Genentech
A Member of the Roche Group

LUNG CANCER PORTFOLIO

COMMITTED TO THE FIGHT AGAINST LUNG CANCER

4 PRODUCTS[1-4]
10 APPROVALS[1-4]
1 PORTFOLIO

TECENTRIQ® atezolizumab 840 mg | 1200 mg INJECTION FOR IV USE

ALECENSA® alectinib 150 mg capsules

ROZLYTREK® entrectinib 100 mg | 200 mg capsules

GAVRETO® pralsetinib 100 mg capsules

GAVRETO was discovered by Blueprint Medicines and is co-commercialized with Blueprint Medicines in the U.S.

Please see additional Important Safety Information for TECENTRIQ, ALECENSA, ROZLYTREK, and GAVRETO at the end of this brochure, and click the following links for full Prescribing Information for TECENTRIQ, ALECENSA, ROZLYTREK, and GAVRETO.

SELECT IMPORTANT SAFETY INFORMATION

TECENTRIQ INDICATIONS

NSCLC

TECENTRIQ, as a single agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II-IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥1% of tumor cells, as determined by an FDA-approved test.

TECENTRIQ, as a single agent, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1–stained ≥50% of tumor cells [TC ≥50%] or PD-L1–stained tumor-infiltrating immune cells [IC] covering ≥10% of the tumor area [IC ≥10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

TECENTRIQ, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous, non-small cell lung cancer (nsqNSCLC) with no EGFR or ALK genomic tumor aberrations.

TECENTRIQ, in combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.

TECENTRIQ, as a single agent, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving TECENTRIQ.

SCLC

TECENTRIQ, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

SELECT IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal adverse reactions occurred with TECENTRIQ treatment. Warnings and precautions include severe and fatal immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions, nephritis with renal dysfunction, and solid organ transplant rejection. Other warnings and precautions include infusion-related reactions, complications of allogeneic HSCT, and embryo-fetal toxicity.

Please see additional Important Safety Information for TECENTRIQ on pages 9-13 and click here for full Prescribing Information.

TECENTRIQ®
atezolizumab 840 mg | 1200 mg INJECTION FOR IV USE

ALECENSA INDICATION

ALECENSA is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (mNSCLC) as detected by an FDA-approved test.

SELECT IMPORTANT SAFETY INFORMATION

Hepatotoxicity: Monitor liver function tests 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 reaction, withhold then dose reduce, or permanently discontinue ALECENSA.

Please see additional Important Safety Information for ALECENSA on page 14 and click here for full Prescribing Information.

ALECENSA®
alectinib 150 mg capsules

SELECT IMPORTANT SAFETY INFORMATION

ROZLYTREK INDICATIONS

ROS1-Positive Non-Small Cell Lung Cancer

ROZLYTREK is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS1*-positive.

***NTRK* Gene Fusion-Positive Solid Tumors**

ROZLYTREK is indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that:

- have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation,
- are metastatic or where surgical resection is likely to result in severe morbidity, and
- have either progressed following treatment or have no satisfactory alternative therapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

SELECT IMPORTANT SAFETY INFORMATION

Congestive Heart Failure (CHF): Assess left ventricular ejection fraction (LVEF) prior to initiation of ROZLYTREK in patients with symptoms or known risk factors for CHF. Monitor patients for clinical signs and symptoms of CHF. For patients with myocarditis with or without a decreased ejection fraction, MRI or cardiac biopsy may be required to make the diagnosis. For new onset or worsening CHF, withhold ROZLYTREK, reassess LVEF and institute appropriate medical management. Reduce dose or permanently discontinue ROZLYTREK based on severity of CHF or worsening LVEF.

Please see additional Important Safety Information for ROZLYTREK on page 15 and click here for full Prescribing Information.

ROZLYTREK® entrectinib 100 mg | 200 mg capsules

GAVRETO INDICATION

GAVRETO is indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

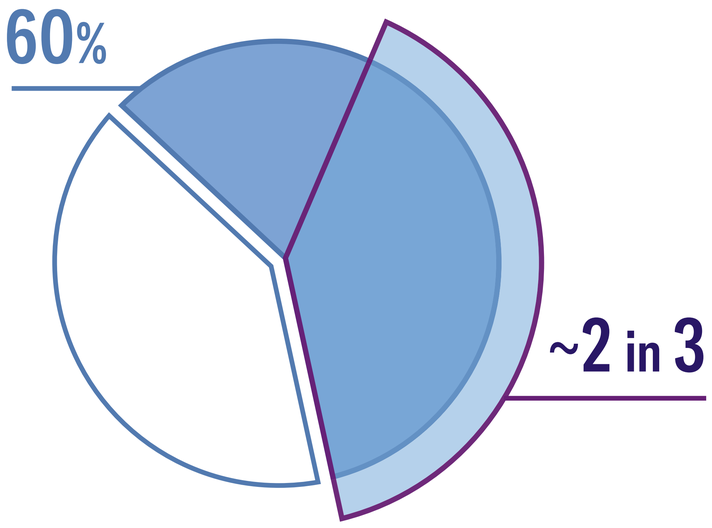
Interstitial Lung Disease (ILD)/Pneumonitis: Withhold GAVRETO for Grade 1 or 2 reactions until resolution and then resume at a reduced dose. Permanently discontinue for recurrent ILD/pneumonitis. Permanently discontinue for Grade 3 or 4 reactions.

