

Ipsen delivers robust sales growth in the first quarter of 2023 and confirms its full-year guidance

Paris (France), 27 April 2023

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

	Q1 2023	Q1 2022	% change	
	€m	€m	Actual	CER ¹
Oncology	570.8	556.4	2.6%	1.1%
Neuroscience	156.4	120.2	30.2%	24.4%
Rare Disease	14.7	11.3	29.8%	29.0%
Total Sales²	741.9	687.9	7.8%	5.7%

Highlights

- Total-sales growth of 5.7% at CER¹, or 7.8% as reported, driven by the performance of the growth platforms³, up by 14.7%¹, with Dysport® (abobotulinumtoxinA) up by 25.2%¹ and Cabometyx® (cabozantinib) up by 31.0%¹, respectively. The performance included contributions from newly acquired Tazverik® (tazemetostat) and Bylvay® (odevixibat)
- Completion of the definitive merger agreement for the acquisition of Albireo, expanding Ipsen's scope in Rare Disease
- Regulatory-decision dates in the U.S. confirmed for Bylvay in Alagille syndrome and palovarotene in fibrodysplasia ossificans progressiva (FOP), respectively
- Full-year 2023 guidance confirmed, with total-sales growth greater than 4.0% at CER¹ and a core operating margin of around 30% of total sales

David Loew, Chief Executive Officer, commented:

"Ipsen continues to make excellent progress in its transformation. We delivered further robust sales growth in the quarter, led by the standout performances of Dysport and Cabometyx. Based on the continued sales momentum, we are confirming our guidance for the full year. I was also delighted by the further enhancement of our pipeline, portfolio and organization as a result of the recent acquisition of Albireo; through our global presence, we will continue to meet the unmet medical needs of an increasing number of patients. As we replenish the pipeline and execute on recent transactions, we look forward to several milestones for our business, including the Phase III data readout for elafibranor and anticipated regulatory developments for Onivyde, palovarotene and Bylvay."

¹ At constant exchange rates (CER), which exclude any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

² Total sales in this announcement are unaudited IFRS consolidated sales.

³ Dysport, Decapeptyl® (triptorelin), Cabometyx and Onivyde® (irinotecan).

Full-year 2023 guidance

Ipsen has confirmed its financial guidance for FY 2023⁴:

- Total-sales growth greater than 4.0%, at constant exchange rates. Based on the average level of exchange rates in Q1 2023, an adverse impact on total sales of around 2% from currencies is expected
- Core operating margin around 30% of total sales, excluding any potential impact of incremental investments from future external-innovation transactions

Business development

In March 2023, Ipsen announced that it had completed the acquisition of Albireo Pharma, Inc., a leading innovator in bile-acid modulators to treat rare liver conditions. Ipsen acquired all issued and outstanding shares at a price of \$42.00 per share in cash, plus one non-transferable contingent value right of \$10.00 per share.

Pipeline development

In February 2023, it was announced that the U.S. Food and Drug Administration had accepted the supplemental New Drug Application for a second Bylvay indication, for patients with Alagille syndrome. The administration also issued a Prescription Drug User Fee Act (PDUFA) action date of 15 June 2023.

In March 2023, it was announced that the PDUFA action date in the U.S., for the resubmitted New Drug Application for palovarotene as a potential treatment for FOP, will be 16 August 2023. The Company also recently requested a re-examination of the negative opinion from the CHMP⁵ for palovarotene, received in January 2023.

Conference call

A conference call and webcast for investors and analysts will begin today at 2pm, Paris time. Participants can access the call and its details by registering [here](#); webcast details can be found [here](#). A recording will be available on ipsen.com.

Calendar

Ipsen intends to publish its half-year and second-quarter results on 27 July 2023.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the three-month period to 31 March 2023 (the first quarter or Q1 2023), compared to the three-month period to 31 March 2022 (Q1 2022), 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 life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has around 5,400 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 ipsen.com.

⁴ The performance of Consumer HealthCare, divested in July 2022, has been excluded from all commentary and comparisons to prior performance.

⁵ The Committee for Medicinal Products for Human Use, the European Medicines Agency's committee responsible for human medicines.

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Total sales by therapy area and medicine

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

	Q1 2023	Q1 2022	% change	
	€m	€m	Actual	CER ⁶
Oncology	570.8	556.4	2.6%	1.1%
Somatuline®	263.2	286.0	-8.0%	-9.8%
Cabometyx	130.4	98.9	31.9%	31.0%
Decapeptyl	130.0	129.2	0.6%	0.8%
Onivyde	36.9	40.1	-7.9%	-12.3%
Tazverik	9.2	-	n/a	n/a
Other Oncology	1.0	2.2	-54.0%	-53.6%
Neuroscience	156.4	120.2	30.2%	24.4%
Dysport	154.6	118.4	30.5%	25.2%
Other Neuroscience	1.8	1.7	4.5%	-18.0%
Rare Disease	14.7	11.3	29.8%	29.0%
Bylvay	5.0	-	n/a	n/a
NutropinAq®	5.4	7.1	-24.1%	-24.0%
Increlex®	4.2	4.2	-0.6%	-3.2%
Total Sales	741.9	687.9	7.8%	5.7%

⁶ 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.

