LENVIMA®: Efficacy that drives results

Offering more time without disease progression[1]

- **Superior 18.3-month median PFS** (95% CI: 15.1-NE) was observed with LENVIMA vs 3.6 months (95% CI: 2.2-3.7) with placebo (HR: 0.21 [95% CI: 0.16-0.28]; *P*<0.001); primary endpoint[1]
  - Number of events: 107 (41%) with LENVIMA vs 113 (86%) with placebo

NCCN PREFERRED FIRST-LINE SYSTEMIC THERAPY OPTION (CATEGORY 1)*

Lenvatinib (LENVIMA) is the only category 1 preferred first-line systemic therapy option by the National Comprehensive Cancer Network® (NCCN®) for locally recurrent or metastatic, progressive radioactive iodine-refractory differentiated thyroid cancer†

*Category 1 recommendation is based on high-level evidence. There is uniform NCCN consensus that the intervention is appropriate.

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INDICATION

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

SUMMARY OF WARNINGS AND PRECAUTIONS

Adverse reactions, some of which can be serious or fatal, may occur with LENVIMA, including hypertension, cardiac dysfunction, arterial thromboembolic events, hepatotoxicity, renal failure or impairment, proteinuria, diarrhea, fistula formation and gastrointestinal perforation, QT interval prolongation, hypocalcemia, reversible posterior leukoencephalopathy syndrome, hemorrhagic events, impairment of thyroid stimulating hormone suppression/thyroid dysfunction, impaired wound healing, osteonecrosis of the jaw, and embryo-fetal toxicity. Based on its mechanism of action and data from animal reproduction studies, LENVIMA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception. Based on the severity of the adverse reaction, LENVIMA should be interrupted, reduced, and/or discontinued.

NCCN=National Comprehensive Cancer Network® (NCCN®).
PFS=progression-free survival; CI=confidence interval; NE=not estimable; HR=hazard ratio.

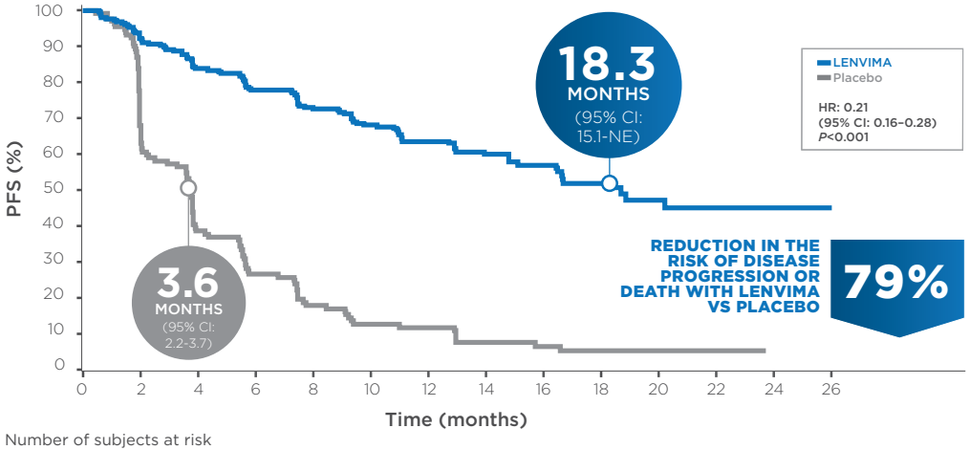
Please see Selected Safety Information throughout and full Prescribing Information

LENVIMA® (lenvatinib) capsules 10 mg and 4 mg

PRIMARY ENDPOINT

Superior PFS benefit

Median PFS: 18.3 months with LENVIMA® vs 3.6 months with placebo[1]



Number of subjects at risk

LENVIMA	261	225	198	176	159	148	136	92	66	44	24	11	3	0
Placebo	131	71	43	29	19	13	11	5	4	2	2	2	0	0

- 107 events (41%) occurred in the LENVIMA arm vs 113 events (86%) in the placebo arm[1]
  - 93 patients (36%) who received LENVIMA progressed vs 109 patients (83%) who received placebo
  - Death occurred in 14 patients (5%) who received LENVIMA vs 4 patients (3%) who received placebo

SELECT study design

SELECT study results based on a phase 3, multicenter, randomized, double-blind, placebo-controlled trial in patients with locally recurrent or metastatic RAI-refractory DTC (N=392) who have had radiographic evidence of disease progression within 12 months prior to randomization as confirmed by independent radiologic review. The primary endpoint was PFS as determined by blinded independent radiologic review using Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. Secondary endpoints included objective response rate and overall survival.[1,2]

SELECTED SAFETY INFORMATION

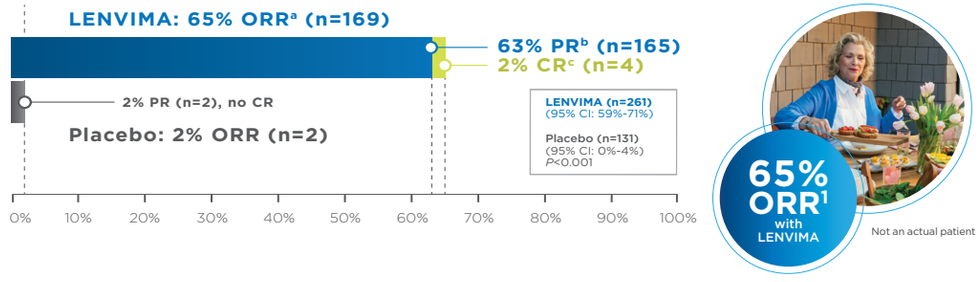
Warnings and Precautions

Hypertension. In DTC (differentiated thyroid cancer), hypertension occurred in 73% of patients on LENVIMA (44% grade 3-4). In RCC (renal cell carcinoma), hypertension occurred in 42% of patients on LENVIMA + everolimus (13% grade 3). Systolic blood pressure ≥160 mmHg occurred in 29% of patients, and 21% had diastolic blood pressure ≥100 mmHg. In HCC (hepatocellular carcinoma), hypertension occurred in 45% of LENVIMA-treated patients (24% grade 3). Grade 4 hypertension was not reported in HCC.

