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Genentech Oncology

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-oncology@info.genentech.com

-oncology@mail.genentech.com

-To:

-John Doe <john.doe@example.com>

-Subject Line Option 1:

-Have you seen the data for ALECENSA® (alectinib)?

-Subject Line Option 2:

-See clinical data for ALECENSA® (alectinib)

-Subject Line Option 3:

-Here's pivotal trial data for ALECENSA® (alectinib)

-Subject Line Option 4:

-Read about an option for resectable ALK+ NSCLC

-Subject Line Option 5:

-See data on an option for resectable ALK+ NSCLC

-Subject Line Option 6:

-An option for your patients with resectable ALK+ NSCLC

-Preheader Text Option 1:

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See what this could mean for your patients

-Preheader Text Option 2:

-Learn more about the data

-See what this could mean for your patients

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+THE FIRST AND ONLY ADJUVANT TREATMENT FOR PATIENTS WITH RESECTABLE ALK+
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+Dear Dr A,
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+For patients with ALK+ NSCLC,
+ALECENSA is available in 2 settings. In addition to its metastatic indication,
+ALECENSA is also the first and only adjuvant treatment for resectable (T ≥4 cm
+or N+) disease. Read about the data and download the ALINA Trial Overview
+below.¹
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+EXTEND DFS POST-RESECTION FOR PATIENTS WITH ALK+ NSCLC1
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+ALECENSA delivered superior DFS vs chemotherapy¹
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 +In the ITT population (stage IB-IIIa NSCLC), median DFS
 +was not reached for ALECENSA (95% CI: NE, NE) vs
 +41.3 months (95% CI: 28.5, NE) for chemotherapy
 +(HR=0.24 [95% CI: 0.13, 0.43]; P<0.0001)¹
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 Median survival follow-up: 27.8 months for
 ALECENSA; 28.4 months for chemotherapy²
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 Established safety profile¹
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 -The most common ARs (≥20% for all NCI CTCAE
 -Grades) in patients treated with ALECENSA were
 -hepatotoxicity (61%), constipation (42%), myalgia
 -(34%), COVID-19 (29%), fatigue (25%), rash
 -(23%), and cough (20%)
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 +The most common ARs (≥20% for all NCI CTCAE Grades) in
 +patients treated with ALECENSA were hepatotoxicity (61%), constipation
 +(42%), myalgia (34%), COVID-19 (29%), fatigue (25%), rash (23%), and
 +cough (20%)
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 ARs were generally mild to moderate
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 -Serious adverse reactions occurred in 13% of
 -patients treated with ALECENSA
 -aBased on UICC/AJCC Staging System, 7th edition.¹
 -The efficacy and safety of ALECENSA were established in the global,
 -open-label, Phase 3 ALINA trial. Patients with completely resected
 -stage IB (≥4 cm) to IIIa ALK+ NSCLC were randomized to receive
 -ALECENSA 600 mg orally twice daily (n=130) or 4 cycles of platinum-
 -based chemotherapy (n=127). Staging was based on UICC/AJCC 7th
 -edition. Randomization was stratified by race (Asian and other races)
 -and stage of disease (IB, II, and IIIa). Stratification factors were applied
 -to hazard ratio and P-value analysis (stratified by race in stage II-IIIa,
 -stratified by race and stage in stage IB-IIIa). Treatment in the

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+ALECENSA
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+Based on UICC/AJCC
+Staging System, 7th edition.¹
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+The efficacy
+and safety of ALECENSA were established in the global, open-label, Phase 3
+ALINA trial. Patients with completely resected stage IB (≥ 4 cm) to IIIA ALK+
+NSCLC were randomized to receive ALECENSA 600 mg orally twice daily (n=130) or
+4 cycles of platinum-based chemotherapy (n=127). Staging was based on

+UICC/AJCC 7th edition. Randomization was stratified by race (Asian and other
+races) and stage of disease (IB, II, and IIIA). Stratification factors were
+applied to hazard ratio and P-value analysis (stratified by race in
+stage II-IIIA, stratified by race and stage in stage IB-IIIA). Treatment in
+the ALECENSA arm continued for 2 years or until disease recurrence or death
+due to any cause. Treatment in the chemotherapy arm continued until completion
+of the fourth cycle. The primary efficacy endpoint was DFS as determined by
+the investigator. Secondary efficacy endpoint was OS and an exploratory
+endpoint was time to CNS recurrence.^{1,2}

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+See

+more data from the trial

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Indications

-ALECENSA is a kinase

-inhibitor indicated for:

- adjuvant treatment in
- adult patients following
- tumor resection of
- anaplastic lymphoma
- kinase (ALK)-positive
- non-small cell lung
- cancer (NSCLC)
- (tumors ≥ 4 cm or node
- positive), as detected
- by an FDA-approved
- test
- treatment of adult
- patients with ALK-
- positive metastatic
- NSCLC as detected by
- an FDA-approved test

-Important Safety
-Information
-Warnings and
-Precautions

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+ALECENSA is a kinase inhibitor indicated

+for:

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+adjuvant treatment in

+adult patients following tumor resection of anaplastic lymphoma kinase

+(ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node

+positive), as detected by an FDA-approved test

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+treatment of adult patients with ALK-positive

+metastatic NSCLC as detected by an FDA-approved test

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+Important Safety Information

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+Warnings and Precautions

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Hepatotoxicity

-• Severe hepatotoxicity,

-including drug-induced

-liver injury, occurred in
-patients treated with
-ALECENSA.
-Hepatotoxicity
-occurred in 41% of
-533 patients treated
-with ALECENSA and
-the incidence of Grade
- ≥ 3 hepatotoxicity was
-8%. In the ALINA
-study, hepatotoxicity
-occurred in 61% of
-patients treated with
-ALECENSA and the
-incidence of Grade ≥ 3
-hepatotoxicity was
-4.7%. The majority
-(72% of 136 patients)
-of elevated
-transaminases
-occurred during the
-first 3 months of
-treatment. Treatment
-discontinuation due to
-hepatotoxicity
-occurred in 3.6% of
-patients who received
-ALECENSA in the
-pooled safety
-population and 1.6% of
-patients treated in the
-ALINA study
-Please see additional
-Important Safety
-Information
-continued below and
-in full Prescribing
-Information.

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[Extra in HTML: Severe](#)

+hepatotoxicity, including drug-induced liver injury, occurred in patients
+treated with ALECENSA. Hepatotoxicity occurred in 41% of 533 patients treated
+with ALECENSA and the incidence of Grade ≥ 3 hepatotoxicity was 8%. In the
+ALINA study, hepatotoxicity occurred in 61% of patients treated with ALECENSA
+and the incidence of Grade ≥ 3 hepatotoxicity was 4.7%. The majority (72% of
+136 patients) of elevated transaminases occurred during the first 3 months of
+treatment. Treatment discontinuation due to hepatotoxicity occurred in 3.6% of
+patients who received ALECENSA in the pooled safety population and 1.6% of
+patients treated in the ALINA study

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+potential causes of ILD/pneumonitis have been identified

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Renal Impairment

- Renal impairment occurred in 12% of 533 patients treated with ALECENSA, including Grade ≥ 3 in 1.7% of patients, of which 0.4% were fatal events
- The median time to Grade ≥ 3 renal impairment was 3.7 months (range 0.5 to 31.8 months). Dosage modifications for renal impairment were required in 2.4% of patients
- Permanently discontinue ALECENSA for Grade 4 renal toxicity. Withhold ALECENSA for Grade 3 renal toxicity until recovery to less than or equal to 1.5 times ULN, then resume at reduced dose

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+12% of 533 patients treated with ALECENSA, including Grade ≥ 3 in 1.7% of patients, of
+which 0.4% were fatal events

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+months (range 0.5 to 31.8 months). Dosage modifications for renal impairment were
+required in 2.4% of patients

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+Permanently discontinue ALECENSA for Grade 4 renal
+toxicity. Withhold ALECENSA for Grade 3 renal toxicity until recovery to less than or
+equal to 1.5 times ULN, then resume at reduced dose

