

Ipsen delivers encouraging sales growth in the first quarter of 2021 despite the pandemic, and confirms its full-year guidance

Paris (France), 22 April 2021 - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, publishes its sales performance for the first quarter of 2021:

Q1 2021 sales summary

(unaudited IFRS consolidated sales)

	Q1 2021		
	€m	Actual	% change CER ¹
Specialty Care	611.5	1.5	6.4
Consumer Healthcare	47.0	-9.6	-5.4
Total Sales	658.5	0.6	5.5

Highlights

- Total Sales growth of 5.5% at CER, or 0.6% as reported, to €658.5m, despite impact of the pandemic
- An increase in Specialty Care sales of 6.4%¹ to €611.5m, driven by the growth of Cabometyx[®] (*cabozantinib*), Decapeptyl[®] (*triptorelin*), Somatuline[®] (*lanreotide*) and Dysport[®] (*botulinum toxin type A*)
- A Consumer Healthcare sales decline of 5.4%¹ to €47.0m, reflecting the ongoing effects of COVID-19, partly offset by recovery in China
- European Commission approval of Cabometyx[®], in combination with nivolumab, as a first-line treatment for patients living with advanced renal cell carcinoma
- Guidance for FY 2021 confirmed

David Loew, Chief Executive Officer, commented:

“We delivered a strong performance in the first quarter, despite the persistently difficult COVID-19 environment, driven by our unrelenting focus on patients. Our execution was in line with our plans and our financial guidance for the year. Ipsen’s Oncology medicines stood out in the period, while the regulatory approval in Europe of the Cabometyx[®] combination with nivolumab in first-line renal cell carcinoma marked the start of an important launch. The anticipated registration of a lanreotide-generic medicine in Europe is fully aligned with our expectations.

In the near term, we look forward to trial results in first-line liver cancer for the Cabometyx[®] combination with atezolizumab, as well as regulatory progress with palovarotene in FOP. We continue to support our ambitions of strengthening the pipeline and driving sustainable growth, based on our patient-focused strategy. I am very proud of the great execution by colleagues around the world, especially as many teams continue to experience challenging conditions during the pandemic.”

¹ 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.

FY 2021 guidance

The Company today confirms its financial guidance for FY 2021, which incorporates an assumed progressive global recovery from COVID-19 by H2 2021. A phased launch of generic lanreotide in Europe by mid-2021 is also assumed, as is a limited impact of the potential launch of octreotide or lanreotide generics in the U.S.

Total Sales	Growth of more than 4.0% at CER
Core Operating Margin	Greater than 30.0%, excluding any potential impact of incremental investments from external innovation

Currency impact

Ipsen anticipates an adverse impact of 2% from currencies on Total Sales in FY 2021, based on the level of exchange rates at the end of March 2021.

Somatuline[®]-generic update

During the quarter, a positive outcome was received for a generic formulation of lanreotide in 60mg, 90mg and 120mg dose presentations by the Reference Member State, Denmark; the closure of the Decentralized Procedure was also achieved. National marketing authorizations have recently been granted for a lanreotide generic medicine in France, Denmark, Hungary and Latvia. These developments were consistent with Ipsen's expectations.

Business development

In the quarter, Ipsen and Fusion Pharmaceuticals Inc. completed an asset purchase agreement to acquire Ipsen's intellectual property and assets related to IPN-1087, a small molecule in Phase I development targeting neurotensin receptor 1, a protein expressed on multiple solid-tumor types.

Conference call

A conference call and webcast for investors and analysts will begin at 2:30pm Paris time today. Participants should dial in to the call early and can register [here](#); a recording will be available on ipsen.com, while the webcast can be accessed [here](#). The event ID is 2495337.

Calendar

The Company intends to publish its H1 2021 results on 29 July 2021 and its nine-months' sales update on 21 October 2021. The Annual Shareholders' Meeting will be held behind closed doors on 27 May 2021.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the three-month period to 31 March 2021 (the quarter, the first quarter or Q1 2021), compared to three-month period to 31 March 2020 (Q1 2020) respectively, unless stated otherwise. Growth rates are at CER, unless stated otherwise. Commentary on performance is based on CER, unless stated otherwise.

Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Neuroscience and Rare Disease; it also has a well-established Consumer Healthcare business. With Total Sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. 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 c.5,700 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.

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Sales by therapeutic area and product

	Q1 2021		
	€m	% change	
		Actual	CER ¹
Total Specialty Care	611.5	1.5	6.4
Oncology	495.4	0.6	4.9
Somatuline®	277.0	-3.0	2.5
Decapeptyl®	106.3	10.0	12.0
Cabometyx®	83.3	15.0	16.4
Onivyde®	26.5	-15.0	-6.9
Other Oncology	2.4	-65.6	-65.7
Neuroscience	103.1	10.3	19.8
Dysport®	101.8	9.6	18.9
Rare Disease	13.1	-21.1	-19.4
NutropinAq®	8.5	-24.0	-23.9
Increlex®	4.6	-15.2	-9.7
Total Consumer Healthcare	47.0	-9.6	-5.4
Smecta®	16.3	-8.8	-4.9
Forlax®	9.1	-7.6	-5.6
Tanakan®	8.5	-16.4	-10.0
Fortrans/Eziclen®	6.8	-0.7	6.1
Other Consumer Healthcare	6.3	-13.5	-10.6
Total Sales	658.5	0.6	5.5

¹ 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.

Specialty Care

Sales amounted to €611.5m, an increase of 6.4%¹. Oncology and Neuroscience sales increased by 4.9%¹ and 19.8%¹ to €495.4m and €103.1m, respectively, while Rare Disease sales declined by 19.4%¹ to €13.1m.

In the quarter, Specialty Care comprised 93% of Total Sales (Q1 2020: 92%).

Oncology

Sales of €495.4m represented growth of 4.9%¹. The performance was encouraging, particularly after challenges for the treatment of cancer patients during the pandemic, as well as the comparative impact of limited increased stocking in Q1 2020 in some European countries. Improved conditions in China underpinned the strong performance of Decapeptyl[®], while there were also good results for Cabometyx[®] and Somatuline[®] globally.

In the quarter, Oncology sales comprised 75% of Total Sales (Q1 2020: 75%).

- a) **Somatuline[®]** sales reached €277.0m, an increase of 2.5%¹, with growth of 5.1%¹ in North America that reflected strong volumes, even with the adverse ongoing impacts of COVID-19 on patient diagnoses and treatments. The performance was also a result of continued market-share gains in most geographies, despite the high level of Somatuline[®] orders in March 2020. There was only a limited impact from generic-octreotide sales in Europe.
- b) **Decapeptyl[®]** sales of €106.3m reflected growth of 12.0%¹, mainly driven by China, which significantly recovered from the impacts of COVID-19. This was offset by lower sales in Europe, reflecting the level of pandemic-related stocking in Q1 2020.
- c) **Cabometyx[®]** sales reached €83.3m, up by 16.4%¹, driven by a strong volume uptake across most geographies in both renal cell carcinoma and hepatocellular carcinoma.
- d) **Onivyde[®]** sales of €26.5m, down by 6.9%¹, reflected mainly the impact of the pandemic on cancer treatment in the U.S.

Neuroscience

Dysport[®] sales reached €101.8m, up by 18.9%¹, mainly driven by Galderma's solid performance in the aesthetics market in Brazil and North America, along with growth in the Middle East and higher volumes in the Brazil and Mexico therapeutics markets. Sales in Europe continued to be impacted by the pandemic across aesthetics and therapeutics markets.

In the quarter, Neuroscience sales comprised 16% of Total Sales (Q1 2020:14%).

Rare Disease

NutropinAq[®] (*somatropin*) sales of €8.5m, a decline of 23.9%¹, reflected a slowdown in the market and competitive pressures across Europe. A decline in **Increlex[®]** (*mecasermin*) sales of 9.7%¹ to €4.6m was a result of lower demand in the U.S., reflecting the ongoing effects of COVID-19.

In the quarter, Rare Disease sales comprised 2% of Total Sales (Q1 2020: 3%).

