



PRESS RELEASE

Ipsen showcases commitment to patient-centric advances in oncology with record number of abstracts to be presented at ESMO 2020 Virtual Congress

- 17 abstracts¹ to be shared, spanning a wide range of different cancer types, therapies and clinical study and real-world evidence designs
- Presentations will feature promising data across multiple cancers, including renal cell carcinoma, small cell lung cancer, pancreatic ductal adenocarcinoma, prostate cancer and various neuroendocrine tumors
- Highlights include detailed results from the pivotal Phase III CheckMate -9ER trial, which demonstrated that Cabometyx[®] (cabozantinib) in combination with Opdivo[®] (nivolumab) significantly improved progression-free survival and overall survival with favorable safety profile in patients with previously untreated advanced renal cell carcinoma versus sunitinib

PARIS, FRANCE, 14 September 2020 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that novel clinical trial and real-world evidence data across a variety of tumor types and oncology therapeutic settings, will be the subject of multiple oral and poster presentations at the European Society for Medical Oncology (ESMO) 2020 Congress, taking place virtually 19–21 September 2020. Results from these 17 abstracts reflect Ipsen's commitment to oncology research and mission to provide treatment options tailored to patients with significant unmet needs. The impact of this progress is highlighted by the selection of three abstracts for proffered paper presentations, with one featuring in the ESMO Presidential Symposium.

“The breadth of oncology research we’re presenting at ESMO this year highlights our commitment to prioritize the development of innovative treatment options that enhance patient care,” said Prof. Dr. Steven Hildemann, Executive Vice President, Chief Medical Officer, Head of Global Medical Affairs and Patient Safety, Ipsen. “The positive results from the pivotal Phase III CheckMate -9ER trial are just one example of our successful partnership strategy to catalyze and broaden our progress in delivering potential new or improved options in cancers with significant unmet needs.”

Highlights from key data on Ipsen medicines to be presented during the ESMO 2020 Congress include:

- Superior survival and response rates in previously untreated patients with advanced clear cell renal cell carcinoma (aRCC) with Cabometyx[®] (cabozantinib) in combination with Opdivo[®] (nivolumab) versus sunitinib.
- Real-world evidence on Cabometyx[®] (cabozantinib) from the CABOREAL study in non-clear cell metastatic renal cell carcinoma and sarcomatoid renal cell carcinoma, and from an interim analysis of the European CASSIOPE study in aRCC after VEGF-targeted therapy.¹
- Results from the Phase II CLARINET FORTE trial detailing the efficacy and safety of increasing the frequency of Somatuline[®] Autogel (lanreotide) dosing in progressive pancreatic and midgut neuroendocrine tumors (NETs).¹

Aligned with the virtual format of the ESMO 2020 Congress, Ipsen is launching a new virtual congress platform, which will include a virtual press office to support media in accessing further information and insights around Ipsen's data and contribution to the ESMO 2020 scientific program, the company's mission to advance oncology research, and its commitment to address patients' unmet needs.

The virtual congress platform is available [here](#) and the virtual press office is available [here](#). To receive a recording of the virtual media briefing and receive exclusive media content, please register your interest here: <https://ipsenglobal.ipsemultichannel.com/ipsem-esmo-virtual-media-briefing-19-sept/>

Follow Ipsen on Twitter via [@IpsenGroup](#) and keep up to date with ESMO 2020 Congress news and updates

by using the hashtag #ESMO20.

Overview of presentations featuring Ipsen medicines in development at the ESMO 2020 Congress:

Medicine	Abstract title	Presentation number/timing (CEST)
Cabometyx® (cabozantinib)	Nivolumab + cabozantinib vs sunitinib in first-line treatment for advanced renal cell carcinoma: first results from the randomized phase 3 CheckMate -9ER trial	Presentation number: 696O Date/time: 19 September, 19:34 – 19:46
	Cabozantinib in elderly patients: results from a subanalysis of the CABOREAL study	Presentation number: 722P Date/time: 17 September, on-demand
	Cabozantinib in non-clear cell metastatic renal cell carcinoma and sarcomatoid renal cell carcinoma: real-world data from the CABOREAL study	Presentation number: 732P Date/time: 17 September, on-demand
	CaboPoint: a phase II study of second-line cabozantinib in patients with metastatic renal cell carcinoma (RCC)	Presentation number: 804TiP Date/time: 17 September, on-demand
	Interim analysis of CASSIOPE, a real-world study of cabozantinib for the treatment of advanced renal cell carcinoma (aRCC) after VEGF-targeted therapy in Europe	Presentation number: 741P Date/time: 17 September, on-demand
	Clinical outcomes stratified by Charlson Comorbidity Index (CCI) score from a retrospective study of patients with advanced renal cell carcinoma (aRCC) who received cabozantinib as part of the UK Managed Access Program (MAP)	Presentation number: 1645P Date/time: 17 September, on-demand
	Cabozantinib (C) in combination with atezolizumab (A) in non-clear cell renal cell carcinoma (nccRCC): results from cohort 10 of the COSMIC-021 study	Presentation number: 709P Date/time: 17 September, on-demand
	Cabozantinib (C) in combination with atezolizumab (A) as first-line therapy for advanced clear cell renal cell carcinoma (ccRCC): results from the COSMIC-021 study	Presentation number: 702O Date/time: 21 September, 17:04–17:16
Onivyde® (liposomal irinotecan)	RESILIENT part 1: pharmacokinetics of second-line (2L) liposomal irinotecan in patients with small cell lung cancer (SCLC)	Presentation number: 1793P Date/time: 17 September, on-demand
	First-line (1L) liposomal irinotecan + 5 fluorouracil/leucovorin (5-FU/LV) + oxaliplatin (OX) in patients with locally advanced or metastatic pancreatic ductal adenocarcinoma (mPDAC): exploratory subgroup analyses of survival by changes in CA 19-9 levels	Presentation number: 1529P Date/time: 17 September, on-demand
	Multivariable analysis of real-world clinical outcomes associated with dose reductions (DRs) for patients (pts) with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with liposomal irinotecan	Presentation number: 1534P Date/time: 17 September, on-demand
	Real-world treatment patterns and effectiveness of liposomal irinotecan in a NAPOLI1-based regimen among patients	Presentation number: 1555P Date/time: 17 September, on-demand