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Bradycardia

- Symptomatic bradycardia occurred in patients treated with ALECENSA.
- Bradycardia occurred in 11% of 533 patients treated with ALECENSA. Twenty percent of 521 patients for whom serial electrocardiograms (ECGs) were available had post-dose heart rates of less than 50 beats per minute (bpm)
- Monitor heart rate and blood pressure regularly. For asymptomatic bradycardia, dose modification is not required. For symptomatic bradycardia that is not life-threatening, withhold ALECENSA until recovery to asymptomatic bradycardia or to a heart rate ≥ 60 bpm and evaluate concomitant medications known to cause bradycardia, as well as anti-hypertensive medications. If bradycardia is attributable to a concomitant medication, resume ALECENSA at a reduced dose upon recovery to asymptomatic bradycardia or to a heart rate of ≥ 60 bpm, with

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+Severe myalgia and creatine
+phosphokinase (CPK) elevation occurred in patients treated with ALECENSA. Myalgia
+(including muscle- and musculoskeletal-related reactions) occurred in 31% of 533
+patients treated with ALECENSA, including Grade ≥ 3 in 0.8% of patients. Dosage
+modifications for myalgia events were required in 2.1% of patients

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+Of the 491 with CPK laboratory data available, elevated
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+CPK occurred in 56% of patients, including 6% Grade ≥ 3 . The median time to Grade ≥ 3
+CPK elevation was 15 days (interquartile range 15-337 days). Dosage modifications for
+elevation of CPK occurred in 5% of patients. In the ALINA study, elevated CPK occurred
+in 77% of 128 patients with CPK laboratory data, including 6% Grade ≥ 3 elevations

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+Advise patients to report any unexplained muscle pain,
+tenderness, or weakness. Assess CPK levels every 2 weeks for the first month of
+treatment and as clinically indicated in patients reporting symptoms. Based on the
+severity of the CPK elevation, withhold ALECENSA, then resume or reduce dose

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Hemolytic Anemia

-• Hemolytic anemia occurred in patients treated with ALECENSA. Hemolytic
-anemia was initially reported with ALECENSA in the postmarketing setting,
-including cases associated with a negative direct antiglobulin test (DAT) result.
-Assessments for the determination of hemolytic anemia were subsequently
-collected in the ALINA study, where hemolytic anemia was observed in 3.1% of
-patients treated with ALECENSA
-• If hemolytic anemia is suspected, withhold ALECENSA and initiate appropriate
-laboratory testing. If hemolytic anemia is confirmed, consider resuming at a
-reduced dose upon resolution or permanently discontinue ALECENSA

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+antiglobulin test (DAT) result. Assessments for the determination of hemolytic anemia
+were subsequently collected in the ALINA study, where hemolytic anemia was observed in
+3.1% of patients treated with ALECENSA

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+If hemolytic anemia is suspected, withhold ALECENSA and

+initiate appropriate laboratory testing. If hemolytic anemia is confirmed, consider
+resuming at a reduced dose upon resolution or permanently discontinue ALECENSA

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Embryo-Fetal Toxicity

- ALECENSA can cause fetal harm when administered to pregnant women.
- Administration of alectinib to pregnant rats and rabbits during the period of organogenesis resulted in embryo-fetal toxicity and abortion at maternally toxic doses with exposures approximately 2.7-fold those observed in humans with alectinib 600 mg twice daily. Advise pregnant women of the potential risk to a fetus
- Advise females of reproductive potential to use effective contraception during treatment with ALECENSA and for 5 weeks following the last dose
- Advise males with female partners of reproductive potential to use effective contraception during treatment with ALECENSA and for 3 months following the

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+ALECENSA can cause fetal harm

+when administered to pregnant women. Administration of alectinib to pregnant rats and rabbits during the period of organogenesis resulted in embryo-fetal toxicity and abortion at maternally toxic doses with exposures approximately 2.7-fold those observed in humans with alectinib 600 mg twice daily. Advise pregnant women of the potential risk to a fetus

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+Advise females of reproductive potential to use effective contraception during treatment with ALECENSA and for 5 weeks following the last dose

-Most Common Adverse Reactions

- The most common adverse reactions ($\geq 20\%$) were hepatotoxicity (41%), constipation (39%), fatigue (36%), myalgia (31%), edema (29%), rash (23%), and cough (21%)

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+Advise males with female partners of reproductive potential to use effective contraception during treatment with ALECENSA and for 3 months following the last dose

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+Most

+Common Adverse Reactions

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+The most common adverse
+reactions (≥20%) were hepatotoxicity (41%), constipation (39%), fatigue (36%), myalgia
+(31%), edema (29%), rash (23%), and cough (21%)

Use in Specific Populations

Lactation

- Because of the potential for serious adverse reactions in breastfed infants from -ALECENSA, advise a lactating woman not to breastfeed during treatment with -ALECENSA and for 1 week after the last dose
- You may report side effects to the FDA at 1-800-FDA-1088 or -www.fda.gov/medwatch. You may also report side effects to Genentech at -1-888-835-2555.
- Please see additional Important Safety Information in full
- Prescribing Information.

-AJCC=American Joint Committee on Cancer; ALK=anaplastic lymphoma kinase; AR=adverse reaction;
-CI=confidence interval; CNS=central nervous system; DFS=disease-free survival; HR=hazard ratio; ITT=intent-
to-treat; N+=node positive; NE=not estimable; NCI CTCAE=National Cancer Institute Common Terminology
-Criteria for Adverse Events; NSCLC=non-small cell lung cancer; OS=overall survival; T=tumor size;
-UICC=Union for International Cancer Control.

- +Because of the potential for
- +serious adverse reactions in breastfed infants from ALECENSA, advise a lactating woman
- +not to breastfeed during treatment with ALECENSA and for 1 week after the last dose

+You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also
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+AJCC=American Joint
+Committee on Cancer; ALK=anaplastic lymphoma kinase; AR=adverse reaction; CI=confidence
+interval; CNS=central nervous system; DFS=disease-free survival; HR=hazard ratio;
+ITT=intent-to-treat; N+=node positive; NE=not estimable; NCI CTCAE=National Cancer Institute
+Common Terminology Criteria for Adverse Events; NSCLC=non-small cell lung cancer; OS=overall
+survival; T=tumor size; UICC=Union for International Cancer Control.

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References

- 1. ALECENSA [prescribing information]. South San Francisco, CA: Genentech
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- 2. Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib in resected ALK-positive non-
-small-cell lung cancer. N Engl J Med. 2024;390(14):1265-1276.

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doi:10.1056/NEJMoa2310532.

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-conditions

-See what this could mean for your patients

-View in browser

-Prescribing Information

-Important Safety Information

-THE FIRST AND ONLY ADJUVANT

-TREATMENT FOR PATIENTS WITH

-RESECTABLE ALK+ NSCLC¹

-Dear Dr {{Last Name}},

-For patients with ALK+ NSCLC, ALECENSA is

-available in 2 settings. In addition to its metastatic

-indication, ALECENSA is also the first and only

-adjuvant treatment for resectable (T ≥4 cm or N+)

-disease. Read about the data and download the

-ALINA Trial Overview below.¹

-EXTEND DFS POST-RESECTION

-FOR PATIENTS WITH ALK+ NSCLC¹

-ALECENSA delivered superior DFS

-vs chemotherapy¹

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-In the ITT population (stage IB-IIIa NSCLC),

-median DFS was not reached for ALECENSA

-(95% CI: NE, NE) vs 41.3 months (95% CI: 28.5,

-NE) for chemotherapy (HR=0.24 [95% CI: 0.13,

-0.43]; P<0.0001)¹

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-Median survival follow-up: 27.8 months for

-ALECENSA; 28.4 months for chemotherapy²

-Established safety profile¹

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-The most common ARs (≥20% for all NCI CTCAE

-Grades) in patients treated with ALECENSA were

-hepatotoxicity (61%), constipation (42%), myalgia

-(34%), COVID-19 (29%), fatigue (25%), rash

-(23%), and cough (20%)

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-ARs were generally mild to moderate

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-Serious adverse reactions occurred in 13% of

-patients treated with ALECENSA

-aBased on UICC/AJCC Staging System, 7th edition.¹

-The efficacy and safety of ALECENSA were established in the global,

-open-label, Phase 3 ALINA trial. Patients with completely resected stage

-IB (≥4 cm) to IIIa ALK+ NSCLC were randomized to receive ALECENSA

-600 mg orally twice daily (n=130) or 4 cycles of platinum-based

-chemotherapy (n=127). Staging was based on UICC/AJCC 7th edition.