Please see additional Important Safety Information for GAVRETO on page 16 and click here for full Prescribing Information.

blueprint™ MEDICINES | Genentech A Member of the Roche Group

GAVRETO® pralsetinib 100 mg capsules

LEVERAGING ALL BIOMARKER TEST RESULTS CAN LEAD TO MORE INFORMED TREATMENT DECISIONS



MORE THAN 60%

of all non-squamous mNSCLC patients have oncogenic drivers—and of these patients, about 2 in 3 have an actionable biomarker[5-9]*

*Regardless of PD-L1 expression.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend molecular testing be performed via a broad panel-based approach such as next-generation sequencing (NGS), when feasible, for patients with metastatic NSCLC[7a]

Up-front broad panel NGS testing may improve overall patient experience when compared to sequential single gene testing[10]:

- Multiple alterations tested with a single sample
- Fewer rebiopsies and complications

At Genentech we are committed to helping every lung cancer patient find an effective therapy

We have treatment options for [5 out of 9] National Comprehensive Cancer Network® (NCCN®) recommended biomarkers in patients with metastatic non-squamous NSCLC[7]

ALK | ROS1 | NTRK | RET | PD-L1

[a]The NCCN Guidelines® for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays.

ALK=anaplastic lymphoma kinase; mNSCLC=metastatic non-small cell lung cancer; NGS=next-generation sequencing; NSCLC=non-small cell lung cancer; NTRK=neurotrophic tyrosine receptor kinase; PD-L1=programmed death-ligand 1; RET=rearranged during transfection; ROS1=ROS proto-oncogene 1.

Please see additional Important Safety Information for TECENTRIQ, ALECENSA, ROZLYTREK, and GAVRETO at the end of this brochure, and click the following links for full Prescribing Information for TECENTRIQ, ALECENSA, ROZLYTREK, and GAVRETO.

GENENTECH OFFERS TARGETED THERAPIES FOR mNSCLC PATIENTS WITH ALK, ROS1, NTRK, AND RET BIOMARKERS

ALECENSA® alectinib 150 mg capsules

ROZLYTREK® entrectinib 100 mg | 200 mg capsules

GAVRETO® pralsetinib | 100 mg capsules

ALK+ mNSCLC[2]	ROS1+ mNSCLC[3]	NTRK fusion-positive solid tumors (Advanced or mNSCLC)[3]	RET fusion-positive mNSCLC[4]
✓ Alectinib (ALECENSA) **is NCCN Category 1, Preferred**[7a,b]	✓ Entrectinib (ROZLYTREK) **is NCCN Category 2A, Preferred**[7a,b]	✓ Entrectinib (ROZLYTREK) **is NCCN Category 2A, Preferred**[7a-c]	✓ Pralsetinib (GAVRETO) **is NCCN Category 2A, Preferred**[7a,b,d]
SELECT IMPORTANT SAFETY INFORMATION **Interstitial Lung Disease (ILD)/ Pneumonitis**: ILD/pneumonitis occurred in 0.7% of patients. Immediately withhold ALECENSA in patients diagnosed with ILD/ pneumonitis and permanently discontinue if no other potential causes of ILD/ pneumonitis have been identified.	**SELECT IMPORTANT SAFETY INFORMATION** **Central Nervous System (CNS) Effects**: CNS adverse reactions including cognitive impairment, mood disorders, dizziness, and sleep disturbances can occur with ROZLYTREK. Withhold and then resume at same or reduced dose upon improvement or permanently discontinue ROZLYTREK based on severity.		**SELECT IMPORTANT SAFETY INFORMATION** **Hypertension**: Do not initiate GAVRETO in patients with uncontrolled hypertension. Optimize blood pressure (BP) prior to initiating GAVRETO. Monitor BP after 1 week, at least monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue GAVRETO based on severity.

Make precision medicine a reality for eligible 1L mNSCLC patients by leveraging all biomarker test results in addition to PD-L1.[2-4]

[a]NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way. See the NCCN Guidelines® for detailed recommendations, including other preferred options. [b]Preferred for first-line treatment.[7] [c]Preferred as first-line treatment for patients with NTRK1/2/3 gene fusion-positive mNSCLC.[7] [d]Also approved for additional tumor types. See full Prescribing Information for details.[3,4]

Category 1: based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[7]
Category 2A: based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[7]

1L=first-line.

