

Ipsen delivers strong sales growth of 22.6%¹ for the third quarter of 2017 and confirms full year guidance

Paris (France), 26 October 2017 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, today announced sales for the third quarter of 2017.

Financial highlights

- Q3 2017 Group sales growth of 22.6%¹ driven by Specialty Care sales growth of 26.5%¹ reflecting continued Somatuline[®] momentum and increasing contribution of new products Cabometyx[®] and Onivyde[®], and solid Consumer Healthcare sales growth of 5.0%¹
- YTD Group sales growth of 20.1%¹ fueled by Specialty Care sales growth of 24.3%¹ and Consumer Healthcare back to growth at 2.5%¹
- Full Year 2017 guidance confirmed: Specialty Care sales growth greater than 24%¹, Consumer Healthcare back to growth¹ and a Core Operating Income margin greater than 25% of net sales

Recent pipeline highlights

- Approval of Somatuline[®] by FDA² for the treatment of carcinoid syndrome in the U.S.
- Approval of Xermelo[®] by EMA² for the treatment of carcinoid syndrome diarrhea in combination with SSA² therapy
- Validation by EMA² of the application of Cabometyx[®] for the addition of a new indication in first-line treatment of advanced renal cell carcinoma (RCC)
- Phase 3 CELESTIAL trial of cabozantinib meets primary endpoint of overall survival in patients with advanced hepatocellular carcinoma

Key figures

Third quarter and nine months 2017 unaudited IFRS consolidated sales

(in million euros)	Third Quarter				Nine Months			
	2017	2016	% Variation	% Variation at constant currency	2017	2016	% Variation	% Variation at constant currency
Specialty Care	396.2	319.7	23.9%	26.5%	1,160.8	933.2	24.4%	24.3%
Consumer Healthcare	73.9	70.9	4.3%	5.0%	228.8	221.2	3.4%	2.5%
Group sales	470.1	390.6	20.4%	22.6%	1,389.6	1,154.4	20.4%	20.1%

David Meek, Chief Executive Officer of Ipsen stated: “The excellent performance in the third quarter reflects the continued execution against our 2017 objectives with an accelerated momentum of our Specialty Care business. We achieved several important pipeline milestones during the quarter, notably in Oncology, further strengthening our leadership position in the neuroendocrine tumor market and increasing the potential value of the Cabometyx franchise. We remain focused on the launch execution of our new products and building an innovative and sustainable pipeline.”

¹ Year-on-year growth excluding foreign exchange impacts

² Food and Drug Administration (FDA), European Medicines Agency (EMA), Somatostatin Analog (SSA)

Third quarter 2017 sales highlights

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts.

Third quarter 2017 unaudited IFRS consolidated sales

		Third Quarter			
(in million euros)		2017	2016	% Variation	% Variation at constant currency
Specialty Care		396.2	319.7	23.9%	26.5%
	Somatuline®	173.0	137.0	26.2%	29.9%
	Decapeptyl®	88.2	84.2	4.7%	6.4%
	Cabometyx®	14.3	0.0	NA	NA
	Onivyde®	17.9	0.0	NA	NA
	Dysport®	77.4	73.9	4.8%	6.1%
Consumer Healthcare		73.9	70.9	4.3%	5.0%
	Smecta®	23.3	25.3	-7.8%	-6.4%
	Forlax®	10.4	9.0	16.0%	16.7%
	Tanakan®	11.2	8.9	26.1%	24.7%
Group sales		470.1	390.6	20.4%	22.6%

Consolidated Group sales grew 22.6% to €470.1 million.

Sales of **Specialty Care** products reached €396.2 million, up 26.5% year-on-year.

Somatuline® sales reached €173.0 million, up 29.9%, year-on-year, driven by the continued excellent growth in the United States, and by strong performance in Europe, notably in the UK, Germany and France.

Decapeptyl® sales reached €88.2 million, up 6.4% year-on-year, supported by strong volume growth in China despite some pricing pressure as well as good sales trends in France and Spain.