-Randomization was stratified by race (Asian and other races) and stage

-of disease (IB, II, and IIIa). Stratification factors were applied to hazard

-ratio and P-value analysis (stratified by race in stage II-IIIa, stratified by

-race and stage in stage IB-IIIa). Treatment in the ALECENSA arm

-continued for 2 years or until disease recurrence or death due to any

-cause. Treatment in the chemotherapy arm continued until completion
-of the fourth cycle. The primary efficacy endpoint was DFS as
-determined by the investigator. Secondary efficacy endpoint was OS
-and an exploratory endpoint was time to CNS recurrence.^{1,2}

-See more data from the trial

-Contact a representative

-Indications

-ALECENSA is a kinase inhibitor indicated for:

- adjuvant treatment in adult patients following
-tumor resection of anaplastic lymphoma kinase

- (ALK)-positive non-small cell lung cancer

- (NSCLC) (tumors ≥ 4 cm or node positive), as

- detected by an FDA-approved test

- treatment of adult patients with ALK-positive

- metastatic NSCLC as detected by an FDA-

- approved test

-Important Safety Information

-Warnings and Precautions

-Hepatotoxicity

- Severe hepatotoxicity, including drug-induced

- liver injury, occurred in patients treated with

- ALECENSA. Hepatotoxicity occurred in 41% of

- 533 patients treated with ALECENSA and the

- incidence of Grade ≥ 3 hepatotoxicity was 8%. In

- the ALINA study, hepatotoxicity occurred in 61%

- of patients treated with ALECENSA and the

- incidence of Grade ≥ 3 hepatotoxicity was 4.7%.

- The majority (72% of 136 patients) of elevated

- transaminases occurred during the first 3 months

- of treatment. Treatment discontinuation due to

- hepatotoxicity occurred in 3.6% of patients who

- received ALECENSA in the pooled safety

- population and 1.6% of patients treated in the

- ALINA study

- Concurrent elevations in alanine transaminase

- (ALT) or aspartate transaminase (AST) greater

- than or equal to 3 times the ULN and total

- bilirubin greater than or equal to 2 times the

- ULN, with normal alkaline phosphatase,

- occurred in less than 1% of patients treated with

- ALECENSA. Three patients with Grades 3-4

- AST/ALT elevations had drug-induced liver injury

- (documented by liver biopsy in 2 cases)

- Monitor liver function tests including ALT, AST,

- and total bilirubin every 2 weeks during the first 3

- months of treatment, then once a month and as

- clinically indicated, with more frequent testing in

- patients who develop transaminase and bilirubin

- elevations. Based on the severity of the adverse

- drug reaction, withhold ALECENSA and resume

- at a reduced dose, or permanently discontinue

- ALECENSA

-Interstitial Lung Disease (ILD)/Pneumonitis

- ILD/pneumonitis occurred in 1.3% of 533

- patients treated with ALECENSA with 0.4% of

- patients experiencing Grade 3 ILD/pneumonitis.

- Five patients (0.9%) discontinued ALECENSA

- due to ILD/pneumonitis. The median time-to-

- onset of Grade 3 or higher ILD/pneumonitis was

- 2.1 months (range: 0.6 months to 3.6 months)

- Promptly investigate for ILD/pneumonitis in any

- patient who presents with worsening of
- respiratory symptoms indicative of
- ILD/pneumonitis (eg, dyspnea, cough, and fever)
- Immediately withhold ALECENSA treatment in
- patients diagnosed with ILD/pneumonitis and
- permanently discontinue ALECENSA if no other
- potential causes of ILD/pneumonitis have been
- identified
- Renal Impairment
- Renal impairment occurred in 12% of 533
- patients treated with ALECENSA, including
- Grade ≥ 3 in 1.7% of patients, of which 0.4%
- were fatal events
- The median time to Grade ≥ 3 renal impairment
- was 3.7 months (range 0.5 to 31.8 months).
- Dosage modifications for renal impairment were
- required in 2.4% of patients
- Permanently discontinue ALECENSA for Grade
- 4 renal toxicity. Withhold ALECENSA for Grade 3
- renal toxicity until recovery to less than or equal
- to 1.5 times ULN, then resume at reduced dose
- Bradycardia
- Symptomatic bradycardia occurred in patients
- treated with ALECENSA. Bradycardia occurred
- in 11% of 533 patients treated with ALECENSA.
- Twenty percent of 521 patients for whom serial
- electrocardiograms (ECGs) were available had
- post-dose heart rates of less than 50 beats per
- minute (bpm)
- Monitor heart rate and blood pressure regularly.
- For asymptomatic bradycardia, dose
- modification is not required. For symptomatic
- bradycardia that is not life-threatening, withhold
- ALECENSA until recovery to asymptomatic
- bradycardia or to a heart rate ≥ 60 bpm and
- evaluate concomitant medications known to
- cause bradycardia, as well as anti-hypertensive
- medications. If bradycardia is attributable to a
- concomitant medication, resume ALECENSA at
- a reduced dose upon recovery to asymptomatic
- bradycardia or to a heart rate of ≥ 60 bpm, with
- frequent monitoring as clinically indicated
- Permanently discontinue ALECENSA in cases of
- life-threatening bradycardia if no contributing
- concomitant medication is identified or for
- recurrence of life-threatening bradycardia
- Severe Myalgia and Creatine Phosphokinase
- (CPK) Elevation
- Severe myalgia and creatine phosphokinase
- (CPK) elevation occurred in patients treated with
- ALECENSA. Myalgia (including muscle- and
- musculoskeletal-related reactions) occurred in
- 31% of 533 patients treated with ALECENSA,
- including Grade ≥ 3 in 0.8% of patients. Dosage
- modifications for myalgia events were required in
- 2.1% of patients
- Of the 491 with CPK laboratory data available,
- elevated CPK occurred in 56% of patients,
- including 6% Grade ≥ 3 . The median time to
- Grade ≥ 3 CPK elevation was 15 days
- (interquartile range 15-337 days). Dosage

- modifications for elevation of CPK occurred in
- 5% of patients. In the ALINA study, elevated CPK
- occurred in 77% of 128 patients with CPK
- laboratory data, including 6% Grade ≥ 3
- elevations
- Advise patients to report any unexplained
- muscle pain, tenderness, or weakness. Assess
- CPK levels every 2 weeks for the first month of
- treatment and as clinically indicated in patients
- reporting symptoms. Based on the severity of the
- CPK elevation, withhold ALECENSA, then
- resume or reduce dose
- Hemolytic Anemia
- Hemolytic anemia occurred in patients treated
- with ALECENSA. Hemolytic anemia was initially
- reported with ALECENSA in the postmarketing
- setting, including cases associated with a
- negative direct antiglobulin test (DAT) result.
- Assessments for the determination of hemolytic
- anemia were subsequently collected in the
- ALINA study, where hemolytic anemia was
- observed in 3.1% of patients treated with
- ALECENSA
- If hemolytic anemia is suspected, withhold
- ALECENSA and initiate appropriate laboratory
- testing. If hemolytic anemia is confirmed,
- consider resuming at a reduced dose upon
- resolution or permanently discontinue
- ALECENSA
- Embryo-Fetal Toxicity
- ALECENSA can cause fetal harm when
- administered to pregnant women. Administration
- of alectinib to pregnant rats and rabbits during
- the period of organogenesis resulted in embryo-
- fetal toxicity and abortion at maternally toxic
- doses with exposures approximately 2.7-fold
- those observed in humans with alectinib 600 mg
- twice daily. Advise pregnant women of the
- potential risk to a fetus
- Advise females of reproductive potential to use
- effective contraception during treatment with
- ALECENSA and for 5 weeks following the last
- dose
- Advise males with female partners of
- reproductive potential to use effective
- contraception during treatment with ALECENSA
- and for 3 months following the last dose
- Most Common Adverse Reactions
- The most common adverse reactions ($\geq 20\%$)
- were hepatotoxicity (41%), constipation (39%),
- fatigue (36%), myalgia (31%), edema (29%),
- rash (23%), and cough (21%)
- Use in Specific Populations
- Lactation
- Because of the potential for serious adverse
- reactions in breastfed infants from ALECENSA,
- advise a lactating woman not to breastfeed
- during treatment with ALECENSA and for 1 week
- after the last dose
- You may report side effects to the FDA at
- 1-800-FDA-1088 or www.fda.gov/medwatch. You