- **Somatuline®** (lanreotide): in North America, limited sales erosion of 2.7%⁷, with adverse U.S. pricing partly offset by a favourable impact reflecting the reduced level of U.S wholesaler-buying levels in Q1 2022. In Europe, sales declined by 25.7%⁷, driven by the impact of generic lanreotide in a number of markets, including France, Spain and Italy. Sales in the Rest of the World increased by 7.3%⁷, a result of solid performances in several geographies, including Latin America
- **Decapeptyl**: performance impacted by reduced sales in China, reflecting the prior-year benefit from increased stocking in anticipation of COVID-19 lockdown restrictions, partly offset by continuous market-share uptakes across a number of geographies
- **Cabometyx**: performance reflected strong volume uptakes in renal cell carcinoma across most geographies, as a second-line monotherapy and as a first-line therapy in combination with nivolumab in more countries
- **Onivyde**: performance impacted by phasing of shipments to Ipsen’s ex-U.S. partner, partly offset by the solid underlying growth in the U.S.
- **Tazverik**: sales consolidated for the full quarter, following the completion of the acquisition of Epizyme in August 2022. Commercial sales growing by 21% year on year^{7,8}
- **Dysport**: performance driven by further growth in the aesthetics market, reflected in increased sales to Ipsen’s partner, Galderma, and strong demand in most therapeutics markets
- **Bylvay**: sales consolidated for one month, following the acquisition of Albireo that was completed in March 2023

Total sales by geographical area

	Q1 2023	Q1 2022	% change	
	€m	€m	Actual	CER ⁷
North America	244.8	226.4	8.1%	3.6%
Europe ⁹	296.3	304.7	-2.7%	-2.3%
Rest of the World	200.8	156.9	28.0%	23.2%
Total Sales	741.9	687.9	7.8%	5.7%

- **North America**: sales grew by 3.6%⁷, driven by a solid performance from Onivyde and the contribution from newly acquired medicines Tazverik and Bylvay, partly offset by reduced sales of Dysport to Galderma in aesthetics, as well as the gradual erosion of Somatuline
- **Europe**: sales declined by 2.3%⁷, mainly driven by the performance of Somatuline that reflected the impact of generic lanreotide and by reduced Onivyde sales to Ipsen’s ex-U.S. partner, offset by strong growth of Cabometyx, as well as Dysport in the therapeutics and aesthetics markets
- **Rest of the World**: sales grew by 23.2%⁷, driven by a solid Cabometyx performance and Dysport, primarily in Latin America, the Middle East and North Africa

⁷ 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.

⁸ Reference to Epizyme’s published Q1 2022 performance.

⁹ Defined in this announcement as the E.U., the U.K., Iceland, Liechtenstein, Norway and Switzerland.

Appendix: geographic breakdown of total sales by medicine

	Total				North America				Europe				Rest of the World			
	Q1 2023 €m	Q1 2022 €m	% change Actual CER ¹⁰		Q1 2023 €m	Q1 2022 €m	% change Actual CER ¹⁰		Q1 2023 €m	Q1 2022 €m	% change Actual CER ¹⁰		Q1 2023 €m	Q1 2022 €m	% change Actual CER ¹⁰	
Oncology	570.8	556.4	2.6%	1.1%	202.9	184.3	10.1%	5.7%	239.8	267.9	-10.5%	-10.0%	128.0	104.3	22.8%	19.9%
Somatuline	263.2	286.0	-8.0%	-9.8%	153.7	151.5	1.4%	-2.7%	77.4	105.5	-26.7%	-25.7%	32.1	29.0	10.9%	7.3%
Cabometyx	130.4	98.9	31.9%	31.0%	4.2	4.0	4.8%	6.9%	87.1	75.2	15.7%	16.3%	39.2	19.7	99.1%	85.8%
Decapeptyl	130.0	129.2	0.6%	0.8%	-	-	-	-	73.3	73.7	-0.5%	0.1%	56.7	55.5	2.2%	1.6%
Onivyde	36.9	40.1	-7.9%	-12.3%	35.7	28.7	24.7%	19.1%	1.2	11.4	-89.5%	-90.9%	-	-	-	-
Tazverik	9.2	-	n/a	n/a	9.2	-	n/a	n/a	-	-	-	-	-	-	-	-
Other Oncology	1.0	2.2	-54.0%	-53.6%	0.1	0.1	50.8%	53.8%	0.9	2.0	-55.9%	-55.8%	0.0	0.1	n/a	n/a
Neuroscience	156.4	120.2	30.2%	24.4%	36.5	39.5	-7.5%	-11.9%	47.7	28.4	68.1%	69.6%	72.2	52.3	38.0%	29.0%
Dysport	154.6	118.4	30.5%	25.2%	36.5	39.5	-7.5%	-11.9%	47.7	28.4	68.1%	69.6%	70.3	50.5	39.1%	31.0%
Other Neuroscience	1.8	1.7	4.5%	-18.0%	-	-	-	-	-	-	-	-	1.8	1.7	4.5%	-18.0%
Rare Disease	14.7	11.3	29.8%	29.0%	5.3	2.6	n/a	95.6%	8.7	8.4	4.0%	4.2%	0.6	0.3	n/a	n/a
Bylvay	5.0	-	n/a	n/a	3.0	-	n/a	n/a	2.0	-	n/a	n/a	0.0	-	n/a	n/a
NutropinAq	5.4	7.1	-24.1%	-24.0%	-	-	-	-	5.1	6.8	-25.0%	-24.9%	0.3	0.3	-2.3%	-1.5%
Increlex	4.2	4.2	-0.6%	-3.2%	2.3	2.6	-10.2%	-14.1%	1.5	1.5	-2.8%	-2.1%	0.3	0.0	n/a	n/a
Total Sales	741.9	687.9	7.8%	5.7%	244.8	226.4	8.1%	3.6%	296.3	304.7	-2.7%	-2.3%	200.8	156.9	28.0%	23.2%

¹⁰ 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 Ipsen'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 Ipsen'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 2021 Universal Registration Document, available on [ipsen.com](https://www.ipsen.com).