Cabometyx® sales reached €14.3 million, driven primarily by the performance in France and Germany and also in the Netherlands and in the UK.

Onivyde® sales reached €17.9 million, stable versus the second quarter.

Dysport® sales reached €77.4 million, up 6.1% year-on-year, led by a solid performance in the United States, notably in aesthetics through the Galderma partnership (despite some unfavorable phasing of shipments) and in the Middle East.

Consumer Healthcare product sales totaled €73.9 million, up 5.0% year-on-year, supported by the good performance of Tanakan® in Russia, as well as Bedelix® and Forlax® in Algeria, offset by a new contractual set up in China which started to impact Etiasa® in the third quarter.

Smecta® sales reached €23.3 million, down 6.4% year-on-year, mainly affected by a negative stocking impact in China and the performance in Russia.

Forlax® sales reached €10.4 million, up 16.7% year-on-year, positively impacted by a favorable basis of comparison in Algeria where import programs were suspended in the third quarter of 2016.

Tanakan® sales reached €11.2 million, up 24.7% year-on-year, driven by a rebound of sales in Russia as compared to 2016 which was impacted by challenging market conditions.

About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neurosciences and Rare Diseases. Its commitment to oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales close to €1.6 billion in 2016, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,100 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipсен.com.

Forward Looking Statement

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 2016 Registration Document available on its website (www.ipсен.com).

For further information:

Media

Ian Weatherhead

Vice-President, Corporate External communications

Tél.: +44 (0) 7584230549

E-mail: ian.weatherhead@ipсен.com

Brigitte Le Guennec

Senior Manager, Corporate Communications

Tel.: +33 (0)1 58 33 51 17

E-mail : brigitte.le.guennec@ipсен.com

Financial Community

Eugenia Litz

Vice-President Investor Relations

Tel.: +44 (0) 1753 627721

E-mail: eugenia.litz@ipсен.com

Côme de La Tour du Pin

Investor Relations Manager

Tel.: +33 (0)1 58 33 53 31

E-mail: come.de.la.tour.du.pin@ipсен.com

Comparison of Consolidated Sales for the Third Quarter and First Nine Months of 2017 and 2016:

Sales by therapeutic area and by product¹

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts.

The following table shows sales by therapeutic area and by product for the third quarter and the first nine months of 2017 and 2016:

(in millions euros)	3rd Quarter				9 months			
	2017	2016	% Variation	% Variation at constant currency	2017	2016	% Variation	% Variation at constant currency
Oncology	299.2	225.6	32.6%	35.7%	860.0	657.5	30.8%	31.3%
Somatuline®	173.0	137.0	26.2%	29.9%	513.3	391.9	31.0%	31.1%
Decapeptyl®	88.2	84.2	4.7%	6.4%	259.1	251.8	2.9%	3.8%
Cabometyx®	14.3	0.0	NA	NA	31.1	0.0	NA	NA
Onivyde®	17.9	0.0	NA	NA	37.2	0.0	NA	NA
Other Oncology	5.9	4.4	34.6%	34.8%	19.2	13.8	39.4%	39.6%
Neurosciences	78.0	74.2	5.1%	6.4%	243.3	214.7	13.3%	11.3%
Dysport®	77.4	73.9	4.8%	6.1%	241.0	213.5	12.9%	11.0%
Rare Diseases	19.0	19.8	-4.4%	-3.2%	57.4	60.9	-5.8%	-5.5%
NutropinAq®	12.4	13.3	-6.7%	-6.6%	39.5	43.7	-9.6%	-9.2%
Increlex®	6.5	6.5	0.5%	3.7%	17.9	17.2	3.7%	3.8%
Specialty Care	396.2	319.7	23.9%	26.5%	1,160.8	933.2	24.4%	24.3%
Smecta®	23.3	25.3	-7.8%	-6.4%	82.1	79.4	3.4%	2.4%
Forlax®	10.4	9.0	16.0%	16.7%	31.7	29.1	8.9%	8.6%
Tanakan®	11.2	8.9	26.1%	24.7%	26.7	27.7	-3.9%	-5.7%
Fortrans/Eziclen®	7.6	6.2	23.3%	23.6%	23.4	19.0	23.3%	18.2%
Etiasa®	5.3	8.5	-38.0%	-34.8%	14.7	17.9	-17.9%	-15.6%
Other Consumer Healthcare	16.1	13.0	23.7%	23.5%	50.2	48.1	4.4%	3.9%
Consumer Healthcare	73.9	70.9	4.3%	5.0%	228.8	221.2	3.4%	2.5%
Group Sales	470.1	390.6	20.4%	22.6%	1,389.6	1,154.4	20.4%	20.1%

