NOW APPROVED
in PD-L1+ stage II-IIIA NSCLC

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

Approved October 15, 2021

Dear

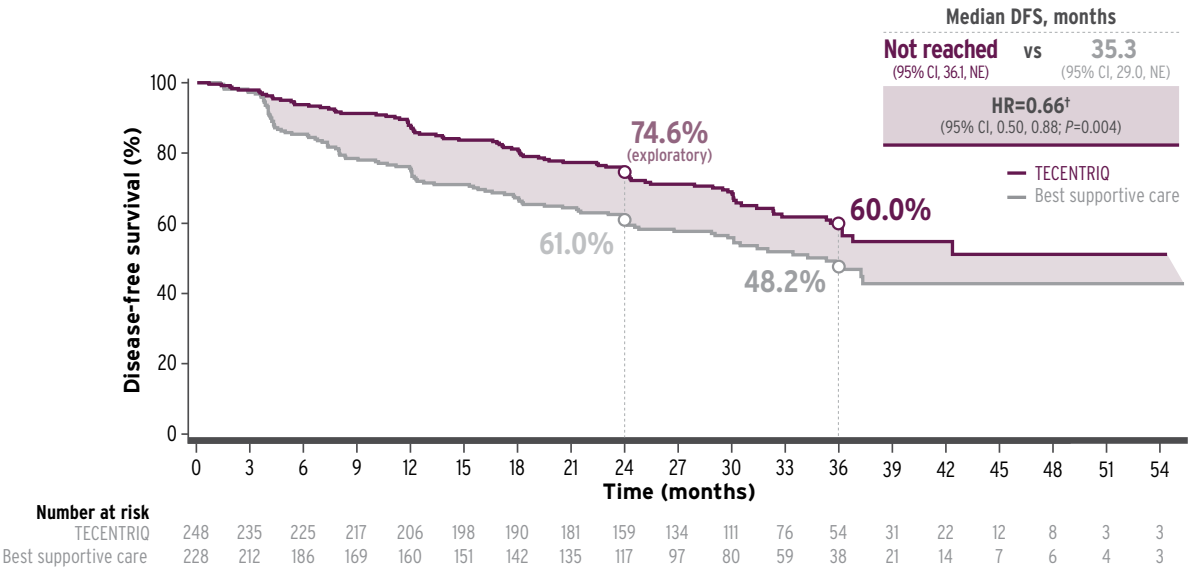
Genentech is pleased to announce that TECENTRIQ is now approved as adjuvant treatment following resection and platinum-based chemotherapy in PD-L1+ (TC ≥1%) stage II-IIIA NSCLC. **As the first and only FDA-approved immunotherapy for adjuvant treatment in PD-L1+ NSCLC, TECENTRIQ advances the standard of care in stage II-IIIA lung cancer.[1,2]**

IMPOWER010: THE FIRST AND ONLY PIVOTAL PHASE III STUDY TO EVALUATE ADJUVANT IMMUNOTHERAPY IN NSCLC[1,2]

IMpower010 was a Phase III, multicenter, international, randomized (1:1), open-label trial evaluating TECENTRIQ following cisplatin-based chemotherapy in patients with completely resected, stage IB (tumors ≥4 cm) to IIIA* NSCLC (N=1280, of whom 1005 were randomized to receive TECENTRIQ or best supportive care). The primary endpoint was investigator-assessed DFS in the PD-L1+ stage II-IIIA population (n=476). Randomization was stratified by sex, stage of disease (IB vs II vs IIIA), histology, and PD-L1 expression.

A PARADIGM SHIFT IN PD-L1+ NSCLC TREATMENT: ADJUVANT TECENTRIQ DELIVERED SUPERIOR DFS[1,2]

34% reduction in the risk of relapse achieved with TECENTRIQ vs best supportive care in stage II-IIIA NSCLC



Landmark analyses were not powered to demonstrate statistically significant differences and no conclusions can be drawn from these analyses. The 36-month DFS rate was a prespecified secondary endpoint. The 24-month DFS rate was not prespecified and is considered exploratory.

