CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Division of Risk Management (DRM)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Application Type	NDA
Application Number	220305
PDUFA Goal Date	November 30, 2025
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Reviewer Name(s)	Ingrid N. Chapman, PharmD, BCPS
Team Leader(s)	Naomi Boston, PharmD
Division Director	Laura Zendel, PharmD
Review Completion Date	November 12, 2025
Subject	Evaluation of Need for a REMS
[Established/Proper] Name	Ziftomenib
Trade Name	Komzifti
Name of Applicant	Kura Oncology Inc.
Therapeutic Class	Menin inhibitor
Dosage Form	200 mg capsules for oral administration
Dosing Regimen	600 mg orally once daily

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EXECUTIVE SUMMARY

This review by the Division of Risk Management (DRM) evaluates whether a risk evaluation and mitigation strategy (REMS) for the new molecular entity (NME) Komzifti (ziftomenib) is necessary to ensure the benefits outweigh its risks.

Kura Oncology Inc. submitted a New Drug Application (NDA) 220305 for ziftomenib with the proposed indication: for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a nucleophosmin 1 (NPM1) mutation. During the course of the review, the indication was revised to the following:

Komzifti is a menin inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative treatment options.

This application was reviewed by the Division of Hematologic Malignancies I (DHMI). The efficacy of ziftomenib for the treatment of patients with relapsed or refractory AML with an *NPM1* mutation was demonstrated in Study KO-MEN-001. Results showed the rate of complete remission (CR) plus CR with partial hematological recovery (CRh) rate was 21.4% (95% CI 14.2, 30.2), the median duration of CR + CRh was 5 months (95% CI 1.9, 8.1), and the rate of conversion to 56-day transfusion independent (TI-56) was 21.2% (95% CI 12.1%, 33.0%). The FDA team noted the low point estimates for CR + CRh and TI-56 rates, along with the short duration of response. There was a short duration of treatment (median 2.2 months), with only 19% of participants receiving at least 6 months of ziftomenib therapy.

The results from the Phase 2 efficacy cohort of Study KO-MEN-001 and the additional confirmatory data from the Phase 1b portion of KO-MEN-001 are considered substantial evidence of effectiveness of ziftomenib for the treatment of relapsed or refractory AML with a susceptible NPM1 mutation who have no satisfactory alternative treatment options.

The serious risks associated with ziftomenib includes differentiation syndrome and QTc interval prolongation. The Applicant did not submit a proposed REMS or risk management plan with this application.

DRM has determined that a REMS is not needed to ensure the benefits of ziftomenib outweigh its risks. FDA expects the labeling to be sufficient to communicate the risk of differentiation syndrome and QTc interval prolongation. FDA also expects the likely prescribers of ziftomenib (hematologists and oncologists) to be familiar with managing these risks because other products they prescribe have these similar risks. Monitoring and managing serious toxicities are incorporated into standard oncology clinical practice.

1. Introduction

This review by the Division of Risk Management (DRM) evaluates whether a risk evaluation and mitigation strategy (REMS) for the new molecular entity (NME) Komzifti (ziftomenib) is necessary to

ensure the benefits outweigh its risks. Kura Oncology Inc. submitted a New Drug Application (NDA) 220305 for ziftomenib with the proposed indication: for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a nucleophosmin 1 (*NPM1*) mutation. This application was reviewed by the Division of Hematologic Malignancies I (DHMI). The Applicant did not submit a proposed REMS or risk management plan with this application.