Nine months 2017 sales highlights

Group sales amounted to €1,389.6 million, up 20.1%, driven by 24.3% growth of Specialty Care sales and 2.5% growth of Consumer Healthcare sales.

Specialty Care sales amounted to €1,160.8 million, up 24.3% year-on-year. Oncology and Neurosciences sales grew by 31.3% and 11.3%, respectively, while Rare Diseases sales decreased by 5.5%. Over the period, the relative weight of Specialty Care continued to increase to reach 83.5% of Group sales, compared to 80.8% in the previous year.

In **Oncology**, sales reached €860.0 million, up 31.3% year-on-year, driven by the launches of Onivyde® and Cabometyx®, as well as the continued strong performance of Somatuline®. Over the period, Oncology sales represented 61.9% of total Group sales, compared to 57.0% in the previous year.

¹ New sales reporting according to main therapeutic indication of each project

Somatuline[®] – Sales reached €513.3 million, up 31.1% year-on-year, driven by strong volume growth in North America as well as good performance in most European countries, notably in the UK, Germany and France.

Decapeptyl[®] – Sales reached €259.1 million, up 3.8% year-on-year, positively impacted by volume growth in Europe, East Middle East and Algeria, as well as a good sales trend in China despite pricing pressure.

Cabometyx[®] – Sales reached €31.1 million, driven by good performance across Europe, especially in France and Germany which accounted for the majority of product sales.

Onivyde[®] – Sales amounted to €37.2 million, reflecting two quarters of sales following completion of the acquisition from Merrimack in April 2017.

In **Neurosciences**, sales of **Dysport**[®] reached €241.0 million, up 11.0% year-on-year, driven by the good performance of Galderma in North America as well as strong growth in the Middle East, offset by the aesthetics sales decrease in Brazil due to temporary importation issues. Over the period, Neurosciences sales represented 17.5% of total Group sales, compared to 18.6% in the previous year.

In **Rare Diseases**, sales of **NutropinAq**[®] reached €39.5 million, down 9.2% year-on-year, impacted by lower volumes across Europe especially in Germany. Sales of **Increlex**[®] reached €17.9 million, up 3.8% year-on-year, driven by the United States. Over the period, Rare Diseases sales represented 4.1% of total Group sales, compared to 5.3% in the previous year.

Consumer Healthcare sales reached €228.8 million, up 2.5% year-on-year driven the launch of **Diosmectal**[®] in Italy following the acquisition of an equity stake in Akkadeas Pharma in January 2017 and the good performance of **Fortrans/Eziclen**[®]. Over the period, Consumer Healthcare sales represented 16.5% of total Group sales, compared to 19.2% in the previous year.

Smecta[®] – Sales reached €82.1 million, up 2.4% year-on-year, driven by the **Diosmectal**[®] launch in Italy, **Smebiocta**[®] launch in France and Eastern Europe and a good sales dynamic in China reflecting the commercial efforts deployed to support the implementation of the OTx strategy, partly offset by a negative inventory impact in China that occurred in Q3 2017.

Forlax[®] – Sales reached €31.7 million, up 8.6% year-on-year, driven by growing sales to partners.

Tanakan[®] – Sales reached €26.7 million, down 5.7 % year-on-year impacted by a continuous market slowdown in France despite higher sales in Russia in the third quarter.

