INDICATIONS

TAZVERIK is indicated for the treatment of:

- 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 2 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. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Secondary Malignancies**: TAZVERIK increases the risk of developing secondary malignancies, including T-cell lymphoblastic lymphoma, myelodysplastic syndrome, acute myeloid leukemia, and B-cell acute lymphoblastic leukemia. Monitor patients long-term for the development of secondary malignancies.
- **Embryo-Fetal Toxicity**: TAZVERIK can cause fetal harm. Advise patients of potential risk to a fetus and to use effective non-hormonal contraception.

The most common (>20%) adverse reactions in patients with follicular lymphoma are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea, and abdominal pain.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

R/R=relapsed or refractory; EZH2=enhancer of zeste homolog 2.

STUDY DESIGN: A SINGLE-ARM, PHASE 2 TRIAL OF RELAPSED OR REFRACTORY FL PATIENTS

TAZVERIK® was studied in an open-label, single-arm, multicenter, phase 2 trial with 6 cohorts of patients, including 2 cohorts with histologically-confirmed R/R FL[1,2]

Enrolled 2 cohorts: *EZH2* WT (n=54) and MT (n=45) patients[1]

- Patients in the *EZH2* MT cohort had the following mutations: Y646X [S,H,C] (36%), Y646F (29%), Y646N (27%), A682G (11%), and A692V (2%).

Selected inclusion criteria

R/R FL after ≥2 systemic therapies[1]

ECOG PS 0-2[1]

Selected exclusion criteria[2]:

- Noncutaneous malignancies other than B-cell lymphomas
- Leptomeningeal metastases or brain metastases
- Thrombocytopenia, neutropenia, or anemia of Grade ≥3

TAZVERIK® dosing was 800 mg (4 tablets X 200 mg) twice daily until confirmed disease progression or unacceptable toxicity[1]

Assessments by IRC every 8 weeks through 24 weeks, then every 12 weeks[1]

Median duration of follow up was 36 months (WT; range: 32 to 39) and 22 months (MT; range: 3 to 44)[1]

- **Primary endpoint[1,2]:** Overall response rate (ORR)[1]
- **Selected secondary endpoint[1,2]:** Median duration of response (DOR)

WT and MT *EZH2* cohorts were analyzed independently and were not intended to be compared directly.

IMPORTANT SAFETY INFORMATION *(continued)*

Warnings and Precautions

• Secondary Malignancies

The risk of developing secondary malignancies is increased following treatment with TAZVERIK. Across clinical trials of 758 adults who received TAZVERIK 800 mg twice daily as monotherapy, myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), or B-cell acute lymphoblastic leukemia (B-ALL) occurred in 1.7% of patients. One pediatric patient developed T-cell lymphoblastic lymphoma (T-LBL). Monitor patients long-term for the development of secondary malignancies.

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TAZVERIK WAS STUDIED IN A HEAVILY PRETREATED FL PATIENT POPULATION

TAZVERIK® (tazemetostat) tablets 200 mg

A TWICE DAILY ORAL THERAPY FOR BUSY LIVES

BASELINE DISEASE CHARACTERISTICS[1,2]	WT *EZH2* (n=54)	MT *EZH2* (n=45)
ECOG PS 0 or 1, %	91	100
ECOG PS 2, %*	7	0
POD24, %	59	42
Median time from initial diagnosis, years	6.3	4.7
Median number of lines of prior systemic therapy (range)	3 (1 to 8)	2 (1 to 11)
Refractory to rituximab, %	59	49
Double refractory to rituximab, %†	28	20
Refractory to last therapy, %	41	49
Prior stem cell transplant, %	39	9

Baseline characteristics were notably different across the WT and MT *EZH2* cohorts with more clinically challenging patients in the WT cohort.[1,2]

IMPORTANT SAFETY INFORMATION *(continued)*

Warnings and Precautions *(continued)*

- **Embryo-Fetal Toxicity**

Based on findings from animal studies and its mechanism of action, TAZVERIK can cause fetal harm when administered to pregnant women. There are no available data on TAZVERIK use in pregnant women to inform the drug-associated risk. Administration of tazemetostat to pregnant rats and rabbits during organogenesis resulted in dose-dependent increases in skeletal developmental abnormalities in both species beginning at maternal exposures approximately 1.5 times the adult human exposure (area under the plasma concentration time curve [$AUC_{0\text{-}45h}$]) at the 800 mg twice daily dose.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

FL=follicular lymphoma; R/R=relapsed or refractory; EZH2=enhancer of zeste homolog 2; WT=wild type; MT=mutant type; ECOG PS=Eastern Cooperative Oncology Group Performance Status; POD24=early progression within 24 months following front-line therapy; IRC=Independent Radiology Committee.

