PRESS RELEASE

# Ipsen provides update on Phase III CONTACT-01 trial evaluating cabozantinib in combination with atezolizumab in patients with metastatic non-small cell lung cancer previously treated with immunotherapy and chemotherapy

- The trial did not meet its primary endpoint of overall survival (OS)
- The safety profile of the combination of cabozantinib and atezolizumab was consistent with the known safety profiles for each single agent
- The clinical trial results will be presented at a future medical meeting

**PARIS, FRANCE,** 8 December 2022 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that the CONTACT-01 study did not meet its primary endpoint of overall survival (OS) at the final analysis. CONTACT-01 is a phase III clinical trial evaluating Cabometyx® (cabozantinib) in combination with atezolizumab (Tecentriq®) versus docetaxel in patients with unmutated metastatic non-small cell lung cancer (NSCLC) who experienced disease progression on or after treatment with an immune checkpoint inhibitor and platinum-containing chemotherapy.

Howard Mayer, M.D., Executive Vice President, Head of Research and Development at Ipsen, said: "The results from the CONTACT-01 clinical trial have shown the challenge of treating NSCLC patients after prior lines of treatment have failed. While the findings of the study have not met the primary endpoint in this setting, we remain confident in the clinical efficacy of cabozantinib alone and in combination with another treatment in existing indications in difficult-to-treat tumor types. We wish to thank the patients, their families and healthcare teams for their participation in this clinical trial."

The safety profile of the combination of cabozantinib and atezolizumab observed in the trial was consistent with the known safety profiles for each single agent, and no new safety signals were identified. Detailed findings from CONTACT-01 will be submitted for presentation at a future medical meeting.

**ENDS**

**About CONTACT-01**
CONTACT-01 is a global, multicenter, randomized, phase 3, open-label study that enrolled 366 patients who were randomized 1:1 to the experimental arm of cabozantinib in combination with atezolizumab and the control arm of docetaxel. The study enrolled patients with both squamous and non-squamous NSCLC who progressed during or following anti-PD-1/PD-L1 therapy administered either concurrently or sequentially with chemotherapy. The primary endpoint of the trial was overall survival. Secondary endpoints included progression-free survival, objective response rate and duration of response. Results from cohort 7 of the phase 1b COSMIC-021 trial informed the CONTACT-01 trial design. CONTACT-01 was sponsored by Roche and co-funded by Exelixis. Both Ipsen and Takeda Pharmaceutical Company Limited (Takeda) opted in to participate in the trial and are contributing to the funding for this study under the terms of the companies' respective collaboration agreements with Exelixis. More information about the trial is available at ClinicalTrials.gov.

**About CABOMETYX® (cabozantinib)**
Cabometyx is a multi-targeted tyrosine kinase inhibitor (TKI) with targets including vascular endothelial growth factor receptor (VEGFR), c-MET and the TAM receptor family, which block the growth of cancer.

Exelixis granted Ipsen exclusive rights for the commercialization and further clinical development of Cabometyx outside of the U.S. and Japan. Exelixis granted exclusive rights to Takeda for the commercialization and further clinical development of Cabometyx for all future indications in Japan. Exelixis holds the exclusive rights to develop and commercialize Cabometyx in the U.S.

In over 60 countries outside of the United States and Japan, including in the European Union (E.U.), Cabometyx is currently indicated as:

- Monotherapy for advanced renal cell carcinoma:
  - as first-line treatment of adult patients with intermediate or poor risk
  - in adults following prior vascular endothelial growth factor (VEGF)-targeted therapy
- In combination with nivolumab for the first-line treatment of advanced renal cell carcinoma in adults
- Monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to radioactive iodine (RAI) who have progressed during or after prior systemic therapy
- Monotherapy for the treatment of hepatocellular carcinoma (HCC) in adults who have previously been treated with sorafenib.

**About Ipsen**

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With Specialty Care sales of €2.6bn in FY 2021, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, 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 around 5,000 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

**Ipsen's Forward-Looking Statements**

The forward-looking statements, objectives and targets contained herein are based on Ipsen'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 Ipsen'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 Ipsen'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 Ipsen. 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 medicine 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. Ipsen must face or might face competition from generic medicine 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 Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen 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 medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine 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 healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen'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 Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen 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 Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen 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. Ipsen'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 Ipsen's 2021 Universal Registration Document, available on ipsen.com

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