Fortrans/Eziclen[®] – Sales reached €23.4 million up 18.2% year-on-year helped by favorable basis of comparison after **Fortrans**[®] shortage issues in the first half of 2016.

Etiasa[®] – Sales reached €14.7 million, down 15.6% year-on-year, impacted by accounting changes due to the new contractual set up in China which started to occur in the third quarter of 2017.

Other Consumer Healthcare – Sales reached €50.2 million, up 3.9% year-on-year supported by **Prontalgine**[®] and **Buscopan**[®] sales despite some pressure on **Nisis**[®]/**Nisisco**[®] after the price cut that occurred in January 2017.

Sales by geographical area

Group sales by geographical area in the third quarter and first nine months of 2017 and 2016:

(in million euros)	3rd Quarter				9 months			
	2017	2016	% Variation	% Variation at constant currency	2017	2016	% Variation	% Variation at constant currency
France	58.6	52.5	11.6%	11.6%	182.8	164.0	11.4%	11.4%
Germany	38.5	30.8	25.2%	25.2%	108.8	91.6	18.8%	18.8%
Italy	19.3	19.4	-0.7%	-0.7%	68.2	62.4	9.3%	9.3%
United Kingdom	19.5	17.5	11.8%	17.5%	57.9	54.6	6.1%	15.5%
Spain	17.8	15.8	12.5%	12.5%	53.1	50.7	4.8%	4.8%
Major Western European countries	153.7	136.0	13.0%	13.8%	470.9	423.3	11.2%	12.4%
Eastern Europe	44.4	40.4	9.8%	8.1%	142.5	125.6	13.5%	6.8%
Others Europe	48.0	41.8	14.9%	15.8%	144.3	125.9	14.6%	15.3%
Other European countries	92.4	82.2	12.4%	12.0%	286.8	251.5	14.1%	11.0%
North America	119.0	71.6	66.3%	74.4%	339.4	189.7	78.9%	78.7%
Asia	50.2	54.6	-8.1%	-3.5%	150.2	156.0	-3.7%	-1.8%
Other countries in the Rest of the world	54.9	46.2	18.7%	18.0%	142.3	134.0	6.2%	3.4%
Rest of the World	105.0	100.8	4.2%	6.3%	292.5	289.9	0.9%	0.6%
Group Sales	470.1	390.6	20.4%	22.6%	1,389.6	1,154.4	20.4%	20.1%

Sales in **Major Western European countries** reached €470.9 million, up 12.4% year-on-year. Over the period, sales in Major Western European countries represented 33.9% of total Group sales, compared to 36.7% in the previous year.

France – Sales reached €182.8 million, up 11.4% year-on-year, driven by the Cabometyx[®] launch contribution, the sustained growth of Somatuline[®] and the positive sales trend of Decapeptyl[®].

Germany – Sales reached €108.8 million, up 18.8% year-on-year, driven by Cabometyx[®] sales and the strong growth of Somatuline[®] slightly offset by lower sales in Rare Diseases.

Italy – Sales reached €68.2 million, up 9.3% year-on-year, mainly driven by the launch of Diosmectal[®] in Italy following the acquisition of an equity stake in Akkadeas Pharma in January 2017, and the good performance of Somatuline[®].

United Kingdom – Sales reached €57.9 million, up 15.5% year-on-year, mainly driven by the strong performance of Somatuline[®] and the first sales contribution of Cabometyx[®].

Spain – Sales reached €53.1 million, up 4.8% year-on-year, driven by the good performance of Somatuline[®] and Decapeptyl[®].

Sales in **Other European countries** reached €286.8 million, up 11.0% year-on-year, supported by the strong performance of Dysport[®] and the launch of Cabometyx[®] in certain countries. Over the period, sales in the region represented 20.6% of total Group sales compared to 21.8% in the previous year.

Sales generated in **North America** reached €339.4 million, up 78.7% year-on-year, supported by continued strong growth of Somatuline[®], partially driven by new contracts, the Onivyde[®] launch contribution and the good performance of Dysport[®] by Galderma in the aesthetics market. Over the period, sales in North America represented 24.4% of total Group sales, compared to 16.4% in the previous year.