	with metastatic pancreatic ductal adenocarcinoma (mPDAC): a multi-academic center chart review	
	Clinical pathway implications and real-world characteristics and outcomes for patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with first line category 1 National Comprehensive Cancer Network (NCCN) regimens	Presentation number: 1564P Date/time: 17 September, on-demand
Decapeptyl® (triptorelin pamoate)	Efficacy of triptorelin after radical prostatectomy in patients with high-risk prostate cancer	Presentation number: 664P Date/time: 17 September, on-demand
Somatuline® (lanreotide)	Efficacy and safety of lanreotide autogel (LAN) 120 mg every 14 days in progressive pancreatic or midgut neuroendocrine tumours (NETs): CLARINET FORTE study results	Presentation Number: 1162MO Date/time: 18 September, on-demand
	Lanreotide autogel (LAN) and temozolomide (TMZ) combination therapy in progressive thoracic neuroendocrine tumours (TNETs): ATLANT study results	Presentation number: 1161MO Date/time: 18 September, on-demand
Satoreotide tetraxetan	An international open-label study on safety and efficacy of 177Lu-satoreotide tetraxetan in somatostatin receptor positive neuroendocrine tumours (NETs): an Interim Analysis	Presentation number: 1160O Date/time: 20 September, 14:37–14:49

About renal cell carcinoma

There are over 400,000 new cases of kidney cancer diagnosed worldwide each year.² Of these, renal cell carcinoma (RCC) is the most common type of kidney cancer, accounting for approximately 90% of cases.^{3,4} It is twice as common in men, and male patients account for over two thirds of deaths.² If detected in the early stages, the five-year survival rate is high, but for patients with advanced or late-stage metastatic RCC the survival rate is much lower, around 12%, with no identified cure for this disease.^{5,6}

About NETs

Neuroendocrine tumors, or NETs, are a group of uncommon tumors that develop in the cells of the neuroendocrine system, throughout the body.^{7,8} NETs occur in both men and women, in general aged 50 to 60 years old, although they can affect anyone of any age.⁹ The three main areas where NETs are found in the body are the gastrointestinal tract, the pancreas and the lungs.^{8,10}

- Gastrointestinal NETs (GI-NETs) are found in the gastrointestinal tract or digestive system and are the most common type of NETs.¹⁰
- Pancreatic NETs (panNETs) are formed in the islet cells of the pancreas and include several uncommon types of NETs.¹⁰
- Lung NETs are less common than other types, accounting for about one quarter of NETs.¹⁰

The symptoms of NETs are often not distinct and difficult to identify, and can sometimes take between five to seven years to fully diagnose.¹¹ The number of people being newly diagnosed with NETs overall is believed to be rising.¹² This is mainly due to increased awareness of the condition and diagnostic testing.¹² NETs are now the fastest growing class of cancers worldwide, accounting for around 2% of all cancers at any time.¹²

About pancreatic cancer

Pancreatic cancer occurs when cells in the pancreas grow uncontrollably from a malignant tumor. It is the seventh leading cause of cancer death globally and the 12th most common cancer,^{13,14} and has the lowest survival rate of the most common cancers.^{15,16} As there are often no symptoms, or symptoms may be non-specific in the early stages,¹⁷ it is most commonly diagnosed at an incurable stage.¹⁸ Around 80% of pancreatic cancer patients are diagnosed with metastatic disease and for these the average survival is less than a year.¹⁹

About the CheckMate -9ER trial

CheckMate -9ER is an open-label, randomized, multi-national Phase III trial evaluating the treatment of patients with previously untreated advanced or metastatic RCC. Patients were randomized 1:1 to Opdivo® and Cabometyx® or sunitinib. The primary endpoint is progression-free survival (PFS). Secondary endpoints include overall survival (OS) and objective response rate (ORR). The primary efficacy analysis compared the doublet combination versus sunitinib in randomized patients. The trial is sponsored by Bristol-Myers Squibb and Ono Pharmaceutical Co. and co-funded by Exelixis, Ipsen and Takeda Pharmaceutical Company Limited.

