Comparison Result: PDF vs HTML

--- PDF Content
+++ HTML Content
@@ -1,1593 +1,829 @@
-Document Number:
-M-US-00022697(v2.0)
-Sender Name:
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 Genentech Oncology
-Sender Email:
-oncology@e.genentech.com
-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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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-IIIAa 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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+THE FIRST AND ONLY ADJUVANT TREATMENT FOR PATIENTS WITH
+RESECTABLE ALK+ NSCLC1

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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-IIIAa 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

-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
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+Serious adverse reactions occurred in 13% of patients treated with
+ALECENSA
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+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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 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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+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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+Please
+see additional Important Safety Information continued below and in full Prescribing Information.
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Important Safety Information (cont'd)
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Warnings and Precautions (cont'd)
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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
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+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)
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+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
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 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
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+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.
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+0.6 months to 3.6 months)
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+Promptly investigate for ILD/pneumonitis in any patient
+who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis (eg,
+dyspnea, cough, and fever)
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+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
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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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+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
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+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
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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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+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)
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+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
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+Permanently discontinue ALECENSA in cases of
+life-threatening bradycardia if no contributing concomitant medication is identified
+or for recurrence of life-threatening bradycardia
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 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
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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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+
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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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+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
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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 (≥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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+(31%), edema (29%), rash (23%), and cough (21%)
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Use in Specific Populations
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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.
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+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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+Please see additional Important Safety Information in full Prescribing Information.
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+AJCC=American Joint
+Committee on Cancer; ALK=anaplastic lymphoma kinase; AR=adverse reaction; CI=confidence
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+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
-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.
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+ALECENSA [prescribing information]. South
+San Francisco, CA: Genentech USA, Inc. 2024.
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+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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-Links to: https://
-www.gene.com/
-contact-us
-Links to: https://
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-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
-•
-In the ITT population (stage IB-IIIAa 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 (≥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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-Grades) in patients treated with ALECENSA were
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-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
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-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
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-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)
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-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 (≥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
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-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-
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-doi:10.1056/NEJMoa2310532.
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-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
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-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
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-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
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-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 (≥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
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-doi:10.1056/NEJMoa2310532.
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-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
-•
-In the ITT population (stage IB-IIIAa 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
-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
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-Hemolytic Anemia
-• Hemolytic anemia occurred in patients treated with ALECENSA. Hemolytic
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-collected in the ALINA study, where hemolytic anemia was observed in 3.1% of
-patients treated with ALECENSA
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-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
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-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
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-• Advise females of reproductive potential to use effective contraception during
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-• Advise males with female partners of reproductive potential to use effective
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-• The most common adverse reactions (≥20%) were hepatotoxicity (41%),
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-• Because of the potential for serious adverse reactions in breastfed infants from
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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 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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-available in 2 settings. In addition to its metastatic
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-(95% CI: NE, NE) vs 41.3 months (95% CI: 28.5,
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-600 mg orally twice daily (n=130) or 4 cycles of platinum-based
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-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
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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
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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
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-received ALECENSA in the pooled safety
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-• Concurrent elevations in alanine transaminase
-(ALT) or aspartate transaminase (AST) greater
-than or equal to 3 times the ULN and total
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-• Monitor heart rate and blood pressure regularly.
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-cause bradycardia, as well as anti-hypertensive
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-• Advise patients to report any unexplained
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-setting, including cases associated with a
-negative direct antiglobulin test (DAT) result.
-Assessments for the determination of hemolytic
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-doses with exposures approximately 2.7-fold
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-• Advise females of reproductive potential to use
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-dose
-• Advise males with female partners of
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-contraception during treatment with ALECENSA
-and for 3 months following the last dose
-Most Common Adverse Reactions
-• 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.
-References
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-2. Wu YL, Dziadziuszko R, Ahn JS, et al. Alectinib
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-doi:10.1056/NEJMoa2310532.
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