- Median follow-up: 32.8 months

Patients received cisplatin 75 mg/m^2 IV on Day 1 of each 21-day cycle for ≤4 cycles with one of the following: vinorelbine 30 mg/m^2 on Days 1 and 8, docetaxel 75 mg/m^2 on Day 1, gemcitabine 1250 mg/m^2 on Days 1 and 8, or pemetrexed 500 mg/m^2 (non-squamous only) on Day 1. Following recovery from surgery and completion of chemotherapy, 1005 patients were randomized (1:1) to receive TECENTRIQ 1200 mg IV q3w for 16 cycles, unless disease recurrence or unacceptable toxicity, or BSC. Tumor assessments were conducted at baseline of the randomization phase and every 4 months for the first year following Cycle 1, Day 1; then every 6 months until Year 5; and annually thereafter. Patients were excluded if they had a history of autoimmune disease; a history of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis; administration of a live, attenuated vaccine within 28 days prior to randomization; and/or administration of systemic immunostimulatory agents within 4 weeks or systemic immunosuppressive medications within 2 weeks prior to randomization.

BSC=best supportive care; CI=confidence interval; DFS=disease-free survival; HR=hazard ratio; HSCT=hematopoietic stem cell transplantation; IV=intravenously; NE=not estimable; NSCLC=non-small cell lung cancer; PD-L1=programmed death-ligand 1; q3w=every 3 weeks; TC=tumor cells.

*Per the Union for International Cancer Control/American Joint Committee on Cancer staging system, 7th edition.
†Stratified by disease stage, sex, and histology.

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 full Prescribing Information and additional Important Safety Information throughout this letter.

IMPOWER010 SAFETY PROFILE: MOST ADVERSE REACTIONS (ARs) WERE GRADE 1 OR 2[1]

ARs in IMpower010 were generally consistent with the established TECENTRIQ safety profile[2]

	TECENTRIQ (n=495)		Best supportive care (n=495)	
ARs with an incidence of ≥10%	**All grades* (%)**	**Grades 3-4* (%)**	**All grades* (%)**	**Grades 3-4* (%)**
Rash†	17	1.2	1.4	0
Cough‡	16	0	11	0
Fatigue§	14	0.6	5	0.2
Hypothyroidism‖	14	0	0.6	0
Musculoskeletal pain¶	14	0.8	9	0.2
Pyrexia#	14	0.8	2.2	0.2
Peripheral neuropathy**	12	0.4	7	0.2
Arthralgia††	11	0.6	6	0
Pruritus	10	0	0.6	0

Additional safety data reported in IMpower010[1,2]

- 1.8% of patients treated with TECENTRIQ experienced fatal ARs
  - These included multiple organ dysfunction syndrome, pneumothorax, interstitial lung disease, arrhythmia, acute cardiac failure, myocarditis, cerebrovascular accident, death of unknown cause, and acute myeloid leukemia (1 patient each)
- Serious ARs occurred in 18% of patients receiving TECENTRIQ vs 8% with best supportive care
  - The most frequent serious ARs (>1%) were pneumonia (1.8%), pneumonitis (1.6%), and pyrexia (1.2%)
  - Treatment-related serious ARs occurred in 7% of patients receiving TECENTRIQ
- ARs leading to discontinuation of TECENTRIQ occurred in 18% of patients
  - The most common ARs (≥1%) leading to TECENTRIQ discontinuation were pneumonitis (2.2%), hypothyroidism (1.6%), increased AST (1.4%), arthralgia (1.0%), and increased ALT (1.0%)
- ARs leading to interruption of TECENTRIQ occurred in 29% of patients
  - The most common (≥1%) were rash (3.0%), hyperthyroidism (2.8%), hypothyroidism (1.6%), increased AST (1.6%), pyrexia (1.6%), increased ALT (1.4%), upper respiratory tract infection (1.4%), headache (1.2%), peripheral neuropathy (1.2%), and pneumonia (1.2%)
- Of all grade laboratory abnormalities that worsened from baseline in ≥20% of patients receiving TECENTRIQ in IMpower010, grade 3 or 4 abnormalities with TECENTRIQ vs best supportive care included increased AST (2.5% vs 0%), increased ALT (3.3% vs 0.4%), hyperkalemia (3.5% vs 2.5%), and increased blood creatinine (0.2% vs 0.2%)

65% of patients completed the full duration of TECENTRIQ treatment[1,2‡‡]

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0.