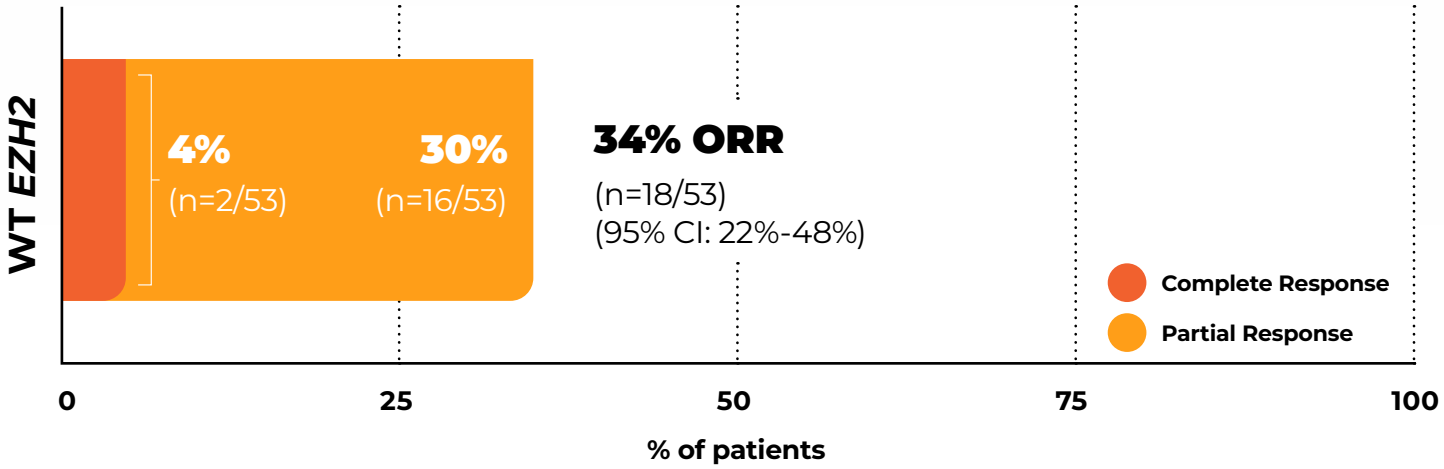
*ECOG PS was missing for one WT patient.
†And an alkylating agent or purine nucleoside antagonist.

WT

TAZVERIK® DEMONSTRATED EFFICACY, REGARDLESS OF *EZH2* MUTATION STATUS

Wild-Type *EZH2* Follicular Lymphoma

Overall Response Rate (ORR, primary endpoint)[1,3]*



Duration of Response (DOR, secondary endpoint)

13.0
months
median DOR

(range=1.0 - ≥22.5 months)
(n=18/53; 95% CI: 5.6–NE)[1,3]

Of those who had a response,[3‡]

- **56%** (n=10/18) responded for >6 months
- **39%** (n=7/18) responded for >12 months

- Median time to overall response for patients with WT *EZH2* FL was 3.9 months (range 1.6 to 16.3).

IMPORTANT SAFETY INFORMATION *(continued)*

Warnings and Precautions *(continued)*

- **Embryo-Fetal Toxicity** ***(continued)***

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TAZVERIK and for 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TAZVERIK and for 3 months after the final dose.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

*According to the International Working Group Non Hodgkin Lymphoma (IWG-NHL) criteria as assessed by Independent Radiology Committee.
‡Percentages are based on the Intent-to-Treat subjects within each group that achieved a complete response or partial response.