2. Background

2.1. Product Information

Komzifti (ziftomenib), a new molecular entity (NME),[a] is an menin inhibitor that blocks the interaction of menin and lysine [K]-specific methyltransferase 2A (*KMT2A*). Pharmacologic disruption of the menin-KMT2A protein-protein interaction by ziftomenib blocks oncogenic activity of mutant NPM1, which induces differentiation of leukemic cells as evidenced by increased expression of differentiation markers. Ziftomenib is proposed for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a nucleophosmin 1 (*NPM1*) mutation.[b]

Ziftomenib is proposed as 200 mg capsules for oral administration. The recommended dosage is 600 mg orally once daily. Treatment with ziftomenib is continued indefinitely or until unacceptable toxicity occurs.[c] Ziftomenib is not currently approved in any other jurisdiction.[b]

2.2. Regulatory History

The following is a summary of the regulatory history for NDA 218881 relevant to this review:

- **03/31/2025**: NDA 220305 submission for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a nucleophosmin 1 (*NPM1)* mutation.
- **07/07/2025**: A Mid-cycle meeting was held between the Agency and the Applicant via teleconference. The Agency informed the Applicant that no safety concerns had been identified that would require a REMS at that time.

3. Therapeutic Context and Treatment Options

3.1. Description of the Medical Condition

Acute leukemia is characterized by uncontrolled expansion of immature leukocytes, either myeloid or lymphoid progenitors, leading to acute myeloid leukemia (AML) and acute lymphoid leukemia (ALL), respectively (Ladikou, 2022). AML interferes with the production of normal blood cells, which can cause fatigue, weakness, infection, bleeding, and other potentially life-threatening complications (Larson, 2025). AML is associated with poor long-term outcomes and is rapidly fatal without

[a] Section 505-1 (a) of the FD&C Act: *FDAAA factor (F): Whether the drug is a new molecular entity.*
[b] Kura Oncology Inc. Komzifti (ziftomenib). NDA 220305. Proposed labeling. March 31, 2025.
[c] Section 505-1 (a) of the FD&C Act: *FDAAA factor (D): The expected or actual duration of treatment with the drug.*

treatment.[d] The median age at diagnosis is 69 years of age in adults, with approximately 60% of patients diagnosed at ≥65 years of age and one-third of patients diagnosed at ≥75 years of age.[e] In 2022, there were an estimated 79,317 people living with AML in the United States (U.S.). The estimated total number of new cases of AML in the U.S. in 2025 is 22,010 (1.1% of all new cancers cases).[f] The estimated number of deaths due to AML is 11,090 (1.8% of all cancer deaths) with the five-year relative survival being 32.9%.[g] With relapse, survival outcomes decline drastically with a 5-year overall survival rate of approximately 10% (DeWolf, 2020).

Table 1 (Larson, 2023): Definitions of Refractory Disease and Relapse	
Refractory (resistant) disease:	• Failure to achieve a complete response (CR) (i.e., failure to eradicate all visible leukemia cells and achieve less than 5 percent blasts in the bone marrow and blood) is described as refractory disease (also referred to as primary induction failure). • Patients who require a second cycle of induction therapy to achieve CR are not considered to have refractory disease. • Achievement of <5% marrow blasts, but failure to restore normal hematopoiesis (normal peripheral blood counts) is referred to as CRi (CR with incomplete hematological recovery); this is not considered refractory disease.
Relapsed disease:	Relapse describes the reappearance of leukemia cells in the bone marrow, peripheral blood, or elsewhere (extramedullary disease) after the attainment of a CR.

Up to 50% of people with AML who achieve remission will later relapse, including those with a nucleophosmin 1 (*NPM1*) mutation.[e] *NPM1* is a gene mutated in approximately one-third of newly diagnosed acute myeloid leukemia (AML) cases (Sharma 2023). NPM1*mut*-AML clinically presents with leukocytosis, high blast percentage and extramedullary involvement. *NPM1* mutations are associated with improved outcomes in younger and older adults and in children with AML, although the mechanism for increased chemosensitivity is not known (Stock 2024). However, this effect may be diminished by concurrent adverse cytogenetic abnormalities and other gene mutations (Schiffer, 2025). Additionally, the presence of *NPM1* mutation at the time of relapse does not confer a positive prognostic value.[e]

[d] Section 505-1 (a) of the FD&C Act: *FDAAA* factor (B): *The seriousness of the disease or condition that is to be treated with the drug.*

[e] Food and Drug Administration. Division of Hematologic Malignancies I. Komzifti (ziftomenib). NDA 220305. NDA Multidisciplinary Review and Evaluation, draft. November 6, 2025.