About CLARINET FORTE

CLARINET FORTE is a prospective single-arm, open-label, exploratory, international Phase II study to explore the efficacy and safety of a reduced lanreotide autogel dosing interval (120 mg every 14 days) in patients with metastatic or locally advanced unresectable pancreatic neuroendocrine tumors (G1/2 panNETs) or midgut NETs, with centrally-accessed progression within the last two years while on a standard lanreotide autogel regimen (120 mg every 28 days) for more than 24 weeks.

About Ipsen Products

This press release mentions investigational uses of Ipsen products. Product indications and approvals for use vary by jurisdiction; please see SmPC/PI for full indications and safety information, including Boxed Warnings.

About Cabometyx® (cabozantinib)

Cabometyx® is currently approved in 54 countries, including in the European Union, the U.S., the U.K., Norway, Iceland, Australia, Switzerland, South Korea, Canada, Brazil, Taiwan, Hong-Kong, Singapore, Macau, Jordan, Lebanon, Russian Federation, Ukraine, Turkey, United Arab Emirates, Saudi Arabia, Serbia, Israel, Mexico, Chile and Panama for the treatment of advanced RCC in adults who have received prior VEGF-targeted therapy; in the European Union, the U.K., Norway, Iceland, Canada, Australia, Brazil, Taiwan, Hong Kong, Singapore, Jordan, Russian Federation, Turkey, United Arab Emirates, Saudi Arabia, Israel, Mexico, Chile and Panama for previously untreated intermediate- or poor-risk advanced RCC; and in the European Union, the U.S., the U.K., Norway, Iceland, Canada, Australia, Switzerland, Saudi Arabia, Serbia, Israel, Taiwan, Hong Kong, South Korea, Singapore, Jordan, Russian Federation, Turkey, United Arab Emirates, and Panama for HCC in adults who have previously been treated with sorafenib.

The detailed recommendations for the use of Cabometyx® are described in the [Summary of Product Characteristics](#) (SmPC) and in the [U.S. Prescribing Information](#) (PI).

Cabometyx® is marketed by Exelixis, Inc. in the United States and by Takeda Pharmaceutical Company Limited in Japan. Ipsen has exclusive rights for the commercialization and further clinical development of Cabometyx® outside of the U.S. and Japan.

About Somatuline® (lanreotide)

Somatuline® Autogel/Depot is made of the active substance lanreotide, which is a long-acting somatostatin analogue that inhibits the secretion of growth hormone and certain hormones secreted by the digestive system. The main indications of Somatuline® and Somatuline® Autogel are:²⁰

- The treatment of individuals with acromegaly when the circulating levels of Growth Hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment.
- The treatment of grade 1 and a subset of grade 2 (Ki-67 index up to 10%) gastroenteropancreatic neuroendocrine tumors (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease.
- The treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumors.

The detailed recommendations for the use of Somatuline® Autogel are described in the [Summary of Product Characteristics](#) (SmPC) and in the [U.S. Prescribing Information](#) (PI).

About Decapeptyl®

Decapeptyl® (triptorelin pamoate) is an agonist analogue of the natural gonadotropin-releasing hormone (GnRH), currently available in three sustained-release formulations (1, 3 and 6 months). First registered in France in 1986, triptorelin is currently marketed by Ipsen under a license agreement from Debiopharm Group in more than 80 countries, being the market leader in many territories worldwide.

The detailed recommendations for the use of Decapeptyl® are described in the [Summary of Product Characteristics](#) (SmPC).

About Onivyde® (irinotecan liposome injection)

Onivyde® is an encapsulated formulation of irinotecan available as a 43 mg/10 mL single dose vial. This liposomal form is designed to increase length of tumor exposure to both irinotecan and its active metabolite, SN- 38. Onivyde® is approved by the U.S. FDA in combination with fluorouracil (5-FU) and leucovorin (LV) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

In 2017 Ipsen completed the acquisition from Merrimack Pharmaceuticals of Onivyde® and gained exclusive commercialization rights for the current and potential future indications for Onivyde® in the U.S.²¹ Servier is responsible for the development and commercialization of Onivyde® outside of the U.S. and Taiwan under an exclusive licensing agreement with Ipsen Biopharm Ltd.

Onivyde® is approved by the U.S. FDA in combination with fluorouracil (5-FU) and leucovorin (LV) for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). More information: www.servier.com/en/.

The detailed recommendations for the use of Onivyde® are described in the [Summary of Product Characteristics](#) (SmPC) and in the [U.S. Prescribing Information](#) (PI).

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, Neuroscience 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 over €2.5 billion in 2019, 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 5,800 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.

Opdivo® is a registered trademark of Bristol-Myers Squibb Company.

Ipsen's 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, and the outcome of this study or other studies. 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 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 product concerned. There can be no guarantee 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 6 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 2019 Universal Registration Document available on its website (www.ipsen.com).

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