-may also report side effects to Genentech at
-1-888-835-2555.
-Please see additional Important Safety
-Information in full Prescribing Information.
-AJCC=American Joint Committee on Cancer; ALK=anaplastic
-lymphoma kinase; AR=adverse reaction; CI=confidence interval;
-CNS=central nervous system; DFS=disease-free survival;
-HR=hazard ratio; ITT=intent-to-treat; N+=node positive; NE=not
-estimable; NCI CTCAE=National Cancer Institute Common
-Terminology Criteria for Adverse Events; NSCLC=non-small cell
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-References
-1. ALECENSA [prescribing information]. South San
-Francisco, CA: Genentech USA, Inc. 2024.
-2. Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib
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-Prescribing Information
-Important Safety Information
-THE FIRST AND ONLY ADJUVANT TREATMENT
-FOR PATIENTS WITH RESECTABLE ALK+ NSCLC1
-Dear Dr {{Last Name}},
-For patients with ALK+ NSCLC, ALECENSA is
-available in 2 settings. In addition to its metastatic
-indication, ALECENSA is also the first and only
-adjuvant treatment for resectable (T ≥4 cm or N+)
-disease. Read about the data and download the
-ALINA Trial Overview below.1
-EXTEND DFS POST-RESECTION
-FOR PATIENTS WITH ALK+ NSCLC1
-ALECENSA delivered superior DFS
-vs chemotherapy1
-Median DFS not reached with ALECENSA
-•
-In the ITT population (stage IB-IIIa NSCLC),
-median DFS was not reached for ALECENSA
- (95% CI: NE, NE) vs 41.3 months (95% CI: 28.5,
-NE) for chemotherapy (HR=0.24 [95% CI: 0.13,
-0.43]; P<0.0001)1
-•
-Median survival follow-up: 27.8 months for
-ALECENSA; 28.4 months for chemotherapy2

-Established safety profile¹

•

-The most common ARs ($\geq 20\%$ for all NCI CTCAE

-Grades) in patients treated with ALECENSA were

-hepatotoxicity (61%), constipation (42%), myalgia

-(34%), COVID-19 (29%), fatigue (25%), rash

-(23%), and cough (20%)

—

-ARs were generally mild to moderate

•

-Serious adverse reactions occurred in 13% of

-patients treated with ALECENSA

-aBased on UICC/AJCC Staging System, 7th edition.¹

-The efficacy and safety of ALECENSA were established in the global,

-open-label, Phase 3 ALINA trial. Patients with completely resected

-stage IB (≥ 4 cm) to IIIA ALK+ NSCLC were randomized to receive

-ALECENSA 600 mg orally twice daily (n=130) or 4 cycles of platinum-

-based chemotherapy (n=127). Staging was based on UICC/AJCC 7th

-edition. Randomization was stratified by race (Asian and other races)

-and stage of disease (IB, II, and IIIA). Stratification factors were applied

-to hazard ratio and P-value analysis (stratified by race in stage II-IIIA,

-stratified by race and stage in stage IB-IIIA). Treatment in the

-ALECENSA arm continued for 2 years or until disease recurrence or

-death due to any cause. Treatment in the chemotherapy arm continued

-until completion of the fourth cycle. The primary efficacy endpoint was

-DFS as determined by the investigator. Secondary efficacy endpoint

-was OS and an exploratory endpoint was time to CNS recurrence.^{1,2}

-See more data from the trial

-Contact a representative

-Indications

-ALECENSA is a kinase

-inhibitor indicated for:

• adjuvant treatment in

-adult patients following

-tumor resection of

-anaplastic lymphoma

-kinase (ALK)-positive

-non-small cell lung

-cancer (NSCLC)

-(tumors ≥ 4 cm or node

-positive), as detected

-by an FDA-approved

-test

• treatment of adult

-patients with ALK-

-positive metastatic

-NSCLC as detected by

-an FDA-approved test

-Important Safety

-Information

-Warnings and

-Precautions

-Hepatotoxicity

• Severe hepatotoxicity,

-including drug-induced

-liver injury, occurred in

-patients treated with

-ALECENSA.

-Hepatotoxicity

-occurred in 41% of

-533 patients treated

-with ALECENSA and
-the incidence of Grade
- ≥ 3 hepatotoxicity was
-8%. In the ALINA
-study, hepatotoxicity
-occurred in 61% of
-patients treated with
-ALECENSA and the
-incidence of Grade ≥ 3
-hepatotoxicity was
-4.7%. The majority
- (72% of 136 patients)
-of elevated
-transaminases
-occurred during the
-first 3 months of
-treatment. Treatment
-discontinuation due to
-hepatotoxicity
-occurred in 3.6% of
-patients who received
-ALECENSA in the
-pooled safety
-population and 1.6% of
-patients treated in the
-ALINA study
-Please see additional
-Important Safety
-Information
-continued below and
-in full Prescribing
-Information.

-Important Safety Information (cont'd)

-Warnings and Precautions (cont'd)

-Hepatotoxicity (cont'd)

- Concurrent elevations in alanine transaminase (ALT) or aspartate transaminase (AST) greater than or equal to 3 times the ULN and total bilirubin greater than or equal to 2 times the ULN, with normal alkaline phosphatase, occurred in less than 1% of patients treated with ALECENSA. Three patients with Grades 3-4 AST/ALT elevations had drug-induced liver injury (documented by liver biopsy in 2 cases)

- Monitor liver function tests including ALT, AST, and total bilirubin every 2 weeks during the first 3 months of treatment, then once a month and as clinically indicated, with more frequent testing in patients who develop transaminase and bilirubin elevations. Based on the severity of the adverse drug reaction, withhold ALECENSA and resume at a reduced dose, or permanently discontinue ALECENSA

-Interstitial Lung Disease (ILD)/Pneumonitis

- ILD/pneumonitis occurred in 1.3% of 533 patients treated with ALECENSA with 0.4% of patients experiencing Grade 3 ILD/pneumonitis. Five patients (0.9%) discontinued ALECENSA due to ILD/pneumonitis. The median time-to-onset of Grade 3 or higher ILD/pneumonitis was 2.1 months (range: 0.6 months to 3.6 months)

- Promptly investigate for ILD/pneumonitis in any patient who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, and fever)

- Immediately withhold ALECENSA treatment in patients diagnosed with ILD/pneumonitis and permanently discontinue ALECENSA if no other potential causes of ILD/pneumonitis have been identified