Please see additional Important Safety Information for ALECENSA, ROZLYTREK, and GAVRETO at the end of this brochure, and click the following links for full Prescribing Information for ALECENSA, ROZLYTREK, and GAVRETO.

TECENTRIQ HAS PIONEERED IMMUNOTHERAPY IN MULTIPLE INDICATIONS WITH HIGH UNMET NEED[1,11,12]

TECENTRIQ® atezolizumab 840 mg / 1200 mg INJECTION FOR IV USE

Adjuvant NSCLC	SCLC
PD-L1+ (TC≥1%) stage II-IIIA NSCLC[1a]	1L ES-SCLC[1]
IMpower010 Atezolizumab monotherapy following resection and chemotherapy	IMpower133 Atezolizumab + carboplatin/etoposide
✓ NCCN Category 2A option[7b,c]	✓ NCCN Category 1, Preferred option[13b]

SELECT IMPORTANT SAFETY INFORMATION

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Please see the Prescribing Information for full dosing and administration recommendations.

TECENTRIQ offers flexible dosing options (Q4W, Q3W, and Q2W) for all of its approvals in lung cancer.[1]

[a]Per the Union for International Cancer Control/American Joint Committee on Cancer staging system, 7th edition. [b]NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way. See the NCCN Guidelines® for detailed recommendations, including other preferred options. Note that Category and Preferred are two separate recommendations. [c]The NCCN Guidelines for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.

Category 1: based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[7]
Category 2A: based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[7]

ES-SCLC=extensive-stage small cell lung cancer; Q2W=once every 2 weeks; Q3W=once every 3 weeks; Q4W=once every 4 weeks; SCLC=small cell lung cancer; TC=tumor cells.

Please see additional Important Safety Information for TECENTRIQ at the end of this brochure, and click here for full Prescribing Information.

TECENTRIQ OFFERS A VERSATILE RANGE OF THERAPEUTIC OPTIONS FOR mNSCLC

TECENTRIQ® atezolizumab 840 mg / 1200 mg INJECTION FOR IV USE

mNSCLC			
1L nsq mNSCLC[1a]	**1L nsq mNSCLC[1a]**	**1L sq or nsq, PD-L1-high (TC≥50% or IC≥10%) mNSCLC[1a]**	**2L+ sq or nsq mNSCLC[1b]**
Atezolizumab (TECENTRIQ) + bevacizumab (Avastin®) + carboplatin/paclitaxel[1a]	**Atezolizumab (TECENTRIQ) + nab-paclitaxel[c]/carboplatin[1a]**	**Atezolizumab (TECENTRIQ) monotherapy[1a]**	**Atezolizumab (TECENTRIQ) monotherapy[1b]**
✓ **NCCN Category 1 option[7d]**	✓ **NCCN Category 2A option[7d]**	✓ **NCCN Category 1, Preferred option[7d]**	✓ **NCCN Category 1, Preferred option[7d,e]**

SELECT IMPORTANT SAFETY INFORMATION

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Please see the Prescribing Information for full dosing and administration recommendations.

TECENTRIQ offers flexible dosing options (Q4W, Q3W, and Q2W) for all of its approvals in lung cancer.[1]

[a]With no EGFR or ALK genomic tumor aberrations.[1] [b]Patients with EGFR or ALK genomic aberrations should have disease progression or FDA-approved therapy for NSCLC harboring these aberrations prior to receiving TECENTRIQ.[1] [c]Nab-paclitaxel (nab-pac) is also referred to as paclitaxel protein-bound (or albumin-bound).[1] [d]NCCN makes no warranties of any kind whatsoever regarding their content, use, or application, and disclaims any responsibility for their application or use in any way. See the NCCN Guidelines® for detailed recommendations, including other preferred options. Note that Category 1 and Preferred are 2 separate recommendations. [e]If progression on PD-1/PD-L1 inhibitor, switching to another PD-1/PD-L1 inhibitor is not recommended.[7]

Category 1: based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[7]
Category 2A: based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[7]

2L=second-line; EGFR=epidermal growth factor receptor; IC=immune cells; nsq=non-squamous; sq=squamous.

Please see additional Important Safety Information for TECENTRIQ at the end of this brochure, and click here for full Prescribing Information.