[f] Section 505-1 (a) of the FD&C Act: *FDAAA factor (A): The estimated size of the population likely to use the drug involved*

[g] Cancer Stat Facts: Leukemia — Acute Myeloid Leukemia (AML). National Cancer Institute. Surveillance, Epidemiology, and End Results Program. Accessed October 30, 2025. https://seer.cancer.gov/statfacts/html/amyl.html

3.2. Description of Current Treatment Options

The standard of care for RR AML is intensive chemotherapy followed by transplantation. Allogeneic hematopoietic cell transplantation (HCT) provides the best chance of cure while myeloablative HCT appears to have the best outcomes after attaining a complete remission. Autologous marrow transplantation is an option for those who achieve a second CR (Larson, 2023).

Fit (≤ 60 years, transplant eligible) adults with *NPM1* mutation are treated with intensive chemotherapy, often an anthracycline and cytarabine followed by consolidation with or without a stem cell transplant (Sharma 2023). In older unfit patients with NPM1*mut*-AML, combining venetoclax with a hypomethylating agent (HMA) induced composite complete remission (i.e., complete response and complete response with incomplete hematological recovery).

At the time of this NDA submission (March 31, 2025), there were no drugs approved specifically for patients with R/R AML with an *NPM1* mutation. Revuforj (revumenib), the first FDA-approved menin inhibitor, was originally approved on November 15, 2024, for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (*KMT2A*) translocation in adults and pediatric patients ≥1 year of age. On October 24, 2025, a labeling supplement was approved for revumenib for the following new indication: the treatment of relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation in adult and pediatric patients 1 year and older who have no satisfactory alternative treatment options. Revumenib is approved with a Boxed Warning for differentiation syndrome, QTc prolongation, and Torsades de pointes.[h]

Currently, there is no standard treatment for managing relapse in patients with AML after HCT. The choice will vary based on the presence of a targetable mutation (e.g., IDH1, IDH2, FLT3, *NPM1*), medical fitness, prior treatments, and patient preference.[i] People with AML are often diagnosed later in life and are unable to tolerate curative treatments with intensive chemotherapy followed by HCT. There remains a high unmet medical need for treatment options for RR AML.

4. Benefit Assessment

The efficacy and safety of ziftomenib for the treatment of patients with relapsed or refractory AML with an *NPM1* mutation was evaluated in Study KO-MEN-001 (NCT04067336). KO-MEN-001 was an open-label, single-arm, multicenter clinical trial in 112 adult patients with relapsed or refractory AML with an *NPM1* mutation identified using next-generation sequencing or polymerase chain reaction.[j]

- Phase 1 consisted of two parts:
    a. Part 1a (dose escalation): 30 subjects received ziftomenib in doses ranging from 50 to 1000 mg orally daily and a maximum tolerable dose (MTD) of 800 mg daily was established.

[h] U.S. Food and Drug Administration. Drugs@FDA: FDA-Approved Drugs. Accessed November 6, 2025. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

[i] Larson R. Treatment of relapsed or refractory acute myeloid leukemia. UpToDate. March 31, 2023. Accessed November 3, 2025.

[j] Kura Oncology Inc. Komzifti (ziftomenib). NDA 220305. Final labeling. October 30, 2025.

b. Part 1b (dose-validation/expansion): Two dose levels, 200 mg (n = 17) and 600 mg (n = 36) orally daily were administered to 53 subjects with *KMT2A*-r or *NPM1-mut* AML, to determine the recommended phase 2 dose (RP2D). The RP2D was determined to be 600 mg daily.

- Phase 2 was a single-cohort study evaluating ziftomenib 600 mg (n = 92) orally once daily in subjects with locally determined RR NPM1-*mut* AML.