-Renal Impairment

- Renal impairment occurred in 12% of 533 patients treated with ALECENSA,

- including Grade ≥ 3 in 1.7% of patients, of which 0.4% were fatal events
- The median time to Grade ≥ 3 renal impairment was 3.7 months (range 0.5 to -31.8 months). Dosage modifications for renal impairment were required in 2.4% -of patients
- Permanently discontinue ALECENSA for Grade 4 renal toxicity. Withhold -ALECENSA for Grade 3 renal toxicity until recovery to less than or equal to 1.5 -times ULN, then resume at reduced dose
- Bradycardia
- Symptomatic bradycardia occurred in patients treated with ALECENSA.
- Bradycardia occurred in 11% of 533 patients treated with ALECENSA. Twenty -percent of 521 patients for whom serial electrocardiograms (ECGs) were -available had post-dose heart rates of less than 50 beats per minute (bpm)
- Monitor heart rate and blood pressure regularly. For asymptomatic bradycardia, -dose modification is not required. For symptomatic bradycardia that is not life- -threatening, withhold ALECENSA until recovery to asymptomatic bradycardia or -to a heart rate ≥ 60 bpm and evaluate concomitant medications known to cause -bradycardia, as well as anti-hypertensive medications. If bradycardia is -attributable to a concomitant medication, resume ALECENSA at a reduced dose -upon recovery to asymptomatic bradycardia or to a heart rate of ≥ 60 bpm, with -frequent monitoring as clinically indicated
- Permanently discontinue ALECENSA in cases of life-threatening bradycardia if -no contributing concomitant medication is identified or for recurrence of life- -threatening bradycardia
- Severe Myalgia and Creatine Phosphokinase (CPK) Elevation
- Severe myalgia and creatine phosphokinase (CPK) elevation occurred in -patients treated with ALECENSA. Myalgia (including muscle- and -musculoskeletal-related reactions) occurred in 31% of 533 patients treated with -ALECENSA, including Grade ≥ 3 in 0.8% of patients. Dosage modifications for -myalgia events were required in 2.1% of patients
- Of the 491 with CPK laboratory data available, elevated CPK occurred in 56% of -patients, including 6% Grade ≥ 3 . The median time to Grade ≥ 3 CPK elevation -was 15 days (interquartile range 15-337 days). Dosage modifications for -elevation of CPK occurred in 5% of patients. In the ALINA study, elevated CPK -occurred in 77% of 128 patients with CPK laboratory data, including 6% Grade ≥ 3 elevations
- Advise patients to report any unexplained muscle pain, tenderness, or -weakness. Assess CPK levels every 2 weeks for the first month of treatment and -as clinically indicated in patients reporting symptoms. Based on the severity of -the CPK elevation, withhold ALECENSA, then resume or reduce dose
- Hemolytic Anemia
- Hemolytic anemia occurred in patients treated with ALECENSA. Hemolytic -anemia was initially reported with ALECENSA in the postmarketing setting, -including cases associated with a negative direct antiglobulin test (DAT) result. -Assessments for the determination of hemolytic anemia were subsequently -collected in the ALINA study, where hemolytic anemia was observed in 3.1% of -patients treated with ALECENSA
- If hemolytic anemia is suspected, withhold ALECENSA and initiate appropriate -laboratory testing. If hemolytic anemia is confirmed, consider resuming at a -reduced dose upon resolution or permanently discontinue ALECENSA
- Embryo-Fetal Toxicity
- ALECENSA can cause fetal harm when administered to pregnant women.
- Administration of alectinib to pregnant rats and rabbits during the period of -organogenesis resulted in embryo-fetal toxicity and abortion at maternally toxic -doses with exposures approximately 2.7-fold those observed in humans with -alectinib 600 mg twice daily. Advise pregnant women of the potential risk to a -fetus
- Advise females of reproductive potential to use effective contraception during -treatment with ALECENSA and for 5 weeks following the last dose
- Advise males with female partners of reproductive potential to use effective -contraception during treatment with ALECENSA and for 3 months following the -last dose

-Most Common Adverse Reactions

- The most common adverse reactions ($\geq 20\%$) were hepatotoxicity (41%), constipation (39%), fatigue (36%), myalgia (31%), edema (29%), rash (23%), and cough (21%)

-Use in Specific Populations

-Lactation

- Because of the potential for serious adverse reactions in breastfed infants from ALECENSA, advise a lactating woman not to breastfeed during treatment with ALECENSA and for 1 week after the last dose
- You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

-Please see additional Important Safety Information in full

-Prescribing Information.

- AJCC=American Joint Committee on Cancer; ALK=anaplastic lymphoma kinase; AR=adverse reaction; CI=confidence interval; CNS=central nervous system; DFS=disease-free survival; HR=hazard ratio; ITT=intent-to-treat; N+=node positive; NE=not estimable; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; NSCLC=non-small cell lung cancer; OS=overall survival; T=tumor size; UICC=Union for International Cancer Control.

-References

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2. Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib in resected ALK-positive non-small-cell lung cancer. *N Engl J Med*. 2024;390(14):1265-1276. doi:10.1056/NEJMoa2310532.

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-THE FIRST AND ONLY ADJUVANT

-TREATMENT FOR PATIENTS WITH

-RESECTABLE ALK+ NSCLC1

-Dear Dr {{Last Name}},

-For patients with ALK+ NSCLC, ALECENSA is available in 2 settings. In addition to its metastatic indication, ALECENSA is also the first and only adjuvant treatment for resectable (T ≥ 4 cm or N+) disease. Read about the data and download the ALINA Trial Overview below.1

-EXTEND DFS POST-RESECTION

-FOR PATIENTS WITH ALK+ NSCLC1

-ALECENSA delivered superior DFS

-vs chemotherapy1

-Median DFS not reached with ALECENSA

•

-In the ITT population (stage IB-IIIa NSCLC), median DFS was not reached for ALECENSA (95% CI: NE, NE) vs 41.3 months (95% CI: 28.5, NE) for chemotherapy (HR=0.24 [95% CI: 0.13, 0.43]; $P < 0.0001$)1

•

-Median survival follow-up: 27.8 months for

-ALECENSA; 28.4 months for chemotherapy2

-Established safety profile¹

•

-The most common ARs ($\geq 20\%$ for all NCI CTCAE

-Grades) in patients treated with ALECENSA were

-hepatotoxicity (61%), constipation (42%), myalgia

-(34%), COVID-19 (29%), fatigue (25%), rash

-(23%), and cough (20%)

—

-ARs were generally mild to moderate

•

-Serious adverse reactions occurred in 13% of

-patients treated with ALECENSA

-aBased on UICC/AJCC Staging System, 7th edition.¹

-The efficacy and safety of ALECENSA were established in the global,

-open-label, Phase 3 ALINA trial. Patients with completely resected stage

-IB (≥ 4 cm) to IIIA ALK+ NSCLC were randomized to receive ALECENSA

-600 mg orally twice daily (n=130) or 4 cycles of platinum-based

-chemotherapy (n=127). Staging was based on UICC/AJCC 7th edition.

-Randomization was stratified by race (Asian and other races) and stage

-of disease (IB, II, and IIIA). Stratification factors were applied to hazard

-ratio and P-value analysis (stratified by race in stage II-IIIA, stratified by

-race and stage in stage IB-IIIA). Treatment in the ALECENSA arm

-continued for 2 years or until disease recurrence or death due to any

-cause. Treatment in the chemotherapy arm continued until completion

-of the fourth cycle. The primary efficacy endpoint was DFS as

-determined by the investigator. Secondary efficacy endpoint was OS

-and an exploratory endpoint was time to CNS recurrence.^{1,2}

-See more data from the trial

-Contact a representative

-Indications

-ALECENSA is a kinase inhibitor indicated for:

• adjuvant treatment in adult patients following

-tumor resection of anaplastic lymphoma kinase

-(ALK)-positive non-small cell lung cancer

-(NSCLC) (tumors ≥ 4 cm or node positive), as

-detected by an FDA-approved test

• treatment of adult patients with ALK-positive

-metastatic NSCLC as detected by an FDA-

-approved test

-Important Safety Information

-Warnings and Precautions

-Hepatotoxicity

• Severe hepatotoxicity, including drug-induced

-liver injury, occurred in patients treated with

-ALECENSA. Hepatotoxicity occurred in 41% of

-533 patients treated with ALECENSA and the

-incidence of Grade ≥ 3 hepatotoxicity was 8%. In

-the ALINA study, hepatotoxicity occurred in 61%

-of patients treated with ALECENSA and the

-incidence of Grade ≥ 3 hepatotoxicity was 4.7%.

