Press release

Intended for international media and investor audiences only

Ipsen delivers strong sales in the first quarter of 2024, driven by growth platforms & new medicines, and confirms its full-year guidance

PARIS, FRANCE, 24 April 2024 - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-care biopharmaceutical company, today presents its sales for the first quarter of 2024.

	Q1 2024	Q1 2023	% change	
	€m	€m	Actual	CER[1]
Growth platforms[2]	509.7	452.0	12.8%	16.2%
New medicines[3]	45.5	14.3	n/a	n/a
Somatuline®	257.8	263.2	-2.0%	-1.3%
Other	9.5	12.4	-23.8%	-20.5%
Total Sales	**822.4**	**741.9**	**10.9%**	**13.3%**

Highlights

- Total-sales growth of 13.3% at CER[1], or 10.9% as reported, driven by the 16.2%[1] increase in sales of the growth platforms[2] and the increased contributions from new medicines, while Somatuline sales declined by only 1.3%[1]
- Regulatory approval and launch of Onivyde in the U.S. as a first-line treatment for metastatic pancreatic ductal adenocarcinoma (mPDAC)
- Confirmation of financial guidance for 2024

"An excellent first-quarter performance has laid a solid foundation for Ipsen's growth in 2024", commented David Loew, Chief Executive Officer, Ipsen. "The delivery of our strategic plan continues to be evidenced by a strong top line, supported by the success of the growth platforms and the increased contribution of the new medicines. Moreover, the pipeline continues to deliver, illustrated this quarter by the regulatory approval in the U.S. of Onivyde as a first-line treatment for pancreatic cancer.

"This year marks a pivotal period for our growth plans, with the launches of four new medicines or indications. Our focus remains on the performance of our portfolio and the expansion of our pipeline, and a well-defined strategy for sustainable growth centred on enhancing the lives and medical outcomes of patients."

[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] Dysport® (abobotulinumtoxinA), Decapeptyl® (triptorelin), Cabometyx® (cabozantinib) and Onivyde® (irinotecan).
[3] Bylvay® (odevixibat), Tazverik® (tazemetostat) and Sohonos® (palovarotene).

Full-year 2024 guidance

Ipsen has confirmed its financial guidance for 2024, which excludes the impact of any potential additional late-stage[4] external-innovation opportunities:

- Total-sales growth greater than 6.0%, at constant currency. Based on the average level of exchange rates in March 2024, an adverse impact on total sales of around 1% from currencies is expected

- Core operating margin around 30% of total sales, which includes additional R&D expenses from anticipated early and mid-stage external-innovation opportunities

Guidance on total sales incorporates expectations for Somatuline of further generic-lanreotide products in the U.S and E.U.

Business update

In February 2024, Ipsen announced that the U.S. Food and Drug Administration (FDA) had approved the supplemental new drug application for Onivyde plus oxaliplatin, fluorouracil and leucovorin (NALIRIFOX) as a first-line treatment for adults living with mPDAC. This was the second approval for an Onivyde regimen in mPDAC, after the FDA's approval in 2015 of Onivyde plus fluorouracil and leucovorin, following disease progression with gemcitabine-based therapy. In conjunction with the approval in the U.S. of Onivyde as a first-line treatment in adults living with mPDAC, Orphan Drug Exclusivity was awarded and regulatory exclusivity was extended to 2031, driven by the automatic seven-year exclusivity period upon approval.

In April 2024, Ipsen announced an exclusive global licensing agreement for STRO-003, an antibody-drug conjugate (ADC) targeting the ROR1 tumor antigen. STRO-003 is in the final stages of pre-clinical development. The agreement gives Ipsen exclusive worldwide rights to develop and commercialize STRO-003 and is the first ADC candidate to join Ipsen's expanding pipeline.

Ipsen and Skyhawk Therapeutics announced, in April 2024, the signing of an exclusive worldwide collaboration to discover and develop novel small molecules that modulate RNA for rare neurological diseases. The agreement includes an option pursuant to which Ipsen would acquire an exclusive licence for the worldwide rights to develop successful development candidates.

Onivyde litigation

In March 2024, Ipsen received a Paragraph IV notice letter regarding a 505(b)(2) submission to the U.S. FDA by Conjupro Biotherapeutics, Inc. (Conjupro), requesting approval to market an irinotecan hydrochloride liposome injection for the treatment of patients with mPDAC, following gemcitabine-based therapy. The letter challenges various patents that protect Onivyde and its use. In response, Ipsen filed in April 2024 a patent infringement lawsuit against Conjupro and certain related corporate entities in the U.S. District Court for the District of New Jersey and will fully defend its rights as its patent portfolio includes U.S. patent protection for the liposome composition to expire in 2027, with additional patents

[4] Phase III clinical development or later.

covering the formulation and approved use in the treatment of patients with mPDAC following gemcitabine-based therapy having expiration dates up to 2033, with additional protection on the first-line use until 2036.