MT

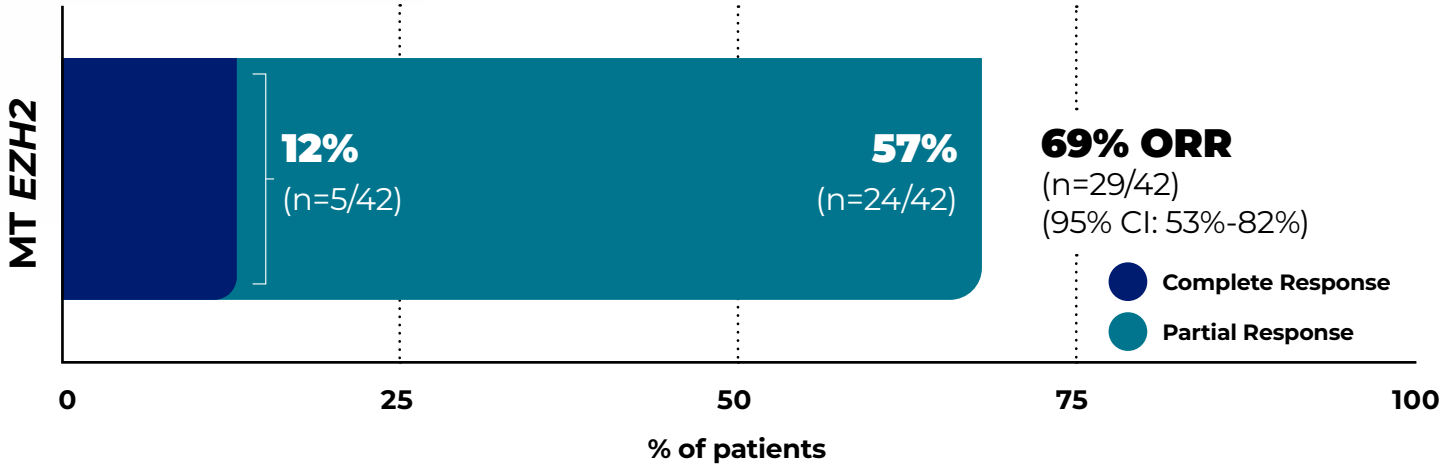
TAZVERIK® DEMONSTRATED EFFICACY, REGARDLESS OF *EZH2* MUTATION STATUS

TAZVERIK® (tazemetostat) tablets 200 mg

A TWICE DAILY ORAL THERAPY FOR BUSY LIVES

Mutant *EZH2* Follicular Lymphoma

*Overall Response Rate (ORR, primary endpoint)[1,3]**



Duration of Response (DOR, secondary endpoint)

10.9 months median DOR

(range=0.0 - ≥22.1 months)
(n=29/42; 95% CI: 7.2–NE)[1,3]

Of those who had a response,[3‡]

- **59%** (n=17/29) responded for >6 months
- **21%** (n=6/29) responded for >12 months

- Median time to overall response for patients with MT *EZH2* FL was 3.7 months (range 1.6 to 10.9)

IMPORTANT SAFETY INFORMATION *(continued)*

Adverse Reactions

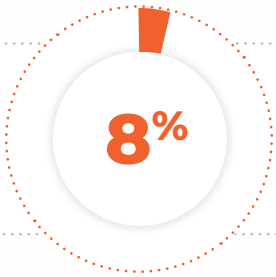
In 99 clinical study patients with relapsed or refractory follicular lymphoma receiving TAZVERIK 800 mg twice daily: Serious adverse reactions occurred in 30% of patients who received TAZVERIK. Serious adverse reactions occurring in ≥2% were general physical health deterioration, abdominal pain, pneumonia, sepsis, and anemia. The most common (≥20%) adverse reactions were fatigue (36%), upper respiratory tract infection (30%), musculoskeletal pain (22%), nausea (24%), and abdominal pain (20%).

Please see additional Important Safety Information on page 10 and full Prescribing Information.

*According to the International Working Group Non Hodgkin Lymphoma (IWG-NHL) criteria as assessed by Independent Radiology Committee.
‡Percentages are based on the Intent-to-Treat subjects within each group that achieved a complete response or partial response.

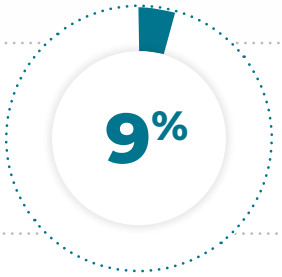
TAZVERIK® SAFETY WAS ASSESSED ACROSS CLINICALLY DIVERSE R/R FOLLICULAR LYMPHOMA (FL) PATIENTS (N=99)[1]

DISCONTINUATIONS



8% of patients **permanently discontinued** treatment due to an adverse reaction. The adverse reaction resulting in permanent discontinuation in ≥2% of patients was second primary malignancy.[1]

REDUCTIONS



9% of patients receiving TAZVERIK® required **dose reductions** due to an adverse reaction.[1]

INTERRUPTIONS

28% of patients receiving TAZVERIK required **dose interruptions** due to an adverse reaction. Adverse reactions requiring dosage interruptions in ≥3% of patients were thrombocytopenia and fatigue.[1]

Serious adverse reactions occurred in 30% of patients who received TAZVERIK. Serious adverse reactions occurring in ≥2% of patients taking TAZVERIK included general physical health deterioration, abdominal pain, pneumonia, sepsis, and anemia.[1]

The most common (≥20%) adverse reactions were fatigue (36%), upper respiratory tract infection (30%), musculoskeletal pain (22%), nausea (24%), and abdominal pain (20%).[1]

Please see additional Important Safety Information on page 10 and full Prescribing Information.