-The majority (72% of 136 patients) of elevated

-transaminases occurred during the first 3 months

-of treatment. Treatment discontinuation due to

-hepatotoxicity occurred in 3.6% of patients who

-received ALECENSA in the pooled safety

-population and 1.6% of patients treated in the

-ALINA study

• Concurrent elevations in alanine transaminase

-(ALT) or aspartate transaminase (AST) greater

-than or equal to 3 times the ULN and total

-bilirubin greater than or equal to 2 times the

- ULN, with normal alkaline phosphatase,
- occurred in less than 1% of patients treated with
- ALECENSA. Three patients with Grades 3-4
- AST/ALT elevations had drug-induced liver injury
- (documented by liver biopsy in 2 cases)
- Monitor liver function tests including ALT, AST,
- and total bilirubin every 2 weeks during the first 3
- months of treatment, then once a month and as
- clinically indicated, with more frequent testing in
- patients who develop transaminase and bilirubin
- elevations. Based on the severity of the adverse
- drug reaction, withhold ALECENSA and resume
- at a reduced dose, or permanently discontinue
- ALECENSA

-Interstitial Lung Disease (ILD)/Pneumonitis

- ILD/pneumonitis occurred in 1.3% of 533
- patients treated with ALECENSA with 0.4% of
- patients experiencing Grade 3 ILD/pneumonitis.
- Five patients (0.9%) discontinued ALECENSA
- due to ILD/pneumonitis. The median time-to-
- onset of Grade 3 or higher ILD/pneumonitis was
- 2.1 months (range: 0.6 months to 3.6 months)
- Promptly investigate for ILD/pneumonitis in any
- patient who presents with worsening of
- respiratory symptoms indicative of
- ILD/pneumonitis (eg, dyspnea, cough, and fever)
- Immediately withhold ALECENSA treatment in
- patients diagnosed with ILD/pneumonitis and
- permanently discontinue ALECENSA if no other
- potential causes of ILD/pneumonitis have been
- identified

-Renal Impairment

- Renal impairment occurred in 12% of 533
- patients treated with ALECENSA, including
- Grade ≥ 3 in 1.7% of patients, of which 0.4%
- were fatal events
- The median time to Grade ≥ 3 renal impairment
- was 3.7 months (range 0.5 to 31.8 months).
- Dosage modifications for renal impairment were
- required in 2.4% of patients
- Permanently discontinue ALECENSA for Grade
- 4 renal toxicity. Withhold ALECENSA for Grade 3
- renal toxicity until recovery to less than or equal
- to 1.5 times ULN, then resume at reduced dose

-Bradycardia

- Symptomatic bradycardia occurred in patients
- treated with ALECENSA. Bradycardia occurred
- in 11% of 533 patients treated with ALECENSA.
- Twenty percent of 521 patients for whom serial
- electrocardiograms (ECGs) were available had
- post-dose heart rates of less than 50 beats per
- minute (bpm)
- Monitor heart rate and blood pressure regularly.
- For asymptomatic bradycardia, dose
- modification is not required. For symptomatic
- bradycardia that is not life-threatening, withhold
- ALECENSA until recovery to asymptomatic
- bradycardia or to a heart rate ≥ 60 bpm and
- evaluate concomitant medications known to
- cause bradycardia, as well as anti-hypertensive
- medications. If bradycardia is attributable to a

- concomitant medication, resume ALECENSA at
- a reduced dose upon recovery to asymptomatic
- bradycardia or to a heart rate of ≥ 60 bpm, with
- frequent monitoring as clinically indicated
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- Embryo-Fetal Toxicity
- ALECENSA can cause fetal harm when
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- of alectinib to pregnant rats and rabbits during
- the period of organogenesis resulted in embryo-
- fetal toxicity and abortion at maternally toxic
- doses with exposures approximately 2.7-fold
- those observed in humans with alectinib 600 mg
- twice daily. Advise pregnant women of the

-potential risk to a fetus

- Advise females of reproductive potential to use effective contraception during treatment with ALECENSA and for 5 weeks following the last dose
- Advise males with female partners of reproductive potential to use effective contraception during treatment with ALECENSA and for 3 months following the last dose

-Most Common Adverse Reactions

- The most common adverse reactions ($\geq 20\%$) were hepatotoxicity (41%), constipation (39%), fatigue (36%), myalgia (31%), edema (29%), rash (23%), and cough (21%)

-Use in Specific Populations

-Lactation

- Because of the potential for serious adverse reactions in breastfed infants from ALECENSA, advise a lactating woman not to breastfeed during treatment with ALECENSA and for 1 week after the last dose

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-View in browser
-Prescribing Information
-Important Safety Information
-THE FIRST AND ONLY ADJUVANT TREATMENT
-FOR PATIENTS WITH RESECTABLE ALK+ NSCLC¹

-Dear Dr {{Last Name}},
-For patients with ALK+ NSCLC, ALECENSA is
-available in 2 settings. In addition to its metastatic
-indication, ALECENSA is also the first and only
-adjuvant treatment for resectable (T ≥4 cm or N+)
-disease. Read about the data and download the
-ALINA Trial Overview below.¹
-EXTEND DFS POST-RESECTION
-FOR PATIENTS WITH ALK+ NSCLC¹
-ALECENSA delivered superior DFS
-vs chemotherapy¹

•
-In the ITT population (stage IB-IIIa NSCLC),
-median DFS was not reached for ALECENSA
-(95% CI: NE, NE) vs 41.3 months (95% CI: 28.5,
-NE) for chemotherapy (HR=0.24 [95% CI: 0.13,
-0.43]; P<0.0001)¹

•
-Median survival follow-up: 27.8 months for
-ALECENSA; 28.4 months for chemotherapy²
-Established safety profile¹

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-The most common ARs (≥20% for all NCI CTCAE
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-hepatotoxicity (61%), constipation (42%), myalgia
-(34%), COVID-19 (29%), fatigue (25%), rash
-(23%), and cough (20%)

—
-ARs were generally mild to moderate

•
-Serious adverse reactions occurred in 13% of
-patients treated with ALECENSA
-aBased on UICC/AJCC Staging System, 7th edition.¹
-The efficacy and safety of ALECENSA were established in the global,
-open-label, Phase 3 ALINA trial. Patients with completely resected
-stage IB (≥4 cm) to IIIa ALK+ NSCLC were randomized to receive
-ALECENSA 600 mg orally twice daily (n=130) or 4 cycles of platinum-
-based chemotherapy (n=127). Staging was based on UICC/AJCC 7th
-edition. Randomization was stratified by race (Asian and other races)
-and stage of disease (IB, II, and IIIa). Stratification factors were applied
-to hazard ratio and P-value analysis (stratified by race in stage II-IIIa,
-stratified by race and stage in stage IB-IIIa). Treatment in the
-ALECENSA arm continued for 2 years or until disease recurrence or
-death due to any cause. Treatment in the chemotherapy arm continued
-until completion of the fourth cycle. The primary efficacy endpoint was
-DFS as determined by the investigator. Secondary efficacy endpoint
-was OS and an exploratory endpoint was time to CNS recurrence.^{1,2}

-See more data from the trial

-Contact a representative

-Indications

-ALECENSA is a kinase

-inhibitor indicated for:

• adjuvant treatment in

-adult patients following

-tumor resection of

- anaplastic lymphoma
- kinase (ALK)-positive
- non-small cell lung
- cancer (NSCLC)
- (tumors ≥ 4 cm or node
- positive), as detected
- by an FDA-approved
- test
- treatment of adult
- patients with ALK-
- positive metastatic
- NSCLC as detected by
- an FDA-approved test
- Important Safety
- Information
- Warnings and
- Precautions
- Hepatotoxicity
- Severe hepatotoxicity,
- including drug-induced
- liver injury, occurred in
- patients treated with
- ALECENSA.
- Hepatotoxicity
- occurred in 41% of
- 533 patients treated
- with ALECENSA and
- the incidence of Grade
- ≥ 3 hepatotoxicity was
- 8%. In the ALINA
- study, hepatotoxicity
- occurred in 61% of
- patients treated with
- ALECENSA and the
- incidence of Grade ≥ 3
- hepatotoxicity was
- 4.7%. The majority
- (72% of 136 patients)
- of elevated
- transaminases
- occurred during the
- first 3 months of
- treatment. Treatment
- discontinuation due to
- hepatotoxicity
- occurred in 3.6% of
- patients who received
- ALECENSA in the
- pooled safety
- population and 1.6% of
- patients treated in the
- ALINA study
- Please see additional
- Important Safety
- Information
- continued below and
- in full Prescribing
- Information.
- Important Safety Information (cont'd)
- Warnings and Precautions (cont'd)
- Hepatotoxicity (cont'd)

- Concurrent elevations in alanine transaminase (ALT) or aspartate transaminase (AST) greater than or equal to 3 times the ULN and total bilirubin greater than or equal to 2 times the ULN, with normal alkaline phosphatase, occurred in less than 1% of patients treated with ALECENSA. Three patients with Grades 3-4 AST/ALT elevations had drug-induced liver injury (documented by liver biopsy in 2 cases)

