Eisai Inc. invites you to attend the following live presentation titled:

LENVIMA®: A First-line Treatment for Radioactive-Iodine Refractory Differentiated Thyroid Cancer

Presented by

Ammar Sukari, MD
Assistant Professor
Karmanos Cancer Institute
Detroit, MI

When

Saturday, March 24, 2018 | 7:30am

Where

La Concha Resort
Meeting Room: Las Nereidas Ballroom
1077 Avenida Doctor Ashford
San Juan, PR 00907
(787) 721-7500

To register for this program, click here or call (877) 869-2854.

You may also contact your Eisai Representative Dora Dopico by calling (786) 229-9508.

Speaker Program Guidelines

Vermont law prohibits, Minnesota law restricts, and Department of Veterans Affairs and Department of Defense policy prohibits Eisai from offering meals at speaker events to certain health care professionals. If you are licensed in either of those states, or employed by either agency, Eisai regrets that due to these restrictions we will not be able to offer a meal in conjunction with this event. Additionally, Eisai is required by Massachusetts, Vermont, Washington, DC, and the Federal Physician Payment Sunshine Act to disclose certain value transfers, e.g., meals, provided to certain health care professionals. If you have questions regarding how Eisai tracks and reports this information, please contact Eisai at 1-855-643-4328.

This invitation is intended for the recipient only; spouses or other guests are not permitted to attend Speaker Programs. This promotional event is sponsored by Eisai and the speaker is a paid consultant presenting on behalf of Eisai. The information being presented by the speaker is consistent with the FDA guidelines.

Indication

LENVIMA® (lenvatinib) is indicated for the treatment of patients with locally recurrent or metastatic, progressive,radioactive iodine-refractory differentiated thyroid cancer (RAI-refractory DTC).

Selected Safety Information

Warnings and Precautions

- Hypertension was reported in 73% of patients on LENVIMA vs 16% with placebo (44% vs 4% grade ≥3). Blood pressure should be controlled prior to treatment and monitored throughout. Withhold dose for grade 3 hypertension despite optimal antihypertensive therapy; resume at reduced dose when controlled at grade ≤2. Discontinue for life-threatening hypertension

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

LENVIMA® (lenvatinib) capsules 10 mg and 4 mg

Selected Safety Information (cont'd)

