lt;sup>3</sup> At CER, which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.



- Tazverik: sales consolidated for nine months, following the completion of the acquisition of Epizyme in August 2022. Commercial-sales growth of 15.6%<sup>4,5</sup> year on year
- Dysport: performance driven by further growth in the aesthetics market, reflected in increased sales to Ipsen's partner and in Ipsen territories, and continued solid demand in most therapeutics markets. Growth in the third quarter was limited by the comparison to significantly strong sales in Q3 2022, when the completion of an increase in manufacturing capacity replenished local inventories, mainly in Europe
- Bylvay: sales consolidated for seven months, following the completion of the acquisition of Albireo in March 2023. Strong momentum continued in the third quarter of the year with the launch in the second indication, Alagille syndrome, in the U.S.

	YTD 2023	YTD 2022	% ch	ange	Q3 2023	Q3 2022	% change	
	€m	€m	Actual	CER⁵	€m	€m	Actual	CER⁵
North America	760.8	759.2	0.2%	2.4%	269.2	279.9	-3.8%	3.9%
Europe <sup>6</sup>	923.2	924.7	-0.2%	0.1%	304.5	301.1	1.1%	1.3%
Rest of World	625.1	524.6	19.2%	26.1%	198.8	193.9	2.5%	18.6%
Total Sales	2,309.1	2,208.5	4.6%	7.1%	772.4	774.8	-0.3%	6.5%

# Total sales by geographical area

- North America: sales growth of 2.4%<sup>5</sup> in the year to date, driven by a solid performance from Onivyde, the contribution from newly acquired medicines Tazverik and Bylvay, as well as the solid growth of Dysport in the therapeutics and aesthetics markets, partly offset by reduced sales of Somatuline
- Europe<sup>6</sup>: stable sales, reflecting the decline of Somatuline, impacted by the penetration of generic lanreotide, and reduced Onivyde sales to Ipsen's ex-U.S. partner, offset by the strong growth of Dysport, a solid Cabometyx performance and the contribution of Bylvay
- Rest of World: sales growth of 26.1%<sup>5</sup>, driven by a solid performance by Cabometyx and by Dysport, primarily in Latin America, the Middle East and North Africa

<sup>&</sup>lt;sup>4</sup> Reference to Epizyme's YTD 2022 performance.

<sup>&</sup>lt;sup>5</sup> At CER, which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

<sup>&</sup>lt;sup>6</sup> Defined in this announcement as the E.U., the U.K., Iceland, Liechtenstein, Norway and Switzerland.

# Appendix: geographic breakdowns of total sales by medicine

Total					North America					Eur	ope <sup>7</sup>		Rest of World			
YTD	YTD 2023	YTD 2022	% ch	% change		YTD 2022	% change		YTD 2023	YTD 2022	% change		YTD 2023	YTD 2022	% change	
	€m	€m	Actual	CER <sup>8</sup>	€m	€m	Actual	CER <sup>8</sup>	€m	€m	Actual	CER <sup>8</sup>	€m	€m	Actual	CER <sup>8</sup>
Oncology	1,744.1	1,767.2	-1.3%	0.8%	600.0	634.5	-5.4%	-3.5%	742.1	789.3	-6.0%	-5.7%	402.1	343.4	17.1%	23.4%
Somatuline	787.9	911.9	-13.6%	-12.0%	450.2	525.5	-14.3%	-12.6%	238.7	292.7	-18.5%	-17.9%	99.1	93.7	5.8%	9.6%
Decapeptyl	407.1	396.0	2.8%	5.5%	-	-	-	-	222.5	221.2	0.5%	0.8%	184.6	174.7	5.7%	11.5%
Cabometyx	397.7	327.7	21.4%	24.4%	13.5	12.9	4.7%	11.9%	266.8	242.4	10.0%	10.3%	117.4	72.4	62.2%	72.8%
Onivyde	120.2	122.0	-1.4%	-0.3%	108.1	93.1	16.2%	18.2%	11.3	26.5	-57.6%	-58.4%	0.9	2.4	-63.2%	-65.2%
Tazverik	28.1	2.8	n/a	n/a	28.1	2.8	n/a	n/a	-	-	-	-	-	-	-	-
Other Oncology	3.1	6.9	-54.7%	-54.5%	0.2	0.3	-37.3%	-33.1%	2.9	6.4	-54.3%	-54.2%	0.0	0.2	n/a	n/a
Neuroscience	489.0	407.7	19.9%	24.5%	125.4	116.7	7.4%	10.1%	144.6	110.9	30.4%	30.8%	219.1	180.1	21.6%	29.9%
Dysport	482.0	400.3	20.4%	24.7%	125.4	116.7	7.4%	10.1%	144.6	110.9	30.4%	30.8%	212.0	172.8	22.7%	30.7%
Other Neuroscience	7.0	7.3	-4.4%	10.8%	-	-	-	-	-	-	-	-	7.0	7.3	-4.4%	10.8%
Rare Disease	76.0	33.6	n/a	n/a	35.4	8.1	n/a	n/a	36.6	24.5	49.3%	49.3%	4.0	1.1	n/a	n/a
Bylvay	45.7	-	n/a	n/a	27.6	-	n/a	n/a	17.7	-	n/a	n/a	0.3	-	n/a	n/a
Sohonos	2.8	0.1	n/a	n/a	-	0.1	n/a	n/a	0.6	-	n/a	n/a	2.2	-	n/a	n/a
NutropinAq	14.8	20.8	-28.7%	-28.5%	-	-	-	-	14.1	19.9	-29.0%	-28.9%	0.7	0.8	-22.0%	-18.5%
Increlex	12.7	12.8	-0.1%	1.3%	7.8	8.0	-2.5%	-0.7%	4.2	4.6	-8.9%	-8.8%	0.8	0.2	n/a	n/a
Total Sales	2,309.1	2,208.5	4.6%	7.1%	760.8	759.2	0.2%	2.4%	923.2	924.7	-0.2%	0.1%	625.1	524.6	19.2%	26.1%

<sup>7</sup> Defined in this announcement as the E.U., U.K., Iceland, Liechtenstein, Norway and Switzerland.
<sup>8</sup> At CER, which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.



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<sup>&</sup>lt;sup>9</sup> Defined in this announcement as the E.U., U.K., Iceland, Liechtenstein, Norway and Switzerland.

<sup>&</sup>lt;sup>10</sup> At CER, which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

## **Forward-looking statements**

The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, 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 herein. 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. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including lpsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external-growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines, which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on lpsen's business, financial position or performance. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to Ipsen's 2022 Universal Registration Document, available on ipsen.com.