Consumer Healthcare

Sales of €47.0m, a decline of 5.4%¹, was a result of a 4.9%¹ fall in sales of **Smecta[®]** (*diosmectite*) that was driven by the slowdown of the diarrhea market in Europe, partly offset by the recovery in China. **Fortrans/Eziclen[®]** (*macrogol 4000*) sales increased by 6.1%¹, also reflecting the China recovery. **Tanakan[®]** (*ginkgo biloba extract*) sales declined by 10.0%¹, mainly due to the level of demand in Q1 2020 in Russia.

In the quarter, Consumer Healthcare sales comprised 7% of Total Sales (Q1 2020: 8%).

¹ 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.

Sales by geographical area

	Q1 2021		
	€m	% change	
		Actual	CER ¹
Major Western European Countries	217.5	-3.0	-2.5
France	74.5	-5.4	-4.8
Germany	53.1	5.6	5.6
Italy	33.0	-6.4	-6.4
UK	28.6	-4.7	-3.0
Spain	28.3	-5.2	-5.2
Other European Countries	120.6	-8.7	-3.7
Eastern Europe	54.0	-5.8	3.7
Other Europe	66.6	-11.0	-9.2
North America	207.0	-3.9	4.8
Rest of the World	113.5	36.8	44.5
Asia	54.0	70.7	73.4
Other Rest of the World	59.6	15.9	26.2
Total Sales	658.5	0.6	5.5

Major Western European countries

Sales reached €217.5m, a decline of 2.5%¹. Major Western European countries comprised 33% of Total Sales (Q1 2020: 34%).

- a) **France:** sales of €74.5m, reflecting a decline of 4.8%¹, were affected by a high level of orders in Q1 2020, due to COVID-19, and a slowdown of the diarrhea market impacting Consumer Healthcare.
- b) **Germany:** sales reached €53.1m, up by 5.6%¹, mainly driven by continued market-share gains for Cabometyx[®] and Somatuline[®], with only a limited impact from the sale of generic octreotide.
- c) **Italy:** Sales of €33.0m, reflecting a decline of 6.4%¹, were a result of a high level of orders of Decapeptyl[®] and Somatuline[®] in Q1 2020, partly compensated by Cabometyx[®] growth from market-share gains.
- d) **U.K.:** Sales reached €28.6m, a decrease of 3.0%¹, with adverse performances of Decapeptyl[®] and Dysport[®], impacted by COVID-19, outweighing solid growth of Somatuline[®].
- e) **Spain:** Sales of €28.3m reflecting a decline of 5.2%¹, with the high level of orders in Q1 2020 from COVID-19 mainly impacting the performance of Cabometyx[®].

Other European countries

Sales reached €120.6m, down by 3.7%¹, mainly driven by reduced Consumer Healthcare sales in Eastern Europe, despite successful launches and market-share gains for Cabometyx[®].

In the quarter, sales in Other European countries comprised 18% of Total Sales (Q1 2020: 20%).

¹ 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.

North America

Sales of €207.0m reflected growth of 4.8%¹, driven by continued strong Somatuline® and Cabometyx® demand, despite an overall adverse impact from the pandemic on cancer treatment. Dysport® sales reflected a good performance in the aesthetics market and growth in the therapeutics market, after the impact of COVID-19 in FY 2020.

In the quarter, sales in North America comprised 31% of Total Sales (Q1 2020: 33%).

Rest of the World

Sales reached €113.5m, an increase of 44.5%¹, driven by a China recovery that resulted in strong Decapeptyl® and Consumer Healthcare sales. This was accompanied by a solid Dysport® performance in Latin America and the Middle East.

In the quarter, sales in the Rest of the World comprised 17% of Total Sales (Q1 2020: 13%).

Forward-looking statements

The forward-looking statements, objectives and targets contained herein are based on the Group'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 the Group'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 the Group'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 the Group. 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 product 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. The Group must face or might face competition from generic products 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 the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical 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 product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product 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 health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group'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 the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group 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 the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group 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. The Group'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 the Group's 2020 Registration Document, available on [ipсен.com](https://www.ipсен.com).

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