- Monitor liver function tests including ALT, AST, and total bilirubin every 2 weeks during the first 3 months of treatment, then once a month and as clinically indicated, with more frequent testing in patients who develop transaminase and bilirubin elevations. Based on the severity of the adverse drug reaction, withhold ALECENSA and resume at a reduced dose, or permanently discontinue ALECENSA

-Interstitial Lung Disease (ILD)/Pneumonitis

- ILD/pneumonitis occurred in 1.3% of 533 patients treated with ALECENSA with 0.4% of patients experiencing Grade 3 ILD/pneumonitis. Five patients (0.9%) discontinued ALECENSA due to ILD/pneumonitis. The median time-to-onset of Grade 3 or higher ILD/pneumonitis was 2.1 months (range: 0.6 months to 3.6 months)

- Promptly investigate for ILD/pneumonitis in any patient who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, and fever)

- Immediately withhold ALECENSA treatment in patients diagnosed with ILD/pneumonitis and permanently discontinue ALECENSA if no other potential causes of ILD/pneumonitis have been identified

-Renal Impairment

- Renal impairment occurred in 12% of 533 patients treated with ALECENSA, including Grade ≥ 3 in 1.7% of patients, of which 0.4% were fatal events
- The median time to Grade ≥ 3 renal impairment was 3.7 months (range 0.5 to 31.8 months). Dosage modifications for renal impairment were required in 2.4% of patients

- Permanently discontinue ALECENSA for Grade 4 renal toxicity. Withhold ALECENSA for Grade 3 renal toxicity until recovery to less than or equal to 1.5 times ULN, then resume at reduced dose

-Bradycardia

- Symptomatic bradycardia occurred in patients treated with ALECENSA. Bradycardia occurred in 11% of 533 patients treated with ALECENSA. Twenty percent of 521 patients for whom serial electrocardiograms (ECGs) were available had post-dose heart rates of less than 50 beats per minute (bpm)
- Monitor heart rate and blood pressure regularly. For asymptomatic bradycardia, dose modification is not required. For symptomatic bradycardia that is not life-threatening, withhold ALECENSA until recovery to asymptomatic bradycardia or to a heart rate ≥ 60 bpm and evaluate concomitant medications known to cause bradycardia, as well as anti-hypertensive medications. If bradycardia is attributable to a concomitant medication, resume ALECENSA at a reduced dose upon recovery to asymptomatic bradycardia or to a heart rate of ≥ 60 bpm, with frequent monitoring as clinically indicated

- Permanently discontinue ALECENSA in cases of life-threatening bradycardia if no contributing concomitant medication is identified or for recurrence of life-threatening bradycardia

-Severe Myalgia and Creatine Phosphokinase (CPK) Elevation

- Severe myalgia and creatine phosphokinase (CPK) elevation occurred in patients treated with ALECENSA. Myalgia (including muscle- and musculoskeletal-related reactions) occurred in 31% of 533 patients treated with ALECENSA, including Grade ≥ 3 in 0.8% of patients. Dosage modifications for myalgia events were required in 2.1% of patients

- Of the 491 with CPK laboratory data available, elevated CPK occurred in 56% of patients, including 6% Grade ≥ 3 . The median time to Grade ≥ 3 CPK elevation was 15 days (interquartile range 15-337 days). Dosage modifications for elevation of CPK occurred in 5% of patients. In the ALINA study, elevated CPK occurred in 77% of 128 patients with CPK laboratory data, including 6% Grade ≥ 3 elevations

- Advise patients to report any unexplained muscle pain, tenderness, or weakness. Assess CPK levels every 2 weeks for the first month of treatment and as clinically indicated in patients reporting symptoms. Based on the severity of the CPK elevation, withhold ALECENSA, then resume or reduce dose

-Hemolytic Anemia

- Hemolytic anemia occurred in patients treated with ALECENSA. Hemolytic anemia was initially reported with ALECENSA in the postmarketing setting, including cases associated with a negative direct antiglobulin test (DAT) result. Assessments for the determination of hemolytic anemia were subsequently collected in the ALINA study, where hemolytic anemia was observed in 3.1% of patients treated with ALECENSA
- If hemolytic anemia is suspected, withhold ALECENSA and initiate appropriate laboratory testing. If hemolytic anemia is confirmed, consider resuming at a reduced dose upon resolution or permanently discontinue ALECENSA

-Embryo-Fetal Toxicity

- ALECENSA can cause fetal harm when administered to pregnant women. Administration of alectinib to pregnant rats and rabbits during the period of organogenesis resulted in embryo-fetal toxicity and abortion at maternally toxic doses with exposures approximately 2.7-fold those observed in humans with alectinib 600 mg twice daily. Advise pregnant women of the potential risk to a fetus

- Advise females of reproductive potential to use effective contraception during treatment with ALECENSA and for 5 weeks following the last dose

- Advise males with female partners of reproductive potential to use effective contraception during treatment with ALECENSA and for 3 months following the last dose

-Most Common Adverse Reactions

- The most common adverse reactions ($\geq 20\%$) were hepatotoxicity (41%), constipation (39%), fatigue (36%), myalgia (31%), edema (29%), rash (23%), and cough (21%)

-Use in Specific Populations

-Lactation

- Because of the potential for serious adverse reactions in breastfed infants from ALECENSA, advise a lactating woman not to breastfeed during treatment with ALECENSA and for 1 week after the last dose

-You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

-Please see additional Important Safety Information in full

-Prescribing Information.

-AJCC=American Joint Committee on Cancer; ALK=anaplastic lymphoma kinase; AR=adverse reaction; CI=confidence interval; CNS=central nervous system; DFS=disease-free survival; HR=hazard ratio; ITT=intent-to-treat; N+=node positive; NE=not estimable; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; NSCLC=non-small cell lung cancer; OS=overall survival; T=tumor size; UICC=Union for International Cancer Control.

-References

-1. ALECENSA [prescribing information]. South San Francisco, CA: Genentech USA, Inc. 2024.

-2. Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib in resected ALK-positive non-small-cell lung cancer. *N Engl J Med*. 2024;390(14):1265-1276. doi:10.1056/NEJMoa2310532.

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- Important Safety Information
- THE FIRST AND ONLY ADJUVANT
- TREATMENT FOR PATIENTS WITH
- RESECTABLE ALK+ NSCLC¹
- Dear Dr {{Last Name}},
- For patients with ALK+ NSCLC, ALECENSA is
- available in 2 settings. In addition to its metastatic
- indication, ALECENSA is also the first and only
- adjuvant treatment for resectable (T ≥4 cm or N+)
- disease. Read about the data and download the
- ALINA Trial Overview below.¹
- EXTEND DFS POST-RESECTION
- FOR PATIENTS WITH ALK+ NSCLC¹
- ALECENSA delivered superior DFS
- vs chemotherapy¹
-
- In the ITT population (stage IB-IIIa NSCLC),
- median DFS was not reached for ALECENSA
- (95% CI: NE, NE) vs 41.3 months (95% CI: 28.5,
- NE) for chemotherapy (HR=0.24 [95% CI: 0.13,
- 0.43]; P<0.0001)¹
-
- Median survival follow-up: 27.8 months for
- ALECENSA; 28.4 months for chemotherapy²
- Established safety profile¹
-
- The most common ARs (≥20% for all NCI CTCAE
- Grades) in patients treated with ALECENSA were
- hepatotoxicity (61%), constipation (42%), myalgia
- (34%), COVID-19 (29%), fatigue (25%), rash
- (23%), and cough (20%)
-
- ARs were generally mild to moderate
-
- Serious adverse reactions occurred in 13% of
- patients treated with ALECENSA
- aBased on UICC/AJCC Staging System, 7th edition.¹
- The efficacy and safety of ALECENSA were established in the global,
- open-label, Phase 3 ALINA trial. Patients with completely resected stage
- IB (≥4 cm) to IIIa ALK+ NSCLC were randomized to receive ALECENSA
- 600 mg orally twice daily (n=130) or 4 cycles of platinum-based
- chemotherapy (n=127). Staging was based on UICC/AJCC 7th edition.
- Randomization was stratified by race (Asian and other races) and stage
- of disease (IB, II, and IIIa). Stratification factors were applied to hazard
- ratio and P-value analysis (stratified by race in stage II-IIIa, stratified by
- race and stage in stage IB-IIIa). Treatment in the ALECENSA arm
- continued for 2 years or until disease recurrence or death due to any
- cause. Treatment in the chemotherapy arm continued until completion
- of the fourth cycle. The primary efficacy endpoint was DFS as
- determined by the investigator. Secondary efficacy endpoint was OS
- and an exploratory endpoint was time to CNS recurrence.^{1,2}
- See more data from the trial
- Contact a representative
- Indications