GENENTECH ACCESS SOLUTIONS

TECENTRIQ® atezolizumab 840 mg / 1200 mg INJECTION FOR IV USE | ALECENSA® alectinib 150 mg capsules | ROZLYTREK® entrectinib 100 mg | 200 mg capsules | GAVRETO® pralsetinib 100 mg capsules

Genentech Access Solutions provides helpful access and reimbursement support to assist your patients and practice by providing:

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Please see additional Important Safety Information for TECENTRIQ, ALECENSA, ROZLYTREK, and GAVRETO at the end of this brochure, and click the following links for full Prescribing Information for TECENTRIQ, ALECENSA, ROZLYTREK, and GAVRETO.

TECENTRIQ IMPORTANT SAFETY INFORMATION

INDICATIONS

NSCLC

TECENTRIQ, as a single agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II-IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥1% of tumor cells, as determined by an FDA-approved test.

TECENTRIQ, as a single agent, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1–stained ≥50% of tumor cells [TC ≥50%] or PD-L1–stained tumor-infiltrating immune cells [IC] covering ≥10% of the tumor area [IC ≥10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

TECENTRIQ, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous, non-small cell lung cancer (nsqNSCLC) with no EGFR or ALK genomic tumor aberrations.

TECENTRIQ, in combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.

TECENTRIQ, as a single agent, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving TECENTRIQ.

SCLC

TECENTRIQ, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions:

TECENTRIQ is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death-receptor 1 (PD-1) or the PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. The following immune-mediated adverse reactions may not include all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions can occur in any organ system or tissue and at any time after starting TECENTRIQ. While immune-mediated adverse reactions usually manifest during treatment with TECENTRIQ, they can also manifest after discontinuation of treatment. Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of TECENTRIQ.

Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue TECENTRIQ depending on severity. In general, if TECENTRIQ requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less, then initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis:

- TECENTRIQ can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation
- Immune-mediated pneumonitis occurred in 3% (83/2616) of patients receiving TECENTRIQ alone, including fatal (<0.1%), Grade 4 (0.2%), Grade 3 (0.8%), and Grade 2 (1.1%) adverse reactions. Pneumonitis led to permanent discontinuation of TECENTRIQ in 0.5% and withholding of TECENTRIQ in 1.5% of patients
- Systemic corticosteroids were required in 55% (46/83) of patients with pneumonitis. Pneumonitis resolved in 69% of the 83 patients. Of the 39 patients in whom TECENTRIQ was withheld for pneumonitis, 25 reinitiated TECENTRIQ after symptom improvement; of these, 4% had recurrence of pneumonitis
- Immune-mediated pneumonitis occurred in 3.8% (19/495) of patients with NSCLC receiving TECENTRIQ alone as adjuvant treatment, including fatal (0.2%), Grade 4 (0.2%), and Grade 3 (0.6%) adverse reactions. Pneumonitis led to permanent discontinuation of TECENTRIQ in 2.2% and withholding of TECENTRIQ in 0.8% of patients. Systemic corticosteroids were required in 63% (12/19) of patients with pneumonitis. Pneumonitis resolved in 84% of the 19 patients

Please click here for full Prescribing Information for TECENTRIQ.

TECENTRIQ®
atezolizumab 840 mg | 1200 mg INJECTION FOR IV USE

TECENTRIQ IMPORTANT SAFETY INFORMATION (cont'd)

IMPORTANT SAFETY INFORMATION (cont'd)

Immune-Mediated Colitis:

- TECENTRIQ can cause immune-mediated colitis. Colitis can present with diarrhea, abdominal pain, and lower gastrointestinal (GI) bleeding. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies
- Immune-mediated colitis occurred in 1% (26/2616) of patients receiving TECENTRIQ alone, including Grade 3 (0.5%) and Grade 2 (0.3%) adverse reactions. Colitis led to permanent discontinuation of TECENTRIQ in 0.2% and withholding of TECENTRIQ in 0.5% of patients. Systemic corticosteroids were required in 50% (13/26) of patients with colitis. Colitis resolved in 73% of the 26 patients. Of the 12 patients in whom TECENTRIQ was withheld for colitis, 8 reinitiated TECENTRIQ after symptom improvement; of these, 25% had recurrence of colitis

Immune-Mediated Hepatitis:

- TECENTRIQ can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 1.8% (48/2616) of patients receiving TECENTRIQ alone, including fatal (<0.1%), Grade 4 (0.2%), Grade 3 (0.5%), and Grade 2 (0.5%) adverse reactions. Hepatitis led to permanent discontinuation of TECENTRIQ in 0.2% and withholding of TECENTRIQ in 0.2% of patients. Systemic corticosteroids were required in 25% (12/48) of patients with hepatitis. Hepatitis resolved in 50% of the 48 patients. Of the 6 patients in whom TECENTRIQ was withheld for hepatitis, 4 reinitiated TECENTRIQ after symptom improvement; of these, none had recurrence of hepatitis

Immune-Mediated Endocrinopathies:

