Ipsen completes acquisition of Epizyme expanding its portfolio in oncology

PARIS, FRANCE, 12 August 2022 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced the closing of the definitive merger agreement under which Ipsen has acquired Epizyme, Inc. (Epizyme). Pursuant to the transaction, Ipsen acquires all outstanding shares of Epizyme for $1.45 per share plus a contingent value right (CVR) of $1.00 per share. Epizyme now operates as ‘an Ipsen company’ at deal close.

As part of the transaction, Ipsen acquires Epizyme’s lead medicine, Tazverik® (tazemetostat), a first-in-class, chemotherapy-free EZH2\(^a\) inhibitor, which was granted Accelerated Approval by the U.S. Food and Drug Administration (FDA) in 2020. It is currently indicated for adults with relapsed or refractory follicular lymphoma (FL) 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, and for adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options, as well as for adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.\(^1\)

Ipsen also acquires Epizyme’s first-in-class, oral SETD2 inhibitor development candidate, EZM0414, which was granted FDA Fast Track status in 2021 and is currently under evaluation in a recently initiated Phase I/II trial in adult patients with relapsed or refractory multiple myeloma and diffuse large B-cell lymphoma, as well as a portfolio of preclinical programs focusing on epigenetic targets.

“Throughout the pre-close phase of planning, we have continued to be impressed by the potential of Tazverik, as well as the rest of the pipeline. Now that the deal is closed, we are excited to be working closely with our Epizyme colleagues to leverage Ipsen’s established infrastructure so that these medicines may reach more patients. Additionally, through this transaction Ipsen gains scientific expertise and we look forward to integrating the two teams which share the goal of delivering innovative treatment options to underserved patients,” said David Loew, Chief Executive Officer of Ipsen.

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About Tazverik® (tazemetostat)
Tazverik is a methyltransferase inhibitor indicated 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 based on overall response rate and duration of response. Post marketing studies are required to confirm the anticipated clinical benefit and retain the labeled Accelerated Approval indications.

The most common (≥20%) adverse reactions in patients with epithelioid sarcoma are pain, fatigue, nausea, decreased appetite, vomiting and constipation. The most common (≥20%) adverse reactions in patients with follicular lymphoma are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea and abdominal pain.

\(^a\) Enhancer of zeste homolog 2.

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About EZM0414
EZM0414 is a potent selective, oral, small molecule, investigational drug agent that inhibits the histone methyltransferase, SETD2, which plays a role in oncogenesis. SETD2 methylates histone as well as non-histone proteins, and this activity is involved in several key biological processes including transcriptional regulation, RNA splicing, and DNA damage repair. Based on the preclinical data on SETD2 inhibition by EZM0414 in multiple settings, including high risk t(4;14) multiple myeloma (MM) and in other B-cell malignancies such as diffuse large B-cell lymphoma (DLBCL), the Company is conducting SET-101, a Phase 1/1b study of EZM0414, for the treatment of adult patients with relapsed or refractory MM and DLBCL.

About follicular lymphoma
Follicular lymphoma is a type of non-Hodgkin lymphoma (NHL) which is a cancer of the lymphatic system. Follicular lymphoma develops when the body makes abnormal B lymphocytes. These lymphocytes are a type of white blood cell that normally helps fight infections. When a patient has a lymphoma, the abnormal lymphocytes build up in the lymph nodes or other body organs. Follicular lymphoma is generally slow growing. Each year, 15-20,000 people in the U.S. are diagnosed with follicular lymphoma. Most affected individuals are diagnosed with advanced disease.

About epithelioid sarcoma
Epithelioid sarcoma is a rare, slow-growing type of soft tissue cancer. Most cases begin in the soft tissue under the skin of a finger, hand, forearm, lower leg or foot, though it can start in other areas of the body. Typically, epithelioid sarcoma starts as a small firm growth or lump that is painless. It usually starts out as a single growth, but multiple growths may occur by the time a person seeks medical help. Sometimes this sarcoma appears as ulcers that don't heal, looking like open wounds over the growths. It is estimated that 13,040 individuals received a diagnosis of soft tissue sarcomas in the U.S. in 2018 with a corresponding 5,150 deaths.

About diffuse large B-cell lymphoma
Diffuse large B cell lymphoma (DLBCL) is a type of NHL. NHL is a cancer of the lymphatic system. It develops when the body makes abnormal B lymphocytes. These lymphocytes are a type of white blood cell that normally help to fight infections. When a patient has a lymphoma, the abnormal lymphocytes build up in lymph nodes or other body organs. DLBCL grows quickly and treatment starts soon after diagnosis. DLBCL is the most common type of NHL in the U.S. and worldwide, accounting for about 22 percent of newly diagnosed cases of B-cell NHL in the U.S. More than 18,000 people in the U.S. are diagnosed with DLBCL each year.

About multiple myeloma
Multiple myeloma is a rare form of cancer characterized by excessive production (proliferation) and improper function of certain cells (plasma cells) found in the bone marrow. Excessive plasma cells may eventually mass together to form a tumor or tumors in various sites of the body, especially the bone marrow. When multiple tumors are present or the bone marrow has greater than 10% plasma cells, the term multiple myeloma is used. In 2019, over 32,000 individuals in the U.S. were diagnosed with this disease. It is believed that approximately 100,000 Americans currently have the disease.

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, excluding its Consumer HealthCare business, has around 4,500 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

Tazverik® is a registered trademark of Epizyme.
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 fulfill 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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