-ALECENSA is a kinase inhibitor indicated for:

- adjuvant treatment in adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive), as detected by an FDA-approved test
- treatment of adult patients with ALK-positive metastatic NSCLC as detected by an FDA-approved test

-Important Safety Information

-Warnings and Precautions

-Hepatotoxicity

- Severe hepatotoxicity, including drug-induced liver injury, occurred in patients treated with ALECENSA. Hepatotoxicity occurred in 41% of 533 patients treated with ALECENSA and the incidence of Grade ≥ 3 hepatotoxicity was 8%. In the ALINA study, hepatotoxicity occurred in 61% of patients treated with ALECENSA and the incidence of Grade ≥ 3 hepatotoxicity was 4.7%. The majority (72% of 136 patients) of elevated transaminases occurred during the first 3 months of treatment. Treatment discontinuation due to hepatotoxicity occurred in 3.6% of patients who received ALECENSA in the pooled safety population and 1.6% of patients treated in the ALINA study

- Concurrent elevations in alanine transaminase (ALT) or aspartate transaminase (AST) greater than or equal to 3 times the ULN and total bilirubin greater than or equal to 2 times the ULN, with normal alkaline phosphatase, occurred in less than 1% of patients treated with ALECENSA. Three patients with Grades 3-4 AST/ALT elevations had drug-induced liver injury (documented by liver biopsy in 2 cases)

- Monitor liver function tests including ALT, AST, and total bilirubin every 2 weeks during the first 3 months of treatment, then once a month and as clinically indicated, with more frequent testing in patients who develop transaminase and bilirubin elevations. Based on the severity of the adverse drug reaction, withhold ALECENSA and resume at a reduced dose, or permanently discontinue ALECENSA

-Interstitial Lung Disease (ILD)/Pneumonitis

- ILD/pneumonitis occurred in 1.3% of 533 patients treated with ALECENSA with 0.4% of patients experiencing Grade 3 ILD/pneumonitis. Five patients (0.9%) discontinued ALECENSA due to ILD/pneumonitis. The median time-to-onset of Grade 3 or higher ILD/pneumonitis was 2.1 months (range: 0.6 months to 3.6 months)
- Promptly investigate for ILD/pneumonitis in any patient who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, and fever)
- Immediately withhold ALECENSA treatment in patients diagnosed with ILD/pneumonitis and permanently discontinue ALECENSA if no other potential causes of ILD/pneumonitis have been

-identified

-Renal Impairment

- Renal impairment occurred in 12% of 533

-patients treated with ALECENSA, including

-Grade ≥ 3 in 1.7% of patients, of which 0.4%

-were fatal events

- The median time to Grade ≥ 3 renal impairment

-was 3.7 months (range 0.5 to 31.8 months).

-Dosage modifications for renal impairment were

-required in 2.4% of patients

- Permanently discontinue ALECENSA for Grade

-4 renal toxicity. Withhold ALECENSA for Grade 3

-renal toxicity until recovery to less than or equal

-to 1.5 times ULN, then resume at reduced dose

-Bradycardia

- Symptomatic bradycardia occurred in patients

-treated with ALECENSA. Bradycardia occurred

-in 11% of 533 patients treated with ALECENSA.

-Twenty percent of 521 patients for whom serial

-electrocardiograms (ECGs) were available had

-post-dose heart rates of less than 50 beats per

-minute (bpm)

- Monitor heart rate and blood pressure regularly.

-For asymptomatic bradycardia, dose

-modification is not required. For symptomatic

-bradycardia that is not life-threatening, withhold

-ALECENSA until recovery to asymptomatic

-bradycardia or to a heart rate ≥ 60 bpm and

-evaluate concomitant medications known to

-cause bradycardia, as well as anti-hypertensive

-medications. If bradycardia is attributable to a

-concomitant medication, resume ALECENSA at

-a reduced dose upon recovery to asymptomatic

-bradycardia or to a heart rate of ≥ 60 bpm, with

-frequent monitoring as clinically indicated

- Permanently discontinue ALECENSA in cases of

-life-threatening bradycardia if no contributing

-concomitant medication is identified or for

-recurrence of life-threatening bradycardia

-Severe Myalgia and Creatine Phosphokinase

-(CPK) Elevation

- Severe myalgia and creatine phosphokinase

-(CPK) elevation occurred in patients treated with

-ALECENSA. Myalgia (including muscle- and

-musculoskeletal-related reactions) occurred in

-31% of 533 patients treated with ALECENSA,

-including Grade ≥ 3 in 0.8% of patients. Dosage

-modifications for myalgia events were required in

-2.1% of patients

- Of the 491 with CPK laboratory data available,

-elevated CPK occurred in 56% of patients,

-including 6% Grade ≥ 3 . The median time to

-Grade ≥ 3 CPK elevation was 15 days

-(interquartile range 15-337 days). Dosage

-modifications for elevation of CPK occurred in

-5% of patients. In the ALINA study, elevated CPK

-occurred in 77% of 128 patients with CPK

-laboratory data, including 6% Grade ≥ 3

-elevations

- Advise patients to report any unexplained

-muscle pain, tenderness, or weakness. Assess

- CPK levels every 2 weeks for the first month of treatment and as clinically indicated in patients reporting symptoms. Based on the severity of the CPK elevation, withhold ALECENSA, then resume or reduce dose
- Hemolytic Anemia
 - Hemolytic anemia occurred in patients treated with ALECENSA. Hemolytic anemia was initially reported with ALECENSA in the postmarketing setting, including cases associated with a negative direct antiglobulin test (DAT) result. Assessments for the determination of hemolytic anemia were subsequently collected in the ALINA study, where hemolytic anemia was observed in 3.1% of patients treated with ALECENSA
 - If hemolytic anemia is suspected, withhold ALECENSA and initiate appropriate laboratory testing. If hemolytic anemia is confirmed, consider resuming at a reduced dose upon resolution or permanently discontinue ALECENSA
- Embryo-Fetal Toxicity
 - ALECENSA can cause fetal harm when administered to pregnant women. Administration of alectinib to pregnant rats and rabbits during the period of organogenesis resulted in embryo-fetal toxicity and abortion at maternally toxic doses with exposures approximately 2.7-fold those observed in humans with alectinib 600 mg twice daily. Advise pregnant women of the potential risk to a fetus
 - Advise females of reproductive potential to use effective contraception during treatment with ALECENSA and for 5 weeks following the last dose
 - Advise males with female partners of reproductive potential to use effective contraception during treatment with ALECENSA and for 3 months following the last dose
- Most Common Adverse Reactions
 - The most common adverse reactions ($\geq 20\%$) were hepatotoxicity (41%), constipation (39%), fatigue (36%), myalgia (31%), edema (29%), rash (23%), and cough (21%)
- Use in Specific Populations
 - Lactation
 - Because of the potential for serious adverse reactions in breastfed infants from ALECENSA, advise a lactating woman not to breastfeed during treatment with ALECENSA and for 1 week after the last dose
- You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.
- Please see additional Important Safety Information in full Prescribing Information.
- AJCC=American Joint Committee on Cancer; ALK=anaplastic lymphoma kinase; AR=adverse reaction; CI=confidence interval; CNS=central nervous system; DFS=disease-free survival;

-HR=hazard ratio; ITT=intent-to-treat; N+=node positive; NE=not
-estimable; NCI CTCAE=National Cancer Institute Common
-Terminology Criteria for Adverse Events; NSCLC=non-small cell
-lung cancer; OS=overall survival; T=tumor size; UICC=Union for
-International Cancer Control.

-References

-1. ALECENSA [prescribing information]. South San
-Francisco, CA: Genentech USA, Inc. 2024.

-2. Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib
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