



## Ipsen to Acquire Epizyme, Expanding Its Portfolio in Oncology

June 27, 2022

- **Transaction focused on lead asset Tazverik<sup>®</sup> (tazemetostat), a first-in-class EZH2<sup>a</sup> inhibitor approved in the U.S.**
- **Acquisition to bolster Ipsen's growing oncology presence and leverage its infrastructure**
- **Ipsen to commence all-cash tender offer to acquire all outstanding shares of Epizyme for \$1.45 per share plus a contingent value right (CVR) of \$1.00 per share**

PARIS & CAMBRIDGE, MASS.--(BUSINESS WIRE)--Jun. 27, 2022-- Regulatory News:

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Ipsen (Euronext: IPN; ADR: IPSEY) and Epizyme (Nasdaq: EPZM) today announced that they have entered into a definitive merger agreement under which Ipsen will acquire Epizyme. The transaction was unanimously approved by both Ipsen and Epizyme Boards of Directors and is anticipated to close by the end of the third quarter of 2022, subject to the satisfaction of all closing conditions. Epizyme is a fully integrated, commercial-stage biopharmaceutical company developing and delivering transformative therapies against novel epigenetic targets for cancer patients.

The primary focus of the acquisition is on the lead medicine, Tazverik<sup>®</sup> (tazemetostat), a first-in-class, chemotherapy-free EZH2<sup>a</sup> 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.<sup>1</sup> Tazverik is currently in the Phase III stage of a registrational confirmatory study (SYMPHONY-1) in combination with rituximab and lenalidomide (R<sup>2</sup>) in patients with relapsed/refractory FL who have received at least one prior therapy. Initial results from the Phase III randomized portion of this study are planned to read out in 2026.

As part of the transaction, Ipsen will also acquire Epizyme's first-in-class, oral SETD2 inhibitor development candidate, EZM0414, which was granted FDA Fast Track status and is currently under evaluation in a recently initiated Phase I/Ib 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.

"Through this agreement, we will expand our assets in oncology. Ipsen's capabilities and resources in oncology combined with Epizyme's will accelerate the growth of Tazverik to achieve its full potential in follicular lymphoma patients. The strength of data support Tazverik's positioning in patients with both EZH2 mutation positive and wild-type follicular lymphoma. We are compelled by the potential of its efficacy and tolerability profile, especially for elderly and/or frail patients who are treated in the community-based setting. Furthermore, we are excited to bring on board epigenetic expertise and the SETD2 inhibitor, as well as several pre-clinical compounds into our portfolio," said David Loew, Chief Executive Officer of Ipsen.

"Epizyme was founded in 2007 with a commitment to rigorous scientific research and a vision of developing novel epigenetic therapies. I am incredibly proud of what our team has accomplished over the past 15 years, from the approval of Tazverik to advancing our next novel investigational agent, EZM0414, to the clinic, as well as the progress made on our preclinical compounds focused on both hematologic malignancies and solid tumors," said Grant Bogle, President and Chief Executive Officer of Epizyme. "We expect that this acquisition and Ipsen's commitment to invest in the oncology space will ensure our epigenetic pipeline continues to advance in a way we could not have done on our own to bring transformative cancer therapies to patients in need."

### Financial highlights

The acquisition of Epizyme will immediately provide incremental sales and will leverage the U.S. commercial infrastructure. Given the level of ongoing R&D expenses, the transaction is expected to be moderately dilutive on Ipsen's core operating income until the end of 2024. This is in line with Ipsen's medium-term outlook regarding its strategic focus on building a high-value and sustainable pipeline through external innovation. The dilutive impact on 2022 core operating margin will be limited, given the expected timing of the transaction.

### Transaction details

The Board of Directors of Epizyme has unanimously approved the transaction and recommended that the stockholders of Epizyme tender their shares in the tender offer. Royalty Pharma, Epizyme's largest stockholder with approximately 20.5% of Epizyme's total shares of common stock outstanding (on a non-diluted basis) as of the date hereof, has entered into a support agreement with Ipsen pursuant to which it has agreed to tender its shares in the tender offer.

Under the terms of the agreement and plan of merger, Ipsen, through a subsidiary, will initiate a tender offer to acquire all outstanding shares of Epizyme at a price of \$1.45 per share in cash at the closing of the transaction, for an initial estimated aggregate consideration of \$247 million<sup>b</sup> plus one contingent value right (CVR) per share. Each CVR will entitle its holder to deferred cash payments of \$0.30 per CVR payable upon the first achievement of \$250 million in aggregate net sales of Tazverik (excluding sales in Japan and Greater China<sup>c</sup>) in any period of four consecutive quarters, by 31 December 2026 and \$0.70 per CVR payable upon receipt of U.S. regulatory approval necessary for the commercial marketing and sale of the combination of Tazverik and R<sup>2</sup> (rituximab and lenalidomide) in second-line follicular lymphoma by 1 January 2028. The \$1.45 per share cash consideration represents a premium of

approximately 144% compared to Epizyme's average closing price of \$0.60 over the 30 trading days preceding announcement of the transaction. The transaction will be fully financed by Ipsen's existing cash and lines of credit.

The closing of the tender offer will be subject to customary conditions, including the tender of shares representing at least a majority of the total number of Epizyme's outstanding shares, the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. Upon the successful completion of the tender offer, Ipsen would acquire all shares not acquired in the tender through a second-step merger for the same consideration as the tendering shareholders.