SAFETY EVALUATION: ADVERSE REACTIONS

TAZVERIK® (tazemetostat) tablets 200 mg

A TWICE DAILY ORAL THERAPY FOR BUSY LIVES

Adverse reactions (≥10%) in patients with relapsed or refractory (R/R) FL who received TAZVERIK (N=99)[1]

ADVERSE REACTION	ALL GRADES (%)	GRADE 3 OR 4 (%)
General		
Fatigue[a]	36	5
Pyrexia	10	0
Infections		
Upper respiratory tract infection[b]	30	0
Lower respiratory tract infection[c]	17	0
Urinary tract infection[d]	11	2
Gastrointestinal		
Nausea	24	1
Abdominal pain[e]	20	3
Diarrhea	18	0
Vomiting	12	1
Musculoskeletal and connective tissue		
Musculoskeletal pain[f]	22	1
Skin and subcutaneous tissue		
Alopecia	17	0
Rash[g]	15	0
Respiratory and mediastinal system		
Cough[h]	17	0
Nervous system		
Headache[i]	13	0

≤5% of patients experienced Grade 3 or 4 adverse reactions.[1]

Please see additional Important Safety Information on page 10 and full Prescribing Information.

[a]Includes fatigue and asthenia.
[b]Includes laryngitis, nasopharyngitis, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, viral upper respiratory tract infection.
[c]Includes bronchitis, lower respiratory tract infection, tracheobronchitis.
[d]Includes cystitis, urinary tract infection, urinary tract infection staphylococcal.
[e]Includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper.
[f]Includes back pain, limb discomfort, musculoskeletal chest pain, musculoskeletal discomfort, musculoskeletal pain, myalgia, neck pain, non-cardiac chest pain, pain in extremity, pain in jaw, spinal pain.
[g]Includes erythema, rash, rash erythematous, rash generalized, rash maculo-papular, rash pruritic, rash pustular, skin exfoliation.
[h]Includes cough and productive cough.
[i]Includes headache, migraine, sinus headache.

FL=follicular lymphoma; R/R=relapsed or refractory.

SELECT LABORATORY ABNORMALITIES (≥10%) WORSENING FROM BASELINE IN PATIENTS WITH R/R FL WHO RECEIVED TAZVERIK®[1]

LABORATORY ABNORMALITY	TAZVERIK®*	
	ALL GRADES (%)	GRADE 3 OR 4 (%)
Hematology		
Decreased lymphocytes	57	18
Decreased hemoglobin	50	8
Decreased platelets	50	7
Decreased white blood cells	41	9
Decreased neutrophils	20	7
Chemistry		
Increased glucose	53	10
Increased aspartate aminotransferase	24	0
Increased alanine aminotransferase	21	2.3
Increased alkaline phosphatase	18	1.0
Increased creatinine	17	0

TAZVERIK does not require special monitoring for laboratory abnormalities.

IMPORTANT SAFETY INFORMATION *(continued)*

Drug Interactions

Avoid coadministration of strong or moderate CYP3A inhibitors with TAZVERIK. If coadministration of strong or moderate CYP3A inhibitors cannot be avoided, reduce TAZVERIK dose.

Avoid coadministration of moderate or strong CYP3A inducers with TAZVERIK, which may decrease the efficacy of TAZVERIK.

Coadministration of TAZVERIK with CYP3A substrates, including hormonal contraceptives, can result in decreased concentrations and reduced efficacy of CYP3A substrates.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

*The denominator used to calculate the rate varied from 88 to 96 based on the number of patients with a baseline value and at least one post-treatment value.

R/R=relapsed or refractory; FL=follicular lymphoma.

TAZVERIK® OFFERS ORAL, TWICE-DAILY DOSING

TAZVERIK® (tazemetostat) tablets 200 mg

A TWICE DAILY ORAL THERAPY FOR BUSY LIVES

Recommended dose of 800 mg (4 x 200 mg tablets) taken orally, twice daily, until disease progression or unacceptable toxicity[1]

NDC number (10 digit): 72607-100-00
NDC number (11 digit): 72607-0100-00
How supplied: 240-count bottle
NDC=National Drug Code

with or without food

1st dose

2nd dose

Tablets shown are not actual size.

Swallow tablets whole. Do not cut, crush, or chew tablets.

