PRESS RELEASE

Ipsen receives positive CHMP opinion recommending Cabometyx® in combination with Opdivo® as first-line treatment for patients living with advanced renal cell carcinoma

- Recommendation based on the Phase III CheckMate -9ER trial, in which Cabometyx® (cabozantinib) in combination with Opdivo® (nivolumab) doubled progression-free survival and significantly improved overall survival and response rates[1]
- Cabometyx® in combination with Opdivo® showed consistent efficacy benefits across key subgroups of patients[1]
- Patients treated with Cabometyx® in combination with Opdivo® reported significantly better health-related quality of life and a lower rate of discontinuation versus sunitinib[2,3]

PARIS, FRANCE, 26 February 2021 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended approval for Cabometyx® (cabozantinib) in combination with Bristol Myers Squibb's Opdivo® (nivolumab) for the first-line treatment of advanced renal cell carcinoma (aRCC). The European Commission, which has the authority to approve medicines for the European Union (E.U.), will now review the CHMP recommendation and a final decision on the application in the E.U. is expected in the coming months.

"Advanced renal cell carcinoma is a disease that significantly impacts the lives of people around the world. We're proud to be able to share that the CHMP has confirmed a positive recommendation for Cabometyx® in combination with Opdivo®, bringing this impactful new treatment option one step closer for patients," said Howard Mayer, Executive Vice President and Head of Research and Development, Ipsen. "At Ipsen, we are committed to progressing treatment for cancers which have an urgent need for additional therapeutic options and this recommendation marks an important milestone in achieving this."

The CHMP adopted the positive opinion based on results from the pivotal Phase III CheckMate -9ER trial, which demonstrated significant and clinically meaningful improvements in progression-free survival (PFS), overall survival (OS) and objective response rate (ORR) compared to sunitinib, with consistent efficacy benefits observed across key subgroups of patients.[1] Cabometyx® combined with Opdivo® was well tolerated and reflected the known safety profiles of the immunotherapy and tyrosine kinase inhibitor (TKI) components in first-line advanced RCC.[1] The full data from the CheckMate -9ER trial were presented during a Presidential Symposium at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. At the recent American Society of Clinical Oncology 2021 Genitourinary Cancers Symposium (ASCO GU), additional data from the CheckMate -9ER trial were also presented, highlighting sustained superior efficacy with a longer duration of follow-up as well as significantly improved health-related quality of life outcomes for the combination versus sunitinib.[2,3]

Ipsen and its partners have shared the CheckMate -9ER data with regulatory authorities around the world. The combination of Cabometyx® and Opdivo® was approved by the U.S. Food and Drug Administration (FDA) as first-line treatment for patients living with advanced renal cell carcinoma in January 2021.

"Today's news is welcomed by physicians treating people living with advanced renal cell carcinoma," said Dr. Cristina Suárez, Medical Oncologist at the Vall d´Hebron University Hospital, Barcelona, Spain, and a lead investigator on the Phase III CheckMate -9ER trial. "The positive CHMP opinion brings us one step closer to the promise of a new approach that combines improved treatment outcomes, a favorable tolerability profile and superior health-related quality of life for patients."

About renal cell carcinoma

There are over 400,000 new cases of kidney cancer diagnosed worldwide each year.[4] Of these, renal

cell carcinoma (RCC) is the most common type of kidney cancer, accounting for approximately 90% of cases.[5,6] It is twice as common in men, and male patients account for over two thirds of deaths.[4] 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.[7,8]

About the CheckMate -9ER trial
CheckMate -9ER is an open-label, randomized, multi-national Phase III trial evaluating patients with previously untreated advanced or metastatic RCC. A total of 651 patients (23% favorable risk, 58% intermediate risk, 20% poor risk; 25% PD-L1 ≥1%) were randomized to Cabometyx® plus Opdivo® (n= 323) versus sunitinib (n= 328). The primary endpoint is progression-free survival (PFS). Secondary endpoints include overall survival (OS) and objective response rate (ORR). The primary efficacy analysis is comparing the doublet combination versus sunitinib in all 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 Cabometyx® (cabozantinib)
Cabometyx® is currently approved in 57 countries, including in the European Union, the U.K., Norway, Iceland, Australia, New Zealand, 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, Peru, Panama, Guatemala, Dominican Republic, Ecuador and Thailand 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, Lebanon, Jordan, Russian Federation, Ukraine, Turkey, United Arab Emirates, Saudi Arabia, Israel, Mexico, Chile, Peru, Panama, Guatemala, Dominican Republic, Ecuador and Thailand for previously untreated intermediate- or poor-risk advanced RCC; and in the European Union, the U.K., Norway, Iceland, Canada, Australia, Switzerland, Saudi Arabia, Serbia, Israel, Taiwan, Hong Kong, South Korea, Singapore, Jordan, Russian Federation, Ukraine, Turkey, Lebanon, United Arab Emirates, Peru, Panama, Guatemala, Chile, Dominican Republic, Ecuador and Thailand 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. Cabometyx® is a registered trademark of Exelixis, Inc.

About Ipsen
Ipsen is a global mid-size biopharmaceutical company with a focus on transformative medicines in Oncology, Rare Disease and Neuroscience. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.5 billion in 2020, 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; Shanghai, China). 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.ipsen.com.fr

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

Ipsen—Cautionary Note Regarding 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

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