Sales in the **Rest of the World** reached €292.5 million, up 0.6% year-on-year, driven by the good performance of Decapeptyl[®] in the Middle East and Somatuline[®] in certain countries, offset by the sales decrease of Dysport[®] in Brazil due to temporary importation issues and of Etiasa[®] in China impacted by

accounting changes due to the new contractual set up in China. Over the period, sales in the Rest of the World represented 21.1% of total Group sales, compared to 25.1% in the previous year.

MAJOR DEVELOPMENTS

During the first nine months 2017, major developments included:

- 9 January 2017 – Ipsen announced that it had entered into a definitive agreement to acquire the global oncology assets from Merrimack Pharmaceuticals, including its key marketed product Onivyde[®] (irinotecan liposome injection) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, in combination with fluorouracil and leucovorin.
- 20 January 2017 – Ipsen announced the appointment of Harout Semerjian as President, Head of Specialty Care International Region & Global Franchises¹, effective February 2, 2017. He reports to David Meek, CEO of Ipsen, and will be a member of the Executive Leadership Team.
- 31 January 2017 – Ipsen announced that it had signed an agreement to take an equity stake in Akkadeas Pharma with the option to take control of the company in the future. Akkadeas Pharma is a privately-held consumer health care company in Italy with a diversified gastrointestinal-focused portfolio including probiotics, medical devices and food supplements. As part of the transaction, Akkadeas Pharma becomes Ipsen's Italian distributor for Smecta[®] (Diosmectal[®]).
- 13 February 2017 – Ipsen announced that it had entered into a definitive agreement to acquire from Sanofi five consumer healthcare products in certain European territories. The most significant product is Prontalgine[®], an analgesic for the treatment of moderate to severe pain.
- 27 February 2017 – Ipsen's partner Exelixis announced clinical collaboration with Bristol Myers Squibb for late-stage combination trial in first-line renal cell carcinoma.
- 2 March 2017 – Ipsen announced the appointment of Benoit Hennion as Executive Vice President and President, Primary Care, effective 13 March 2017. Mr. Hennion reports directly to David Meek, CEO of Ipsen, and joins the Executive Leadership Team.
- 13 March 2017 – Ipsen announced that the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK, in coordination with fourteen other European regulatory agencies, had approved a new indication for Decapeptyl[®] as adjuvant treatment in combination with tamoxifen or an aromatase inhibitor, of endocrine-responsive early-stage breast cancer in women at high-risk of recurrence who are confirmed as pre-menopausal after completion of chemotherapy.
- 3 April 2017 – Ipsen announced that it had completed its acquisition of global oncology assets from Merrimack Pharmaceuticals, in Cambridge, MA., focusing on Onivyde[®] (irinotecan liposome injection) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, in combination with fluorouracil and leucovorin.
- 14 April 2017 – Ipsen announced the appointment of Dr. Alexandre Lebeaut as Executive Vice-President, R&D, and Chief Scientific Officer.
- 8 May 2017 – Ipsen announced that it had completed its previously announced acquisition of a portfolio of five consumer healthcare products from Sanofi.
- 11 May 2017 – Ipsen hosted an Investor Day at which the management team provided a comprehensive update on its current business, corporate strategy and outlook. In Specialty Care, Ipsen is focused on three key therapeutic areas, Oncology, Neurosciences and Rare diseases, where Ipsen can establish a leadership position and leverage its expertise from drug development to commercialization. To build a sustainable pipeline of innovative assets, Ipsen will transform the R&D model and continue to invest in business development. In Consumer Healthcare, to establish a

sustainable and growing business, Ipsen will complete the OTx model transformation and leverage the three main market-leading brands through consumer innovations, capture the underlying market growth in emerging markets and strengthen the European business. Ipsen provided improved 2020 financial targets of Sales greater than €2.5 billion and Core Operating Income margin greater than 30%.