The Phase 2 Study is the primary basis of efficacy with this NDA with supportive confirmatory data provided by the Phase 1b portion of the study (n = 20 received 600 mg and had NPM1-*mu*t AML). Due to the similarities between the Phase 1b and Phase 2 patient populations, the labeled population includes an analysis of all patients in the Phase 1b and Phase 2 portions of the study who received treatment with the recommended dosage of ziftomenib.[k] Overall (Phase 1b [n = 20] and Phase 2 [n = 92]), 112 subjects received ziftomenib orally at a dose of 600 mg once daily until disease progression or unacceptable toxicity. The median duration of exposure was 2.2 months (range 0.1-21.5 months); 18% of participants received treatment with ziftomenib for > 6 months.

The efficacy outcomes included rate of complete remission (CR) plus CR with partial hematological recovery (CRh), the duration of response (DoR)/CR + CRh, and the rate of conversion from transfusion dependence to transfusion independence. The median follow-up was 4.2 months (range, 0.1 to 41.2 months). Results showed the rate of complete remission (CR) plus CR with partial hematological recovery (CRh) rate was 21.4% (95% CI 14.2, 30.2), the median duration of CR + CRh was 5 months (95% CI 1.9, 8.1), and the rate of conversion to 56-day transfusion independent (TI-56) was 21.2% (95% CI 12.1%, 33.0%).[l] The FDA team noted the low point estimates for CR + CRh and TI-56 rates, along with the short duration of response. These low rates required careful consideration of the overall benefit-risk assessment. There was a short duration of treatment (median 2.2 months), with only 19% of participants receiving at least 6 months of ziftomenib therapy.[k]

The Division (DHM1) determined that the totality of evidence, including the observed CR + CRh and TI-56 rates, the overall DoR, and the safety profile, supports a positive benefit-risk assessment of ziftomenib at this time for adult patients with R/R AML with a susceptible *NPM1* mutation who have no satisfactory alternative treatment options.[k]

The revised indication for approval is the following:

> Komzifti is a menin inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation who have no satisfactory alternative treatment options.[m]

[k] Food and Drug Administration. Division of Hematologic Malignancies I. Komzifti (ziftomenib). NDA 220305. NDA Multidisciplinary Review and Evaluation, draft. November 6, 2025.
[l] Section 505-1 (a) of the FD&C Act*: FDAAA factor (C): The expected benefit of the drug with respect to such disease or condition.*
[m] Kura Oncology Inc. Komzifti (ziftomenib). NDA 220305. Final labeling. October 30, 2025.

5. Risk Assessment & Safe-Use Conditions

The safety of ziftomenib was established in Study KO-MEN-001 for the treatment of RR AML with an *NPM1* mutation. Serious adverse reactions (SARs) were reported in 79% of patients who received ziftomenib.[n] Serious adverse reactions occurring in ≥ 5% of patients included infection without an identified pathogen (29%), febrile neutropenia (18%), bacterial infection (16%), differentiation syndrome (16%), and dyspnea (6%).

Fatal adverse reactions occurred in 4 (4%) patients who received ziftomenib, including 2 with differentiation syndrome, 1 with infection, and 1 with sudden death. The Applicant attributed the infection to ziftomenib, the sudden death to coronary arrest, and the two events of differentiation syndrome to respiratory failure and disease progression. The FDA agreed with the Applicant's position that the fatal adverse event of infection was related to ziftomenib, however, the FDA disagreed with the Applicant's assessment of the other three fatal adverse events as not being related to ziftomenib.[o]

Labeling includes three SARs in the Warnings and Precautions: differentiation syndrome, QTc interval prolongation, and embryo-fetal toxicity.[p] Embryo-fetal toxicity is a risk based on animal findings and its mechanism of action (no adverse events occurred in the clinical study).[q] Differentiation syndrome and QTc interval prolongation are discussed below.

