

Ipsen voluntarily withdraws Tazverik[®] (tazemetostat) in follicular lymphoma and epithelioid sarcoma

PARIS, FRANCE, 09 March 2026 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that it is voluntarily withdrawing Tazverik[®] (tazemetostat) in all indications from all Ipsen markets. Ipsen's decision to withdraw is based on emerging data from the ongoing Phase Ib/III SYMPHONY-1 trial (evaluating tazemetostat in combination with lenalidomide plus rituximab (R²) vs R² in follicular lymphoma). The Independent Data Monitoring Committee (IDMC) advised that, based on adverse events of secondary hematologic malignancies, the risks may outweigh potential benefits for patients within this treatment regimen. As a result of these data, Ipsen is withdrawing Tazverik effective immediately, including both for follicular lymphoma (FL) and epithelioid sarcoma (ES).

In addition to withdrawing Tazverik from the market, Ipsen has initiated steps to stop treatment with tazemetostat for all patients currently enrolled in the ongoing SYMPHONY-1 trial. All participants will receive standard of care, lenalidomide plus rituximab only. The study will remain open, with no further enrolment, to continue the long-term safety follow-up of all participants. Ipsen is also discontinuing all active tazemetostat clinical trials and expanded access programs.

"While this is an extremely disappointing outcome, the safety of patients remains our priority", said Christelle Hugué, PhD & EVP Head of R&D at Ipsen. "Emerging data from this confirmatory study have highlighted a safety profile that is unfavorable compared to that previously observed in clinical evaluation. We will now work closely with investigators and clinical teams to support patients through the respective next steps and transition plans."

Ipsen is working with the United States (U.S.) Food and Drug Administration (FDA) on the next steps to execute the withdrawal of Tazverik and provide all necessary information to complete this process. Tazverik is marketed in the U.S. by Ipsen in FL and ES. Tazverik received accelerated approval from the U.S. FDA in 2020 for adults with relapsed or refractory FL whose tumors are positive for an EZH2 mutation and who have received at least two prior therapies as well as relapsed or refractory FL adult patients who have no satisfactory alternative treatment options. Tazverik also received U.S. FDA accelerated approval in 2020 for the treatment of adults and adolescents aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.

The withdrawal is not expected to impact the Company's financial guidance.

About Tazverik

Tazverik is an EZH2 inhibitor indicated in the U.S. for the treatment of:

Adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.

Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies.

Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval regulatory pathways based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

View the U.S. Full Prescribing Information [here](#)

Tazverik is available in Japan, Macau, Hong Kong & China via Ipsen partners.

About SYMPHONY-1

SYMPHONY-1 (EZH-302; NCT04224493) is an Ipsen-led global Phase Ib/III study evaluating Tazverik® in combination with lenalidomide and rituximab (R²) as a second-line therapy for relapsed/refractory follicular lymphoma. This study also serves as the confirmatory trial required under the accelerated approval pathway for Tazverik® in follicular lymphoma.

The trial spans 229 sites across 15 countries, including the U.S., EU, China, and others, and includes independently powered analyses for EZH2-wild-type and EZH2-mutant patient populations.

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Our pipeline is fueled by internal and external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen 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 ipсен.com.

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Disclaimers and/or 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 and risks arising from unexpected regulatory or political changes such as changes in tax regulation and regulations on trade and tariffs, such as protectionist measures, especially in the United States; 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 latest Universal Registration Document, available on ipсен.com.