Adrenal Insufficiency

- TECENTRIQ can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated
- Adrenal insufficiency occurred in 0.4% (11/2616) of patients receiving TECENTRIQ alone, including Grade 3 (<0.1%) and Grade 2 (0.2%) adverse reactions. Adrenal insufficiency led to permanent discontinuation of TECENTRIQ in 1 patient and withholding of TECENTRIQ in 1 patient. Systemic corticosteroids were required in 82% (9/11) of patients with adrenal insufficiency; of these, 3 patients remained on systemic corticosteroids. The single patient in whom TECENTRIQ was withheld for adrenal insufficiency did not reinitiate TECENTRIQ
- Adrenal insufficiency occurred in 1.2% (6/495) of patients with NSCLC receiving TECENTRIQ alone as adjuvant treatment, including Grade 3 (0.4%) adverse reactions. Adrenal insufficiency led to permanent discontinuation of TECENTRIQ in 0.6% and withholding of TECENTRIQ in 0.2% of patients. Systemic corticosteroids were required in 83% (5/6) of patients with adrenal insufficiency; of these, 4 patients remained on systemic corticosteroids

Hypophysitis

- TECENTRIQ can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated
- Hypophysitis occurred in <0.1% (2/2616) of patients receiving TECENTRIQ alone, including Grade 2 (1 patient, <0.1%) adverse reactions. Hypophysitis led to permanent discontinuation of TECENTRIQ in 1 patient and no patients required withholding of TECENTRIQ. Systemic corticosteroids were required in 50% (1/2) of patients with hypophysitis. Hypophysitis did not resolve in these 2 patients

Thyroid Disorders

- TECENTRIQ can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or medical management for hyperthyroidism as clinically indicated
- Thyroiditis occurred in 0.2% (4/2616) of patients receiving TECENTRIQ alone, including Grade 2 (<0.1%) adverse reactions. Thyroiditis did not lead to permanent discontinuation of TECENTRIQ in any of these patients, but led to withholding of TECENTRIQ in 1 patient. Hormone replacement therapy was required in 75% (3/4) of patients with thyroiditis. Systemic corticosteroids were required in 25% (1/4) of patients with thyroiditis. Thyroiditis resolved in 50% of patients. The single patient in whom TECENTRIQ was withheld for thyroiditis reinitiated TECENTRIQ, this patient did not have recurrence of thyroiditis
- Thyroiditis occurred in 1.2% (6/495) of patients with NSCLC receiving TECENTRIQ alone as adjuvant treatment, including Grade 2 (0.4%) adverse reactions. Thyroiditis led to withholding of TECENTRIQ in 1 patient. Hormone replacement therapy was required in 67% (4/6) of patients with thyroiditis. Systemic corticosteroids were required in 33% (2/6) of patients with thyroiditis. Thyroiditis resolved in 50% of patients

Please click here for full Prescribing Information for TECENTRIQ.

TECENTRIQ®
atezolizumab 840 mg | 1200 mg INJECTION FOR IV USE

TECENTRIQ IMPORTANT SAFETY INFORMATION (cont'd)

IMPORTANT SAFETY INFORMATION (cont'd)

Immune-Mediated Endocrinopathies (cont'd):

- Hyperthyroidism occurred in 0.8% (21/2616) of patients receiving TECENTRIQ alone, including Grade 2 (0.4%) adverse reactions. Hyperthyroidism did not lead to permanent discontinuation of TECENTRIQ in any of these patients, but led to withholding of TECENTRIQ in 0.1% of patients. Antithyroid therapy was required in 29% (6/21) of patients with hyperthyroidism. Of these 6 patients, the majority remained on antithyroid treatment. Of the 3 patients in whom TECENTRIQ was withheld for hyperthyroidism, 1 patient reinitiated TECENTRIQ; this patient did not have recurrence of hyperthyroidism
- Hyperthyroidism occurred in 6% (32/495) of patients with NSCLC receiving TECENTRIQ alone as adjuvant treatment, including Grade 3 (0.4%) adverse reactions. Hyperthyroidism led to permanent discontinuation of TECENTRIQ in 0.8% and withholding of TECENTRIQ in 2.8% of patients. Antithyroid therapy was required in 38% (12/32) of patients with hyperthyroidism. Of these 12 patients, the majority remained on antithyroid treatment. Of the 14 patients in whom TECENTRIQ was withheld for hyperthyroidism, 9 patients reinitiated TECENTRIQ
- Hypothyroidism occurred in 4.9% (128/2616) of patients receiving TECENTRIQ alone, including Grade 3 (0.2%) and Grade 2 (3.4%) adverse reactions. Hypothyroidism did not lead to permanent discontinuation of TECENTRIQ in any of these patients, but led to withholding of TECENTRIQ in 0.6% of patients. Hormone replacement therapy was required in 81% (104/128) of patients with hypothyroidism. The majority of patients with hypothyroidism remained on thyroid hormone replacement. Of the 17 patients in whom TECENTRIQ was withheld for hypothyroidism, 8 reinitiated TECENTRIQ after symptom improvement
- Hypothyroidism occurred in 17% (86/495) of patients with NSCLC receiving TECENTRIQ alone as adjuvant treatment. Hypothyroidism led to permanent discontinuation of TECENTRIQ in 1.6% and withholding of TECENTRIQ in 1.6% of patients. Hormone replacement was required in 57% (49/86) of patients with hypothyroidism. The majority of patients with hypothyroidism remained on thyroid hormone replacement. Of the 8 patients in whom TECENTRIQ was withheld for hypothyroidism, 3 reinitiated TECENTRIQ after symptom improvement
- Hypothyroidism occurred in 11% (277/2421) of patients with NSCLC and SCLC receiving TECENTRIQ in combination with platinum-based chemotherapy, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (5.7%) adverse reactions. Hypothyroidism led to permanent discontinuation of TECENTRIQ in 0.1% and withholding of TECENTRIQ in 1.6% of patients. Hormone replacement therapy was required in 71% (198/277) of patients with hypothyroidism. The majority of patients with hypothyroidism remained on thyroid hormone replacement. Of the 39 patients in whom TECENTRIQ was withheld for hypothyroidism, 9 reinitiated TECENTRIQ after symptom improvement