5.1. Differentiation Syndrome

Differentiation syndrome (DS) is a potentially fatal risk of treatment with differentiation agents in patients with acute leukemias including acute promyelocytic leukemia (APL) or AML. It is a known to be associated with several FDA-approved drugs used to treat acute leukemias including all-trans retinoic acid (antineoplastic), arsenic trioxide (antineoplastic), enasidenib (IDH2 Inhibitor), ivosidenib (IDH1 Inhibitor), olutasidenib (IDH1 Inhibitor), gilteritiinib (FLT3 Inhibitor), and revumenib (menin inhibitor). While these drugs have different mechanisms of action than ziftomenib (except revumenib), they share a similar risk factor of promoting differentiation of myeloid blasts and subsequent production of inflammatory cytokines in patients with acute leukemias (Larson, 2023). All these drugs were approved with a Boxed Warning for differentiation syndrome.[r]

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[n] A Serious Adverse Event (SAE) is any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

[o] Food and Drug Administration. Division of Hematologic Malignancies I. Komzifti (ziftomenib). NDA 220305. NDA Multidisciplinary Review and Evaluation, draft. November 6, 2025.

[p] Section 505-1 (a) of the FD&C Act: *FDAAA factor (E): The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.*

[q] Kura Oncology Inc. Komzifti (ziftomenib). NDA 220305. Final labeling. October 30, 2025.

[r] U.S. Food and Drug Administration. Drugs@FDA: FDA-Approved Drugs. Accessed November 6, 2025. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

In Study KO-MEN-001, differentiation syndrome occurred in 29 (26%) of 112 subjects receiving ziftomenib at the recommended dosage. Grade 3 adverse events occurred in 13% of the 112 subjects. The median time to onset was 15 days. Two subjects experienced more than one differentiation syndrome event. Treatment was interrupted and resumed in 15 (13%) subjects, while it was permanently discontinued in 2 (2%) subjects. Two fatal grade 5 adverse events were attributed to differentiation syndrome.[s]

The safe-use conditions for ziftomenib and associated differentiation syndrome includes:[s]

- Prior to starting treatment with ziftomenib, reduce the WBC counts to less than 25 x 10^9/L.
- If differentiation syndrome is suspected:
    - Interrupt ziftomenib, initiate oral or intravenous corticosteroids (e.g., dexamethasone 10 mg every 12 hours) for a minimum of 3 days with hemodynamic and laboratory monitoring.
    - Resume treatment with ziftomenib at the same dose level when signs and symptoms improve and are Grade 2 or lower.
    - Taper corticosteroids over a minimum of 3 days after adequate control or resolution of symptoms.

If approved, labeling for ziftomenib will include a Boxed Warning for differentiation syndrome.[s]

WARNING: DIFFERENTIATION SYNDROME

Differentiation syndrome, which can be fatal, has occurred with KOMZIFTI. Signs and symptoms may include fever, joint pain, hypotension, hypoxia, dyspnea, rapid weight gain or peripheral edema, pleural or pericardial effusions, pulmonary infiltrates, acute kidney injury, and rashes. If differentiation syndrome is suspected, interrupt KOMZIFTI and initiate oral or intravenous corticosteroids with hemodynamic and laboratory monitoring until symptom resolution; resume KOMZIFTI upon symptom improvement *[see Dosage and Administration (2.5), Warnings and Precautions (5.1), and Adverse Reactions (6.1)]*.

5.2. QTc Interval Prolongation

Ziftomenib can cause QTc interval prolongation. Adverse events of QTc interval prolongation were reported in 12% of 112 subjects in Study KO-MEN-001. Grade 3 adverse events occurred in 8% of subjects. Ziftomenib dose reduction was required for 1% of patients due to QTc interval prolongation. The increase in the QTc interval was concentration-dependent with the largest mean increase in QTc interval predicted to be 7.7 milliseconds (ms) (upper confidence interval = 12.6 ms) after administration of ziftomenib 600 mg once daily. There were 9 subjects (7%) with QTcF > 500 ms and an increase in QTc > 60 ms over baseline.[s,t]

The QT Study Reviewer recommended inclusion of a warning for QTc prolongation for ziftomenib because concentration-dependent QTc prolongation was observed and there is potential for further