Conference call

A conference call and webcast for investors and analysts will begin today at 1pm CET. Participants can access the call and its details by registering here; webcast details can be found here.

Calendar

Ipsen intends to publish its half-year and second-quarter results on 25 July 2024.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the three-month period to 31 March 2024 (Q1 2024, the quarter), compared to the three-month period to 31 March 2023 (Q1 2023).

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Our pipeline is fuelled by external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen 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.

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Total sales by therapy area and medicine

	Q1 2024	Q1 2023	% change	
	€m	€m	Actual	CER[5]
Oncology	**603.8**	**570.8**	**5.8%**	**7.5%**
Somatuline®	257.8	263.2	-2.0%	-1.3%
Cabometyx®	154.5	130.4	18.5%	22.2%
Decapeptyl®	130.8	130.0	0.6%	2.6%
Onivyde®	47.3	36.9	28.1%	29.8%
Tazverik®	12.5	9.2	35.3%	37.0%
Other Oncology	0.9	1.0	-8.6%	-8.8%
Neuroscience	**179.2**	**156.4**	**14.6%**	**19.6%**
Dysport®	177.0	154.6	14.5%	19.3%
Aesthetics	*102.0*	*87.7*	*16.3%*	*24.3%*
Therapeutics	*75.0*	*66.9*	*12.1%*	*12.9%*
Other Neuroscience	2.2	1.8	19.3%	49.6%
Rare Disease	**39.4**	**14.7**	**n/a**	**n/a**
Bylvay®	26.0	5.0[6]	n/a	n/a
Sohonos®	7.0	0.1	n/a	n/a
NutropinAq®	2.4	5.4	-55.7%	-55.7%
Increlex®	4.0	4.2	-4.1%	-3.8%
Total Sales	**822.4**	**741.9**	**10.9%**	**13.3%**

- **Somatuline**: limited sales erosion, benefiting from generic-lanreotide shortages in several countries in Europe and a solid performance in Rest of World. In North America, sales declined by 10.0%[5], primarily reflecting adverse U.S. pricing, despite solid volume growth

- **Decapeptyl:** performance mainly driven by growth in China, and impacted by increased competition and pricing pressure in Europe

- **Cabometyx**: growth supported by increased volumes in the first-line combination with nivolumab and second-line monotherapy renal cell carcinoma indications, and some favorable phasing in Rest of World

- **Onivyde**: solid performance in the U.S., supported by the growth in the post-gemcitabine setting and early positive feedback following the U.S. FDA approval in mid-February 2024 of the first-line

[5] 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.
[6] Sales in Q1 2023 consolidated for one month, following the acquisition of Albireo that was completed in March 2023.

indication, as well as sales to Ipsen's ex-U.S. partner that reflected the low 2023 baseline

» **Tazverik**: growth in the U.S., with challenging underlying conditions in the current monotherapy setting

» **Dysport**: strong performance driven by continued growth in the aesthetics market and therapeutics markets, driven mainly by North America & Rest of World, while Europe sales were partly impacted by adverse phasing

» **Bylvay**[7]: sales consolidated for the full quarter, following the completion of the acquisition of Albireo in March 2023. Growth of 78.2%[8], driven by global sales in the PFIC[9] indication and the U.S. launch in the second indication, Alagille syndrome

» **Sohonos**: sales mainly in the U.S., following the launch in the fourth quarter of 2023

» **NutropinAq**: the decline in sales reflected the anticipated end of commercialization of the medicine in April 2024

Total sales by geographical area

	Q1 2024	Q1 2023	% change	
	€m	€m	Actual	CER[10]
North America	269.5	244.8	10.1%	11.3%
Europe[11]	316.2	296.3	6.7%	6.2%
Rest of World	236.7	200.8	17.9%	26.8%
Total Sales	**822.4**	**741.9**	**10.9%**	**13.3%**

» **North America**: sales growth driven by the solid performance of Onivyde and Dysport (in aesthetics, including the favorable phasing of sales to Ipsen's partner), the full-quarter contribution of Bylvay and the launch of Sohonos, partly offset by reduced sales of Somatuline

» **Europe**[11]: sales growth driven by Somatuline benefiting from generic-lanreotide shortages, the solid growth of Cabometyx and Onivyde and a full quarter's contribution of Bylvay, despite lower sales of Dysport mainly from phasing impacts

» **Rest of World**: sales growth driven by the strong performance of Cabometyx, including favorable phasing, the growth of Somatuline, and the perfomance of Dysport across both aesthetics and therapeutics

[7] Sales in Q1 2023 consolidated for one month, following the acquisition of Albireo that was completed in March 2023.
[8] Adjusted growth including sales of Bylvay for the first two months of 2023.
[9] Progressive familial intrahepatic cholestasis.
[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.
[11] Defined in this announcement as the E.U., the U.K., Iceland, Liechtenstein, Norway and Switzerland.