Warnings and Precautions

- Cardiac dysfunction was reported in 7% of patients on LENVIMA vs 2% with placebo (2% vs 0% grade ≥3). Monitor for signs/symptoms of cardiac decompensation. Withhold LENVIMA for development of grade 3 cardiac dysfunction until improvement to grade 0, 1, or baseline. Resume at reduced dose or discontinue based on severity and persistence of cardiac dysfunction. Discontinue for grade 4 cardiac dysfunction
- Arterial thromboembolic events were reported in 5% of patients on LENVIMA vs 2% with placebo (3% vs 1% grade ≥3). Discontinue following an arterial thrombotic event. The safety of resuming LENVIMA after an arterial thromboembolic event has not been established, and LENVIMA has not been studied in patients who have had an arterial thromboembolic event within the previous 6 months
- Across clinical studies in which 1,160 patients received LENVIMA monotherapy, hepatic failure (including fatal events) was reported in 3 patients and acute hepatitis in 1 patient. ALT and AST increases (grade ≥3) occurred in 4% and 5% of patients on LENVIMA, respectively, vs 0% with placebo. Monitor liver function before initiation, then every 2 weeks for the first 2 months, and at least monthly thereafter during treatment. Withhold dose for liver impairment grade ≥3 until resolved to grade 0, 1, or baseline. Resume at reduced dose or discontinue based on severity/persistence of hepatotoxicity. Discontinue for hepatic failure
- Proteinuria was reported in 34% of patients on LENVIMA vs 3% with placebo (11% vs 0% grade 3). Monitor for proteinuria before and during treatment. Withhold dose for proteinuria ≥2 g/24 h. Resume at reduced dose when proteinuria is <2 g/24 h. Discontinue for nephrotic syndrome
- Initiate prompt medical management for the development of diarrhea. Monitor for dehydration. Withhold dose for diarrhea grade ≥3. Resume at a reduced dose when diarrhea resolves to grade 1 or baseline. Permanently discontinue LENVIMA for grade 4 diarrhea despite medical management
- Events of renal impairment were reported in 14% of patients on LENVIMA vs 2% with placebo (3% vs 1% grade ≥3). Withhold LENVIMA for grade 3 or 4 renal failure/impairment. Resume at reduced dose or discontinue, depending on severity/persistence of renal impairment. Active management of diarrhea and any other gastrointestinal (GI) symptoms should be initiated for grade 1 events
- Events of GI perforation or fistula were reported in 2% of patients on LENVIMA vs 0.8% with placebo. Discontinue in patients who develop GI perforation or life-threatening fistula
- QT/QTc interval prolongation was reported in 9% of patients on LENVIMA vs 2% with placebo (2% vs 0% >500 ms). Monitor electrocardiograms in patients with congenital long QT syndrome, congestive heart failure, bradyarrhythmias, or patients taking drugs known to prolong the QT interval. Monitor and correct electrolyte abnormalities in all patients. Withhold dose for QTc interval prolongation >500 ms. Resume at reduced dose when QTc prolongation resolves to baseline
- Hypocalcemia (grade ≥3) was reported in 9% of patients on LENVIMA vs 2% with placebo. Monitor blood calcium levels at least monthly and replace calcium as necessary. Interrupt and adjust LENVIMA as necessary
- Across clinical studies in which 1,160 patients received LENVIMA monotherapy, reversible posterior leukoencephalopathy syndrome (RPLS) was reported in 4 patients. Withhold LENVIMA for RPLS until fully resolved. Resume at reduced dose or discontinue based on the severity and persistence of neurologic symptoms
- Across clinical studies in which 1,160 patients received LENVIMA monotherapy, hemorrhage (grade ≥3) was reported in 2% of patients. Hemorrhagic events occurred in 35% of patients on LENVIMA vs 18% with placebo (2% vs 3% grade ≥3). There was 1 fatal intracranial hemorrhage case among 16 patients who received LENVIMA and had central nervous system metastases at baseline. The most frequently reported hemorrhagic event was epistaxis (11% grade 1, 1% grade 2). Discontinuation due to hemorrhagic events occurred in 1% of patients on LENVIMA. Consider the risk of severe or fatal hemorrhage associated with tumor invasion/infiltration of major blood vessels (eg, carotid artery). Withhold LENVIMA for the development of grade 3 hemorrhage until resolved to grade 0 or 1. Resume at reduced dose or discontinue based on severity/persistence of hemorrhage. Discontinue for grade 4 hemorrhage
- In patients with normal baseline thyroid-stimulating hormone (TSH), elevation of TSH level above 0.5 mU/L was observed postbaseline in 57% of patients on LENVIMA vs 14% with placebo. Monitor thyroid function before initiation of and at least monthly throughout treatment. Treat hypothyroidism according to standard medical practice to maintain a euthyroid state
- LENVIMA can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with LENVIMA and for at least 2 weeks following completion of therapy

Adverse Reactions

- The most common adverse reactions (≥30%) observed in LENVIMA-treated patients vs placebo-treated patients were hypertension (73% vs 16%), fatigue (67% vs 35%), diarrhea (67% vs 17%), arthralgia/myalgia (62% vs 28%), decreased appetite (54% vs 18%), weight decrease (51% vs 15%), nausea (47% vs 25%), stomatitis (41% vs 8%), headache (38% vs 11%), vomiting (36% vs 15%), proteinuria (34% vs 3%), palmar-plantar erythrodysesthesia syndrome (32% vs 1%), abdominal pain (31% vs 11%), and dysphonia (31% vs 5%)
- Adverse reactions led to dose reductions in 68% of patients receiving LENVIMA and in 5% of patients receiving placebo; 18% of patients discontinued LENVIMA and 5% discontinued placebo for adverse reactions. The most common adverse reactions (≥10%) resulting in dose reductions of LENVIMA were hypertension (13%), proteinuria (11%), decreased appetite (10%), and diarrhea (10%); the most common adverse reactions (≥1%) resulting in discontinuation of LENVIMA were hypertension (1%) and asthenia (1%)

Use in Specific Populations

- Because of the potential for serious adverse reactions in nursing infants, advise women to discontinue breastfeeding during treatment
- LENVIMA may result in reduced fertility in females of reproductive potential and may result in damage to male reproductive tissues, leading to reduced fertility of unknown duration

Learn more about LENVIMA at www.LENVIMA.com/hcp

Please see Selected Safety Information throughout and accompanying full Prescribing Information.

LENVIMA® (lenvatinib) capsules 10 mg and 4 mg