[s] Kura Oncology Inc. Komzifti (ziftomenib). NDA 220305. Final labeling. October 30, 2025.
[t] QTcF: QT interval corrected for heart rate using Fridericia's formula

increase in QTc prolongation due to CYP3A4 inhibition and inadvertent administration with food (~4x increase in Cmax). Additionally, the Applicant includes, in the "Adverse Reactions" section of the proposed label, that hypokalemia was observed with administration of ziftomenib, which is a risk factor for QTc prolongation and drug-induced torsade de pointes.[u]

The safe-use conditions for ziftomenib and associated QTc interval prolongation include:[v]

- Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to treatment with ziftomenib.
- Perform an ECG prior to initiation of treatment with ziftomenib, and do not initiate ziftomenib in patients with QTcF > 480 msec.
- Perform an ECG at least once weekly for the first four weeks on treatment, and at least monthly thereafter.
- Interrupt ziftomenib if the QTc interval is > 500 ms or the change from baseline is > 60 ms (Grade 3).
- In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent ECG monitoring may be necessary.
- Concomitant use of ziftomenib with drugs known to prolong the QTc interval may increase the risk of QTc interval prolongation

6. Expected Postmarket Use

Patients with RR AML with an *NPM1* mutation should have an established relationship with a healthcare provider. The likely prescribers of ziftomenib are hematologists and oncologists. If approved, ziftomenib will likely be dispensed from outpatient pharmacy settings and primarily be self-administered by the patient at home. Based on the anticipated medication use process, monitoring for differentiation syndrome, QTc interval prolongation, and embryo-fetal toxicity should be a collaborative effort between the prescriber and the patient or patient's caregiver. It is expected that the likely prescribers of ziftomenib, should be familiar with the management of common toxicities associated with acute leukemia (APL and AML) treatment including differentiation syndrome, QTc interval prolongation, and embryo-fetal toxicity.

No concerning care gaps have been identified within the intended scope of practice. Labeling is sufficient to ensure the safe-use conditions for mitigating the risks of ziftomenib in the expected postmarket setting.

7. Discussion of the Need for a REMS

Based on the efficacy and safety information currently available, FDA determined that a REMS is not necessary to ensure the benefits of ziftomenib outweigh the risks. Differentiation syndrome, QTc

[u] Lars J. Food and Drug Administration. Interdisciplinary Review Team for Cardiac Safety Studies. QT Study Review. Reference ID: 5660446. September 17, 2025.

[v] Kura Oncology Inc. Komzifti (ziftomenib). NDA 220305. Final labeling. October 30, 2025

interval prolongation, and embryo-fetal toxicity are the risks listed in the Warnings and Precautions section of the proposed label. Differentiation syndrome is a serious and life-threatening risk that will be included in the Boxed Warning.

FDA expects the labeling to be sufficient to communicate the serious risk of differentiation syndrome (Boxed Warning) and the risks of QTc interval prolongation, and embryo-fetal toxicity. FDA also expects the likely prescribers of ziftomenib (hematologists and oncologists) to be familiar with managing these risks because other products they prescribe have similar risks. Monitoring and managing serious toxicities are incorporated into standard oncology clinical practice. Given the median age at diagnosis, embryo-fetal toxicity is not expected to be a significant risk for this patient population.

8. Risk Management Activities Proposed by the Applicant

The Applicant did not propose any risk management activities for ziftomenib beyond routine pharmacovigilance and labeling.

9. Conclusion & Recommendations

Based on the available data, a REMS is not necessary for ziftomenib to ensure the benefits outweigh the risks. The safety concerns associated with ziftomenib use are well documented. Additionally, healthcare providers who treat acute leukemias are likely familiar with the risks of differentiation syndrome, QTc interval prolongation, and embryo-fetal toxicity and the importance of patient monitoring.

Should the Division of Hematologic Malignancies I have any concerns or questions or if new safety information becomes available, please send a consult to DRM.

10. Appendix

10.1. References

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