Appendix: quarterly geographic breakdowns of total sales by medicine

	Total				North America				Europe				Rest of World			
	Q1 2024	Q1 2023	% change		Q1 2024	Q1 2023	% change		Q1 2024	Q1 2023	% change		Q1 2024	Q1 2023	% change	
	€m	€m	Actual	CER[12]	€m	€m	Actual	CER[12]	€m	€m	Actual	CER[12]	€m	€m	Actual	CER[12]
Oncology	**603.8**	**570.8**	**5.8%**	**7.5%**	**194.7**	**202.9**	**-4.0%**	**-2.9%**	**258.1**	**239.8**	**7.6%**	**6.9%**	**150.9**	**128.0**	**17.9%**	**25.8%**
Somatuline®	257.8	263.2	-2.0%	-1.3%	136.6	153.7	-11.1%	-10.0%	85.6	77.4	10.6%	9.3%	35.6	32.1	10.8%	14.7%
Cabometyx®	154.5	130.4	18.5%	22.2%	5.1	4.2	22.4%	23.5%	93.3	87.1	7.2%	6.7%	56.1	39.2	43.2%	58.8%
Decapeptyl®	130.8	130.0	0.6%	2.6%	–	–	–	–	72.3	73.3	-1.3%	-1.8%	58.5	56.7	3.1%	8.5%
Onivyde®	47.3	36.9	28.1%	29.8%	40.5	35.7	13.5%	14.8%	5.9	1.2	n/a	n/a	0.8	–	n/a	n/a
Tazverik®	12.5	9.2	35.3%	37.0%	12.5	9.2	35.3%	37.0%	–	–	–	–	–	–	–	–
Other Oncology	0.9	1.0	-8.6%	-8.8%	–	0.1	n/a	n/a	0.9	0.9	5.9%	5.5%	–	–	–	–
Neuroscience	**179.2**	**156.4**	**14.6%**	**19.6%**	**51.0**	**36.5**	**39.6%**	**40.6%**	**43.8**	**47.7**	**-8.2%**	**-8.0%**	**84.4**	**72.2**	**16.9%**	**27.6%**
Dysport®	177.0	154.6	14.5%	19.3%	51.0	36.5	39.6%	40.6%	43.8	47.7	-8.2%	-8.0%	82.2	70.3	16.9%	27.1%
Aesthetics	*102.0*	*87.7*	*16.3%*	*24.3%*	*39.3*	*25.7*	*52.9%*	*53.7%*	*10.9*	*12.3*	*-11.6%*	*-11.0%*	*51.9*	*49.7*	*4.3%*	*17.4%*
Therapeutics	*75.0*	*66.9*	*12.1%*	*12.9%*	*11.7*	*10.8*	*8.2%*	*9.5%*	*33.0*	*35.5*	*-7.0%*	*-7.0%*	*30.3*	*20.6*	*47.2%*	*49.7%*
Other Neuroscience	2.2	1.8	19.3%	49.6%	–	–	–	–	–	–	–	–	2.2	1.8	19.3%	49.6%
Rare Disease	**39.4**	**14.7**	**n/a**	**n/a**	**23.7**	**5.3**	**n/a**	**n/a**	**14.3**	**8.7**	**63.6%**	**63.0%**	**1.4**	**0.6**	**n/a**	**n/a**
Bylvay®	26.0	5.0	n/a	n/a	15.6	3.0	n/a	n/a	10.4	2.0	n/a	n/a	–	–	–	–
Sohonos®	7.0	0.1	n/a	n/a	5.7	–	n/a	n/a	0.1	0.1	-3.1%	-3.1%	1.2	–	–	–
NutropinAq®	2.4	5.4	-55.7%	-55.7%	–	–	–	–	2.3	5.1	-55.0%	-55.0%	0.1	0.3	-69.1%	-68.4%
Increlex®	4.0	4.2	-4.1%	-3.8%	2.5	2.3	6.6%	7.9%	1.4	1.5	-6.1%	-7.2%	0.1	0.3	-74.9%	-74.3%
Total Sales	**822.4**	**741.9**	**10.9%**	**13.3%**	**269.5**	**244.8**	**10.1%**	**11.3%**	**316.2**	**296.3**	**6.7%**	**6.2%**	**236.7**	**200.8**	**17.9%**	**26.8%**

[12] 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

Disclaimers and/or 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 latest Universal Registration Document, available on ipsen.com.