Type 1 Diabetes Mellitus, Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated
- Type 1 diabetes mellitus occurred in 0.3% (7/2616) of patients receiving TECENTRIQ alone, including Grade 3 (0.2%) and Grade 2 (<0.1%) adverse reactions. Type 1 diabetes mellitus led to permanent discontinuation of TECENTRIQ in 1 patient and withholding of TECENTRIQ in 2 patients. Treatment with insulin was required for all patients with confirmed Type 1 diabetes mellitus and insulin therapy was continued long-term. Of the 2 patients in whom TECENTRIQ was withheld for Type 1 diabetes mellitus, both reinitiated TECENTRIQ treatment

Immune-Mediated Nephritis With Renal Dysfunction:

- TECENTRIQ can cause immune-mediated nephritis
- Immune-mediated nephritis with renal dysfunction occurred in <0.1% (1/2616) of patients receiving TECENTRIQ alone, and this adverse reaction was a Grade 3 (<0.1%) adverse reaction. Nephritis led to permanent discontinuation of TECENTRIQ in this patient. This patient required systemic corticosteroids. In this patient, nephritis did not resolve

Immune-Mediated Dermatologic Adverse Reactions:

- TECENTRIQ can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), DRESS, and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes

Please click here for full Prescribing Information for TECENTRIQ.

TECENTRIQ®
atezolizumab 840 mg / 1200 mg
INJECTION FOR IV USE

TECENTRIQ IMPORTANT SAFETY INFORMATION (cont'd)

IMPORTANT SAFETY INFORMATION (cont'd)

Immune-Mediated Dermatologic Adverse Reactions (cont'd):

- Immune-mediated dermatologic adverse reactions occurred in 0.6% (15/2616) of patients receiving TECENTRIQ alone, including Grade 3 (<0.1%) and Grade 2 (0.2%) adverse reactions. Dermatologic adverse reactions led to permanent discontinuation of TECENTRIQ in 0.1% and withholding of TECENTRIQ in 0.2% of patients. Systemic corticosteroids were required in 20% (3/15) of patients with dermatologic adverse reactions. Dermatologic adverse reactions resolved in 87% of the 15 patients. Of the 4 patients in whom TECENTRIQ was withheld for immune-mediated dermatologic adverse reactions, none reinitiated TECENTRIQ

Other Immune-Mediated Adverse Reactions:

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received TECENTRIQ or were reported with the use of other PD-1/PD-L1 blocking antibodies
  - o *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis
  - o *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
  - o *Ocular*: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss
  - o *Gastrointestinal*: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis
  - o *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic
  - o *Endocrine*: Hypoparathyroidism
  - o *Other (Hematologic/Immune):* Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

Infusion-Related Reactions:

- TECENTRIQ can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue TECENTRIQ based on the severity. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses
- Infusion-related reactions occurred in 1.3% of patients receiving TECENTRIQ alone, including Grade 3 (0.2%) reactions
- The frequency and severity of infusion-related reactions were similar whether TECENTRIQ was given as a single agent, in combination with other antineoplastic drugs in NSCLC and SCLC, and across the recommended dose range

Complications of Allogeneic HSCT After PD-1/PD-L1 Inhibitors:

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody
- Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause)
- These complications may occur despite intervening therapy between PD-1/PD-L1 blockage and allogeneic HSCT
- Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefits versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT

Embryo-Fetal Toxicity:

- Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. There are no available data on the use of TECENTRIQ in pregnant women. Animal studies have demonstrated that inhibition of the PD-L1/PD-1 pathway can lead to increased risk of immune-related rejection of the developing fetus, resulting in fetal death
- Verify pregnancy status of females of reproductive potential prior to initiating TECENTRIQ. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with TECENTRIQ and for at least 5 months after the last dose

Please click here for full Prescribing Information for TECENTRIQ.