#### **Advisors**

Barclays is acting as exclusive financial advisor to Ipsen and Orrick Herrington & Sutcliffe LLP as legal counsel to Ipsen. Epizyme is advised by both Jefferies and MTS Health Partners, L.P., joint lead financial advisors in connection with the transaction, with WilmerHale serving as legal counsel. In addition, MTS Securities, LLC (an affiliate of MTS Health Partners, L.P.) provided an opinion to the Board of Directors of Epizyme regarding the fairness of the offer consideration to be received by the holders of Epizyme common stock in the transaction, subject to the qualifications and limitations set forth therein.

#### **Conference call**

A conference call and webcast for investors and analysts will begin today at 2pm Paris time. Participants can join the call by dialling +1 785 424 1876 or, for U.S. participants, +1 877 888 4312 toll-free; the passcode is 63710. A recording will be available on [ipсен.com](https://www.ipсен.com), while the webcast can be accessed [here](#).

- a Enhancer of zeste homolog 2.
- b Assuming 170.54 million Epizyme fully diluted shares.
- c Mainland China, Hong Kong, Macau, Taiwan.

**ENDS**

#### **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.

View the U.S. Full Prescribing Information here: <https://www.epizyme.com/wp-content/uploads/2021/06/TAZVERIK.pdf>

#### **About SYMPHONY-1<sup>2</sup>**

SYMPHONY-1 is a global, multicenter Phase Ib/III study designed to determine the recommended Phase III dose (RP3D) and the efficacy and safety of Tazverik plus R<sup>2</sup> (rituximab and lenalidomide) versus placebo plus R<sup>2</sup>, in patients with relapsed/refractory follicular lymphoma after at least one prior therapy. Updated safety and activity data from the Phase Ib safety run-in portion of the study were presented at the 2022 American Society of Clinical Oncology Annual Meeting. Thirty-eight of the 44 patients were evaluable for tumor assessments as of the data cutoff, with 36 patients responding to treatment. The activity findings showed an objective response rate of 95 percent (50% complete response rate and 45% partial response rate). Two patients achieved stable disease, and two patients had progressive disease (one from the 400-mg cohort and one from the 600-mg cohort). Median progression-free survival (PFS) and duration of response were not yet reached as the study is ongoing. The safety profile of the Tazverik and R<sup>2</sup> combination was consistent with the prescribing information for both Tazverik and R<sup>2</sup>, respectively.

#### **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<sup>3,4</sup>**

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<sup>5</sup>**

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.<sup>6</sup>

### **About diffuse large B-cell lymphoma<sup>7</sup>**

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 are diagnosed with DLBCL each year.<sup>8</sup>

### **About multiple myeloma<sup>9</sup>**

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 Epizyme**

Epizyme is a fully integrated, commercial-stage biopharmaceutical company committed to its mission of rewriting treatment for cancer through novel epigenetic medicines. The Company, headquartered in Cambridge, Massachusetts in the U.S., is focused on creating medicines that are targeted at specific causes of diseases, that are orally administered, tolerable, easy to take and based on a deep understanding of the patients that may benefit from them. The Company aspires to change the standard-of-care for patients and physicians by developing medicines with fundamentally new mechanisms of action. For more information, visit [epizyme.com](http://epizyme.com)

### **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 Depository Receipt program (ADR: IPSEY). For more information, visit [ipсен.com](http://ipсен.com)

*Tazverik<sup>®</sup> is a registered trademark of Epizyme.*

### **Important Information**

The tender offer for the outstanding shares of Epizyme common stock has not yet commenced. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Epizyme common stock. The solicitation and offer to buy shares of Epizyme common stock will only be made pursuant to the tender offer materials that Ipsen intends to file with the U.S. Securities and Exchange Commission (the "SEC"). At the time the tender offer is commenced, Ipsen will file a tender offer statement on Schedule TO with the SEC, and Epizyme will file a solicitation/recommendation statement on Schedule 14D-9 with respect to the tender offer. EPIZYME'S STOCKHOLDERS ARE ADVISED TO READ THE SCHEDULE TO (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND OTHER OFFER DOCUMENTS) AND THE SCHEDULE 14D-9, AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME, AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC WHEN THEY BECOME AVAILABLE BEFORE THEY MAKE ANY DECISION WITH RESPECT TO THE TENDER OFFER BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES THERETO. Both the tender offer statement and the solicitation/recommendation statement will be mailed to Epizyme's stockholders free of charge. Investors and stockholders may obtain free copies of the Schedule TO and Schedule 14D-9, as each may be amended or supplemented from time to time, and other documents filed by the parties (when available) at the SEC's web site at [www.sec.gov](http://www.sec.gov), by contacting Epizyme's Investor Relations either by telephone at (617) 500-0615 or e-mail at [egraves@epizyme.com](mailto:egraves@epizyme.com) or on Epizyme's website at [www.epizyme.com](http://www.epizyme.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 [ipсен.com](https://www.ipсен.com)

### Epizyme Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Epizyme and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties as to the timing of the tender offer; the risk that the proposed transaction may not be completed in a timely manner or at all; the possibility that competing offers or acquisition proposals for Epizyme will be made; uncertainty surrounding how many of Epizyme's stockholders will tender their shares in the tender offer; the possibility that any or all of the various conditions to the consummation of the tender offer may not be satisfied or waived, including the failure to receive any required regulatory approvals from any applicable governmental entities; the possibility of business disruptions due to transaction-related uncertainty; the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement; the risk that stockholder litigation in connection with the proposed transaction may result in significant costs of defense, indemnification and liability; and other factors discussed in the "Risk Factors" section of the company's most recent Form 10-K and Form 10-Q filed with the SEC and in the company's other filings from time to time with the SEC. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof and should not be relied upon as representing the company's views as of any date subsequent to the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so, except as may be required by any applicable securities laws.

### References

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