†Includes rash, dermatitis, genital rash, skin exfoliation, rash maculopapular, rash erythematous, rash papular, lichen planus, eczema asteatotic, dermatitis exfoliative, palmar-plantar erythrodysesthesia syndrome, dyshidrotic eczema, eczema, drug eruption, rash pruritic, toxic skin eruption, and dermatitis acneiform.

‡Productive cough, upper airway cough syndrome, and cough.

§Includes fatigue and asthenia.

‖Includes hypothyroidism, autoimmune hypothyroidism, primary hypothyroidism, and blood thyroid-stimulating hormone increased.

¶Includes myalgia, bone pain, back pain, spinal pain, musculoskeletal chest pain, pain in extremity, neck pain, noncardiac chest pain, musculoskeletal discomfort, musculoskeletal stiffness, and musculoskeletal pain.

#Includes pyrexia, body temperature increased, and hyperthermia.

**Includes paresthesia, neuropathy peripheral, peripheral sensory neuropathy, hypesthesia, polyneuropathy, dysesthesia, neuralgia, and axonal neuropathy.

††Includes arthralgia and arthritis.

‡‡Of the 495 patients receiving TECENTRIQ, 323 patients completed 16 cycles (75% completed at least 8 cycles). Median treatment duration was 10.4 months.

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CODES FOR YOUR REFERENCE

Type	Code		Description
TECENTRIQ NDC[1] Note: payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	**10-digit**	**11-digit**	
	50242-917-01	50242-0917-01	1200 mg/20 mL single-dose vial
	50242-918-01	50242-0918-01	840 mg/14 mL single-dose vial
TECENTRIQ HCPCS[3]	**J9022**		Injection, atezolizumab, 10 mg
Diagnosis: ICD-10-CM	**C33**		Malignant neoplasm of trachea
	C34.00–C34.02		Malignant neoplasm of bronchus and lung; main bronchus
	C34.10–C34.12		Malignant neoplasm of bronchus and lung; upper lobe
	C34.2		Malignant neoplasm of bronchus and lung; middle lobe
	C34.30–C34.32		Malignant neoplasm of bronchus and lung; lower lobe
	C34.80–C34.82		Malignant neoplasm of bronchus and lung; overlapping sites
	C34.90–C34.92		Malignant neoplasm of bronchus and lung; unspecified part
Administration procedures: CPT	**96413**		Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415		Chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)
	96417		Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (list separately in addition to code for primary procedure)

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Genentech does not make any representation or guarantee concerning reimbursement or coverage for any service or item. Many payers will not accept unspecified codes. If you use an unspecified code, please check with your patient's insurance company.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

DISTRIBUTION AND FULFILLMENT INFORMATION

- TECENTRIQ is available through authorized specialty distributors and wholesalers
  - Visit Genentech-Access.com/TECENTRIQ for a list of distributors

If you have any distribution-related questions, please contact your representative or call the Genentech Customer Service Department at (800) 551-2231, 6 AM to 5 PM PT, Monday through Friday.

With this 6th lung approval, TECENTRIQ pioneers adjuvant immunotherapy in lung cancer, offering PD-L1+ patients new hope in the fight against stage II-IIIA disease

Select Important Safety Information

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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

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

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Immune-Mediated Endocrinopathies (cont'd)

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
- 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

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
- 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
  - *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis
  - *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
  - *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
  - *Gastrointestinal*: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis

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Other Immune-Mediated Adverse Reactions (cont'd)

- *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic
- *Endocrine*: Hypoparathyroidism
- *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 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

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%).

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 full Prescribing Information for additional Important Safety Information.

For more information, please visit TECENTRIQ-HCP.com/adjNSCLC.

Sincerely,

Levi Garraway, MD, PhD
Chief Medical Officer and Head of Global Product Development

References: 1. TECENTRIQ Prescribing Information. Genentech, Inc. **2.** Felip E, Altorki N, Zhou C, et al; IMpower010 Investigators. Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIA non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial. *Lancet*. 2021;398:1344-1357. **3.** Medicare Coverage Database. Centers for Medicare & Medicaid Services. Updated July 1, 2020. Accessed July 16, 2021. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52991&ver=101.

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