TECENTRIQ®
atezolizumab 840 mg | 1200 mg INJECTION FOR IV USE

TECENTRIQ IMPORTANT SAFETY INFORMATION (cont'd)

IMPORTANT SAFETY INFORMATION (cont'd)

Use in Specific Populations:

Nursing Mothers

- There is no information regarding the presence of TECENTRIQ in human milk, the effects on the breastfed infant, or the effects on milk production. As human IgG is excreted in human milk, the potential for absorption and harm to the infant is unknown
- Because of the potential for serious adverse reactions in breastfed infants from TECENTRIQ, advise female patients not to breastfeed while taking TECENTRIQ and for at least 5 months after the last dose

Fertility

- Based on animal studies, TECENTRIQ may impair fertility in females of reproductive potential while receiving treatment

Most Common Adverse Reactions:

The most common adverse reactions (rate ≥20%) in patients who received TECENTRIQ alone were fatigue/asthenia (48%), decreased appetite (25%), nausea (24%), cough (22%), and dyspnea (22%).

The most common adverse reactions (rate ≥20%) in patients who received TECENTRIQ in combination with other antineoplastic drugs for NSCLC and SCLC were fatigue/asthenia (49%), nausea (38%), alopecia (35%), constipation (29%), diarrhea (28%), and decreased appetite (27%).

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 click here for full Prescribing Information for TECENTRIQ.

TECENTRIQ®
atezolizumab 840 mg | 1200 mg
INJECTION FOR IV USE

ALECENSA IMPORTANT SAFETY INFORMATION

INDICATION

ALECENSA is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (mNSCLC) as detected by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

Hepatotoxicity: Monitor liver function tests 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 reaction, withhold then dose reduce, or permanently discontinue ALECENSA.

Interstitial Lung Disease (ILD)/Pneumonitis: ILD/pneumonitis occurred in 0.7% of patients. Immediately withhold ALECENSA in patients diagnosed with ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis have been identified.

Renal Impairment: Renal impairment occurred in 8% of patients. Incidence of Grade ≥3 was 1.7%, of which 0.5% were fatal events. Based on the severity of the adverse reaction, withhold then dose reduce, or permanently discontinue ALECENSA.

Bradycardia: Monitor heart rate and blood pressure regularly. If symptomatic, withhold ALECENSA then dose reduce or permanently discontinue.

Severe Myalgia and Creatine Phosphokinase (CPK) Elevation: 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, then resume or dose reduce ALECENSA.

Hemolytic Anemia: If hemolytic anemia is suspected, withhold ALECENSA. If hemolytic anemia is confirmed, consider resuming at a reduced dose upon resolution or permanently discontinue.

Embryo-Fetal Toxicity: ALECENSA can cause fetal harm. 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 1 week following the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALECENSA and for 3 months following the final dose.

Most Common Adverse Reactions

The most common adverse reactions (incidence ≥20%) were constipation (34%), fatigue (26%), myalgia (23%), edema (22%), and anemia (20%).

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 click here for full Prescribing Information for ALECENSA.

ALECENSA® alectinib 150 mg capsules

ROZLYTREK IMPORTANT SAFETY INFORMATION

INDICATIONS

***ROS1*-Positive Non-Small Cell Lung Cancer**

ROZLYTREK is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are *ROS1*-positive.

***NTRK* Gene Fusion-Positive Solid Tumors**

ROZLYTREK is indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that:

- have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation,
- are metastatic or where surgical resection is likely to result in severe morbidity, and
- have either progressed following treatment or have no satisfactory alternative therapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

SELECT IMPORTANT SAFETY INFORMATION

Congestive Heart Failure (CHF): Assess left ventricular ejection fraction (LVEF) prior to initiation of ROZLYTREK in patients with symptoms or known risk factors for CHF. Monitor patients for clinical signs and symptoms of CHF. For patients with myocarditis with or without a decreased ejection fraction, MRI or cardiac biopsy may be required to make the diagnosis. For new onset or worsening CHF, withhold ROZLYTREK, reassess LVEF and institute appropriate medical management. Reduce dose or permanently discontinue ROZLYTREK based on severity of CHF or worsening LVEF.

Central Nervous System (CNS) Effects: CNS adverse reactions including cognitive impairment, mood disorders, dizziness, and sleep disturbances can occur with ROZLYTREK. Withhold and then resume at same or reduced dose upon improvement or permanently discontinue ROZLYTREK based on severity.