- 8 June 2017 – Ipsen announced that it had appointed Natixis to purchase 160,000 Ipsen SA shares, or about 0.2% of the share capital, for a period of at least 2 months. The shares purchased under this agreement will be mainly allocated to cover its free performance share allocation plan.
- 15 June 2017 – Ipsen announced that its partner Exelixis initiated Phase 1b trial of cabozantinib in combination with atezolizumab in patients with locally advanced or metastatic solid tumors.
- 16 June 2017 – Ipsen announced that the U.S. Food and Drug Administration (FDA) has expanded the approved use of Dysport[®] (abobotulinumtoxinA) for injection for the treatment of spasticity in adults, based on its supplemental Biologics License Application (sBLA) in lower limb spasticity.
- 19 June 2017 – Ipsen and its partner Exelixis announced that the analysis of the review by a blinded independent radiology review committee (IRC) had confirmed the primary efficacy endpoint results of investigator-assessed progression-free survival (PFS) from the CABOSUN randomized Phase 2 trial of cabozantinib as compared with sunitinib in patients with previously untreated advanced renal cell carcinoma (RCC) with intermediate- or poor-risk disease per the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC).
- 30 June 2017 – Ipsen announced that its US affiliate had entered into an exclusive, three-year agreement with Saol Therapeutics Inc. to promote Dysport[®] (abobotulinumtoxinA) for injection for approved therapeutic indications in adult spasticity and pediatric lower limb spasticity in the United States.
- 3 July 2017 – Ipsen and Teijin Pharma Limited, the core company of the Teijin Group's healthcare business announced that Teijin Pharma had received approval from the Japanese Ministry of Health, Labour and Welfare for Ipsen's subcutaneous drug Somatuline[®] (lanreotide) for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP NET).
- 10 July 2017 – Ipsen announced that its partners Exelixis and Bristol-Myers Squibb initiated Phase 3 trial of Opdivo[®] in combination with CABOMETYX[®] or Opdivo[®] and Yervoy[®] in combination with CABOMETYX[®], versus Sunitinib in previously untreated advanced or metastatic renal cell carcinoma.
- 21 July 2017 – Ipsen announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion recommending the approval of Xermelo[®] (telotristat ethyl) 250 mg three times a day (tid) for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analogue (SSA) therapy in adults inadequately controlled by SSA therapy.
- 16 August 2017 – Ipsen announced that its partners Exelixis had completed the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for CABOMETYX[®] (cabozantinib) tablets as a treatment for patients with previously untreated advanced renal cell carcinoma (RCC)
- 8 September 2017 – Ipsen announced that the European Medicines Agency (EMA), the European regulatory authority, had validated the application for variation to the Cabometyx[®] (cabozantinib) marketing authorization for the addition of a new indication in first-line treatment of advanced renal cell carcinoma

- 10 September 2017 – Ipsen and Exelixis announced updated results from the CABOSUN randomized phase 2 trial of cabozantinib in patients with previously untreated advanced renal cell carcinoma (RCC) with intermediate- or poor-risk disease per the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC).
- 18 September 2017 – Ipsen announced that the U.S. Food and Drug Administration (FDA) had approved a supplemental indication for Somatuline[®] Depot (lanreotide) Injection 120 mg for the treatment of carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analogue rescue therapy.
- 19 September 2017 – Ipsen announced that the European Commission has approved Xermelo[®] (telotristat ethyl) 250 mg three times a day (tid) for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analogue (SSA) therapy in adults inadequately controlled by SSA therapy.
- 16 October 2017 – Ipsen and its partner Exelixis announced that its global phase 3 CELESTIAL trial met its primary endpoint of overall survival (OS), with cabozantinib providing a statistically significant and clinically meaningful improvement in median OS compared to placebo in patients with advanced hepatocellular carcinoma (HCC).

APPENDIX

RISK FACTORS

The Group operates in an environment which is undergoing rapid change and exposes its operations to a number of risks, some of which are outside its control. The risks and uncertainties set out below are not exhaustive and the reader is advised to refer to the Group's 2016 Registration Document available on its website (www.ipsen.com).

