



PRESS RELEASE

Ipsen to showcase commitment to going beyond traditional outcome measures for patients living with renal cell carcinoma at ASCO GU 2021

- 10 abstracts to be presented showcasing promising data across multiple genitourinary cancers, including renal cell carcinoma (RCC) and prostate cancer¹⁻¹¹
- Highlights include extended follow-up and health-related quality of life data from the pivotal CheckMate -9ER trial, further supporting superiority of Cabometyx[®] (cabozantinib) in combination with Opdivo[®] (nivolumab) versus sunitinib in first-line advanced RCC^{1,2}
- Additionally, a comparative, retrospective real-world evidence study suggested consistent efficacy of Cabometyx[®] after treatment with checkpoint inhibitors (CPI) as well as a significantly higher response rate and a higher time to discontinuation versus other tyrosine kinase inhibitors (TKIs) in second-line metastatic RCC³

PARIS, FRANCE, 5 February 2021– Ipsen (Euronext: IPN; ADR: IPSEY) today announced that new data from its growing oncology portfolio will be presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), taking place virtually from 11-13 February 2021.¹¹ A total of 10 abstracts spanning several genitourinary cancers including advanced RCC, and metastatic, castration-resistant prostate cancer (mCRPC), highlight the utility of Ipsen's medicines and its commitment to advancing patient care.¹⁻¹⁰

"The presentations showcased at ASCO GU exemplify Ipsen's commitment to prioritize outcome measures which directly impact patients' lives," said Amauri Soares, Vice President, Medical Affairs Oncology, Ipsen. "New data from the Phase III CheckMate -9ER trial highlight how first-line treatment with the combination of cabozantinib and nivolumab has the potential to extend the lives of patients living with advanced RCC without having to compromise on quality of life compared with sunitinib. We're looking forward to sharing these data with the medical community at ASCO GU and bringing this important treatment option to patients at the earliest opportunity."

Highlights from key data on Ipsen medicines to be presented during the ASCO GU 2021 Symposium include:

- Extended follow-up outcomes data from the CheckMate -9ER study including patients living with advanced RCC and sarcomatoid features (sRCC) – an aggressive histologic subtype associated with poor prognoses¹
- Patient reported outcomes of patients living with advanced RCC - additional analysis from the CheckMate -9ER study of the combination of Cabometyx[®] (cabozantinib) with Opdivo[®] (nivolumab) versus sunitinib²
- A comparative, retrospective real-world evidence study suggesting Cabometyx[®] (cabozantinib) was associated with a significantly higher response rate versus other TKIs (axitinib, lenvatinib, pazopanib, sorafenib, sunitinib) in patients living with metastatic renal cell carcinoma (mRCC) following checkpoint inhibitor (CPI) treatment³
- Findings from a study using machine learning to explore the potential synergistic effects of Cabometyx[®] (cabozantinib) and a programmed cell death protein 1 (PD1) inhibitor in mRCC⁴
- Trial design of the Phase III randomized, open-label CONTACT-02 study of Cabometyx[®] (cabozantinib) plus Tecentriq[®] (atezolizumab) versus second novel hormone therapy (NHT) in patients living with mCRPC⁵

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Overview of presentations featuring Ipsen medicines in development at the ASCO GU 2021 Congress:¹⁻

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Medicine	Abstract title	Presentation number/timing (EST)
Cabometyx[®] (cabozantinib)	Nivolumab + cabozantinib (NIVO+CABO) vs sunitinib (SUN) for advanced renal cell carcinoma (aRCC): outcomes by sarcomatoid histology and updated trial results with extended follow-up of CheckMate 9ER	Presentation number: 308 Date/time: 13 February, 9:00 – 9:45
	Patient-reported outcomes (PROs) of patients (pts) with advanced renal cell carcinoma (aRCC) treated with first-line (1L) nivolumab plus cabozantinib (NIVO+CABO) vs sunitinib (SUN): the randomized phase 3 CheckMate 9ER trial	Presentation number: 285 Date/time: 13 February, 9:00 – 9:45
	Cabozantinib versus other TKIs after CPI treatment in the real-world management of patients with mRCC	Presentation number: 293 Date/time: 11 February, 8:00 – 18:30
	Exploring the synergistic effects of cabozantinib (cabo) and a programmed cell death protein 1 (PD1) inhibitor in metastatic renal cell carcinoma (mRCC) with artificial intelligence (AI)	Presentation number: 336 Date/time: 11 February, 8:00 – 18:30
	A phase 3, randomized, open-label, study (CONTACT-02) of cabozantinib plus atezolizumab versus second novel hormone therapy (NHT) in patients (pts) with metastatic, castration-resistant prostate cancer (mCRPC) – Exelixis funded	Presentation number: TPS190 Date/time: 11 February, 8:00 – 18:30
	PDIGREE: An adaptive phase III trial of PD-inhibitor nivolumab and ipilimumab (IPI-NIVO) with VEGF TKI cabozantinib (CABO) in metastatic untreated renal cell cancer (Alliance A031704)	Presentation number: TPS366 Date/time: 11 February, 8:00 – 18:30
Decapeptyl[®] (triptorelin pamoate)	Quality of life of prostate cancer (PCa) patients aged 60 years and older: changes in QLQ-ELD14 dimensions after a 6-month gonadotropin-releasing hormone agonist (GnRHa) therapy, according to age groups, primary analysis of PRISME study	Presentation number: 55 Date/time: 11 February, 8:00 – 18:30
	Cognitive status of prostate cancer (PCa) patients aged 60 years and older after a 6-month gonadotropin-releasing hormone agonist (GnRHa) therapy, according to age groups, secondary analysis of PRISME study	Presentation number: 55 Date/time: 11 February, 8:00 – 18:30
	Visual analogue scales (VAS) as exploratory evaluation of 8 dimensions in prostate cancer (PCa) patients aged 60 years and older initiating a gonadotropin-releasing hormone agonist (GnRHa) therapy, secondary analysis of PRISME study	Presentation number: 221 Date/time: 11 February, 8:00 – 18:30
	Treatment of Aggressive prostate cancers in real Life: Initiation, Schedule and MANagement of triptorelin treatment (TALISMAN), design of the study	Presentation number: TPS173 Date/time: 11 February, 8:00 – 18:30

About renal cell carcinoma

There are over 400,000 new cases of kidney cancer diagnosed worldwide each year.¹² Of these, renal cell carcinoma (RCC) is the most common type of kidney cancer, accounting for approximately 90% of cases.^{13,14} It is twice as common in men, and male patients account for over two thirds of deaths.¹² 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.^{15,16}

About castration-resistant prostate cancer

Prostate cancer is the second most commonly occurring cancer in men and the fourth most commonly occurring cancer overall.¹⁷ There were 1.27 million new cases in 2018.¹⁸ Approximately 10-20 percent of prostate cancer

cases are castration-resistant, and up to 16% of these patients show no evidence that the cancer has spread at the time of the castration-resistant diagnosis.¹⁹ Metastatic castration-resistant prostate cancer is when the cancer has spread to parts of the body other than the prostate, and it is able to grow and spread even though drugs or other treatments to lower the amount of male sex hormones are being used to manage the cancer.

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® (nivolumab) and Cabometyx® (cabozantinib) 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 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®

Cabometyx® (cabozantinib) 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 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 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. 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 5,700 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 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 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.ipсен.com).

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