Skeletal Fractures: ROZLYTREK increases the risk of fractures. Promptly evaluate patients with signs or symptoms of fractures.

Hepatotoxicity: Monitor liver tests, including ALT and AST, every 2 weeks during the first month of treatment, then monthly thereafter and as clinically indicated. Withhold or permanently discontinue ROZLYTREK based on severity. If withheld, resume ROZLYTREK at same or reduced dose based on severity.

Please click here for full Prescribing Information for ROZLYTREK.

Hyperuricemia: Assess serum uric acid levels prior to initiation and periodically during treatment with ROZLYTREK. Monitor patients for signs and symptoms of hyperuricemia. Initiate treatment with urate-lowering medications as clinically indicated and withhold ROZLYTREK for signs and symptoms of hyperuricemia. Resume at same or reduced dose upon improvement based on severity.

QT Interval Prolongation: Monitor patients who have or who are at risk for QTc interval prolongation. Assess QT interval and electrolytes at baseline and periodically during treatment. Withhold and then resume at same or reduced dose or permanently discontinue ROZLYTREK based on severity.

Vision Disorders: Withhold for new visual changes or changes that interfere with activities of daily living until improvement or stabilization. Conduct an ophthalmological evaluation as appropriate. Resume at same or reduced dose upon improvement or stabilization.

Embryo-Fetal Toxicity: ROZLYTREK can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception.

Most Common Adverse Reactions

The most common adverse reactions (≥20%) were fatigue (48%), constipation (46%), dysgeusia (44%), edema (40%), dizziness (38%), diarrhea (35%), nausea (34%), dysesthesia (34%), dyspnea (30%), myalgia (28%), cognitive impairment (27%), increased weight (25%), cough (24%), vomiting (24%), pyrexia (21%), arthralgia (21%), and vision disorders (21%).

Drug Interactions

Moderate and Strong CYP3A Inhibitors:

- For adult and pediatric patients 12 years and older with a BSA greater than 1.50 m^2, reduce the dose of ROZLYTREK if coadministration of moderate or strong CYP3A inhibitors cannot be avoided.
- For pediatric patients 12 years and older with a BSA less than or equal to 1.50 m^2, avoid coadministration with ROZLYTREK.

Moderate and Strong CYP3A Inducers: Avoid coadministration with ROZLYTREK.

Use In Specific Populations:

Lactation: Advise not to breastfeed.

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**.

ROZLYTREK®
entrectinib 100 mg | 200 mg capsules

GAVRETO IMPORTANT SAFETY INFORMATION

INDICATION

GAVRETO is indicated for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Interstitial Lung Disease (ILD)/Pneumonitis: Withhold GAVRETO for Grade 1 or 2 reactions until resolution and then resume at a reduced dose. Permanently discontinue for recurrent ILD/pneumonitis. Permanently discontinue for Grade 3 or 4 reactions.

Hypertension: Do not initiate GAVRETO in patients with uncontrolled hypertension. Optimize blood pressure (BP) prior to initiating GAVRETO. Monitor BP after 1 week, at least monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue GAVRETO based on severity.

Hepatotoxicity: Monitor ALT and AST prior to initiating GAVRETO, every 2 weeks during the first 3 months, then monthly thereafter and as clinically indicated. Withhold, reduce dose, or permanently discontinue GAVRETO based on severity.

Hemorrhagic Events: Permanently discontinue GAVRETO in patients with severe or life-threatening hemorrhage.

Tumor Lysis Syndrome: Closely monitor patients at risk and treat as clinically indicated.

Risk of Impaired Wound Healing: Withhold GAVRETO for at least 5 days prior to elective surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of GAVRETO after resolution of wound healing complications has not been established.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective non-hormonal contraception.

Most Common Adverse Reactions

The most common adverse reactions (≥25%) were constipation, hypertension, fatigue, musculoskeletal pain and diarrhea. The most common Grade 3-4 laboratory abnormalities (≥2%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased phosphate, decreased calcium (corrected), decreased sodium, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), decreased platelets, and increased alkaline phosphatase.

Drug Interactions

Strong CYP3A inhibitors: Avoid coadministration.

Combined P-gp and Strong CYP3A inhibitors: Avoid coadministration. If coadministration cannot be avoided, reduce the dose of GAVRETO.

Strong CYP3A inducers: Avoid coadministration. If coadministration cannot be avoided, increase the dose of GAVRETO.

Lactation: Advise not to breastfeed.

Pediatric Use: Monitor open growth plates in adolescent patients. Consider interrupting or discontinuing GAVRETO if abnormalities occur.

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 click here for full Prescribing Information for GAVRETO.

GAVRETO® pralsetinib 100mg capsules

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