- The Group is faced with uncertainty in relation to the prices set for all its products, in so far as medication prices have come under severe pressure over the last few years as a result of various factors, including the tendency for governments and payers to reduce prices or reimbursement rates for certain drugs marketed by the Group in the countries in which it operates, or even to remove those drugs from lists of reimbursable drugs.
- The Group depends on third parties to develop and market some of its products, which generates or may generate substantial royalties for the Group, but these third parties could behave in ways that cause damage to the Group's business. The Group cannot be certain that its partners will fulfill 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.
- Actual results may depart significantly from the objectives given that a new product can appear to be promising at a development stage, or after clinical trials, but never be launched on the market, or be launched on the market but fail to sell, notably for regulatory or competitive reasons.
- The Research and Development process typically lasts between eight and twelve years from the date of discovery to a product being brought to market. This process involves several stages; at each stage, there is a substantial risk that the Group could fail to achieve its objectives and be forced to abandon its efforts in respect of products in which it has invested significant amounts. Thus, in order to develop viable products from a commercial point of view, the Group must demonstrate, by means of pre-clinical and clinical trials, that the molecules in question are effective and are not harmful to humans. The Group cannot be certain that favorable results obtained during pre-clinical trials will subsequently be confirmed during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safety and efficacy of the product in question such that the required marketing approvals can be obtained.
- The Group must deal with or may have to deal with competition (i) from generic products, particularly in relation to Group products which are not protected by patents (ii), products which, although they are not strictly identical to the Group's products or which have not demonstrated their bioequivalence, may obtain a marketing authorization for indications similar to those of the Group's products pursuant to the bibliographic reference regulatory procedure (well established medicinal use) before the patents protecting its products expire. Such a situation could result in the Group losing market share which could affect its current level of growth in sales or profitability.
- Third parties might claim the benefit of intellectual property rights with respect to the Group's inventions. The Group provides the third parties with which it collaborates (including universities and other public or private entities) with information and data in various forms relating to the research, development, manufacturing and marketing of its products. Despite the precautions taken by the Group with regard to these entities, in particular of a contractual nature, they (or certain of their members or affiliates) could claim ownership of intellectual property rights arising from the trials carried out by their employees or any other intellectual property right relating to the Group's products or molecules in development.

- The Group's strategy includes acquiring companies or assets which may enable or facilitate access to new markets, research projects or geographical regions or enable the Group to realize synergies with its existing businesses. Should the growth prospects or earnings potential of such assets as well as valuation assumptions change materially from initial assumptions, the Group might be under the obligation to adjust the values of these assets in its balance sheet, thereby negatively impacting its results and financial situation.
- The marketing of certain products by the Group has been and could be affected by supply shortages and other disruptions. Such difficulties may be of both a regulatory nature (the need to correct certain technical problems in order to bring production sites into compliance with applicable regulations) and a technical nature (difficulties in obtaining supplies of satisfactory quality or difficulties in manufacturing active ingredients or drugs complying with their technical specifications on a sufficiently reliable and uniform basis). This situation may result in inventory shortages and/or in a significant reduction in the sales of one or more products.
- In certain countries exposed to significant public deficits, and where the Group sells its drugs directly to public hospitals, the Group could face discount or lengthened payment terms or difficulties in recovering its receivables in full. The Group closely monitors the evolution of the situation in Southern Europe where hospital payment terms are especially long. More generally, the Group may also be unable to purchase sufficient credit insurance to protect itself adequately against the risk of payment default from certain customers worldwide. Such situations could negatively impact the Group's activities, financial situation and results.
- In the normal course of business, the Group is or may be involved in legal or administrative proceedings. Financial claims are or may be brought against the Group in connection with some of these proceedings.
- The cash pooling arrangements for foreign subsidiaries outside the euro zone expose the Group to financial foreign exchange risk. The variation of these exchange rates may impact significantly the Group's results.