Do not take an additional dose if a dose is missed or vomiting occurs after taking TAZVERIK, but continue with the next scheduled dose.[1]

TAZVERIK works through an epigenetic mechanism. It may take time for your patients to respond to treatment.[1]

For patients who experienced an overall response in the clinical trial, the median time to response was:

3.9 months (range: 1.6 to 16.3) for patients with WT *EZH2*.[1]

and

3.7 months (range: 1.6 to 10.9) for patients with MT *EZH2*.[1]

IMPORTANT SAFETY INFORMATION *(continued)*

Lactation

Because of the potential risk for serious adverse reactions from TAZVERIK in the breastfed child, advise women not to breastfeed during treatment with TAZVERIK and for one week after the final dose.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

WT=wild type; EZH2=enhancer of zeste homolog 2; MT=mutant type.

INDICATIONS & IMPORTANT SAFETY INFORMATION

INDICATIONS

TAVERIK is indicated for the treatment of:

- 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 2 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. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).[1]

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Warnings and Precautions

• Secondary Malignancies

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• Embryo-Fetal Toxicity

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Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TAZVERIK and for 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TAZVERIK and for 3 months after the final dose.

Adverse Reactions

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To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

RESOURCES AND INFORMATION TO SUPPORT YOUR PATIENTS' ACCESS TO TAZVERIK®

TAZVERIK® (tazemetostat) tablets 200 mg

A TWICE DAILY ORAL THERAPY FOR BUSY LIVES

PATIENT ASSISTANCE PROGRAM (PAP)

Patients may be eligible to receive a limited supply of free medication if they are uninsured or underinsured (based on program eligibility criteria).

TEMPORARY PATIENT ASSISTANCE PROGRAM (TPAP)

Helping new or existing commercial patients access their medication should they experience a change or delay in drug coverage.

CO-PAY ASSISTANCE PROGRAM

Patients with commercial health insurance may be eligible to receive co-payment assistance from Ipsen to help reduce out-of-pocket costs for TAZVERIK®.*

MEDICATION SUPPORT NURSE PROGRAM

Patients prescribed Tazverik who are enrolled in IPSEN CARES can receive individualized support services by an IPSEN CARES nurse to help them through their treatment journey.

All patient support is subject to eligibility criteria and program terms and conditions. Medication Support Nurses are provided by Ipsen and do not work under the direction of the patient's healthcare provider or give medical advice. They are trained to direct patients to their provider for treatment-related advice, including referrals.

IPSENCARES®
Coverage, Access, Reimbursement & Education Support

If you are interested in learning more about any of the support offerings mentioned, including eligibility requirements, visit **ipsencares.com** or contact Ipsen Cares at **1-866-435-5677**, Monday through Friday, 8 AM - 8 PM ET.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

*This offer is not valid for cash-paying patients or patients currently enrolled in Medicare, Medicaid, or any other federal or state healthcare program. Limitations apply. Void where prohibited.

IT'S TIME FOR *Their life. Their rhythm.*

TAZVERIK® (tazemetostat) tablets 200 mg

A TWICE DAILY ORAL THERAPY FOR BUSY LIVES

Consider TAZVERIK® for your appropriate adult R/R FL patients

TAZVERIK is indicated for the treatment of:

- 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 2 prior systemic therapies.
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These indications are approved under accelerated approval 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 a confirmatory trial(s).[1]

National Comprehensive Cancer Network® (NCCN®) NCCN recommended

Tazemetostat (TAZVERIK) is included in the NCCN Guidelines® for B-cell lymphomas with an NCCN Category 2A recommendation as an option for select patients with R/R FL*

TAZVERIK demonstrated efficacy, regardless of *EZH2* mutation status

Visit IpsenCares.com for patient and product support

>90% of payer policies support the use of TAZVERIK in patients with R/R FL, regardless of *EZH2* status.[3]

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

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The most common (>20%) adverse reactions in patients with follicular lymphoma are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea, and abdominal pain.

Please see additional Important Safety Information on page 10 and full Prescribing Information.

R/R=relapsed or refractory; FL=follicular lymphoma; NCCN=National Comprehensive Cancer Network; EZH2=enhancer of zeste homolog 2.

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References: 1. TAZVERIK (tazemetostat) Prescribing Information. Cambridge, MA: Epizyme, Inc., August 2024. **2.** Morschhauser F, Tilly H, Chaidos A , et al. Tazemetostat for patients with relapsed or refractory follicular lymphoma: an open-label, single-arm, multicentre, phase 2 trial. *Lancet Oncol.* 2020;21(11):1433-1442. **3.** Data on file.

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