SECONDARY ENDPOINT

Superior response

65% ORR[a] with LENVIMA vs 2% ORR with placebo[1,2]



- First TKI to demonstrate a complete response in a phase 3 trial for locally recurrent or metastatic, progressive RAI-refractory DTC[1-3]

Median OS was not estimable at data cutoff (HR: 0.73 [95% CI: 0.50-1.07]; *P*=0.10).[1]

- 83% (109/131) of placebo-treated patients with confirmed disease progression crossed over to receive LENVIMA in the open-label extension phase (data cutoff: November 15, 2013)[1,2]

PFS=progression-free survival; CI=confidence interval; NE=not estimable; HR=hazard ratio; SELECT=**S**tudy of (**E**7080) **LE**nvatinib in Differentiated **C**ancer of the **T**hyroid; RAI=radioactive iodine; DTC=differentiated thyroid cancer; ORR=objective response rate; TKI=tyrosine kinase inhibitor; OS=overall survival.

Responses evaluated using RECIST 1.1.[2]

P<0.001, according to the Cochran–Mantel–Haenszel chi-square test.[1]

[a]Objective response rate (ORR)=sum of CR and PR.[1,4]

[b]Partial response (PR)=30% or greater decrease in the sum of diameters of target lesions.[4]

[c]Complete response (CR)=disappearance of all target and nontarget lesions.[4]

SELECTED SAFETY INFORMATION

Warnings and Precautions (cont'd)

Hypertension (cont'd). Serious complications of poorly controlled hypertension have been reported. Control blood pressure prior to initiation. Monitor blood pressure after 1 week, then every 2 weeks for the first 2 months, and then at least monthly thereafter during treatment. Withhold and resume at reduced dose when hypertension is controlled or permanently discontinue based on severity.

Cardiac Dysfunction. Serious and fatal cardiac dysfunction can occur with LENVIMA. Across clinical trials in 799 patients with DTC, RCC, and HCC, grade 3 or higher cardiac dysfunction occurred in 3% of LENVIMA-treated patients. Monitor for clinical symptoms or signs of cardiac dysfunction. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

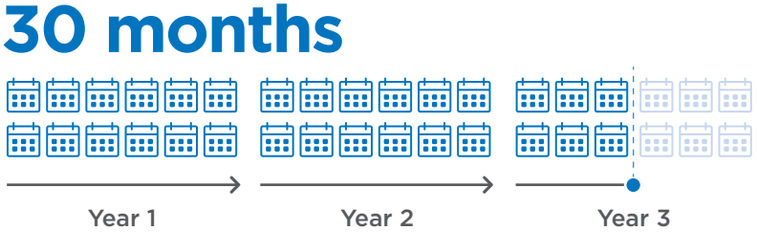
Arterial Thromboembolic Events. Among patients receiving LENVIMA or LENVIMA + everolimus, arterial thromboembolic events of any severity occurred in 2% of patients in RCC and HCC and 5% in DTC. Grade 3-5 arterial thromboembolic events ranged from 2% to 3% across all clinical trials.

Post hoc data

Duration of response analysis

30-month (95% CI: 18.4-36.7) median duration of response among patients who responded to LENVIMA[5]

Not actual patients



- Post hoc analysis (n=261) was conducted based on investigator-assessed response; 157 patients (60.2%) in the LENVIMA arm responded per investigator assessment[5]

Limitations: the post hoc exploratory subgroup analysis (data cutoff: September 1, 2016) was not a prespecified study endpoint. Patients who did not respond were not evaluated. No conclusions can be drawn.

SELECTED SAFETY INFORMATION

Warnings and Precautions (cont'd)

Arterial Thromboembolic Events (cont'd). Among patients receiving LENVIMA with pembrolizumab, arterial thrombotic events of any severity occurred in 5% of patients in CLEAR, including myocardial infarction (3.4%) and cerebrovascular accident (2.3%).

Permanently discontinue following an arterial thrombotic event. The safety of resuming 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.

Hepatotoxicity. Across clinical studies enrolling 1327 LENVIMA-treated patients with malignancies other than HCC, serious hepatic adverse reactions occurred in 1.4% of patients. Fatal events, including hepatic failure, acute hepatitis and hepatorenal syndrome, occurred in 0.5% of patients. In HCC, hepatic encephalopathy occurred in 8% of LENVIMA-treated patients (5% grade 3-5). Grade 3-5 hepatic failure occurred in 3% of LENVIMA-treated patients; 2% of patients discontinued LENVIMA due to hepatic encephalopathy, and 1% discontinued due to hepatic failure.

Monitor liver function prior to initiation, then every 2 weeks for the first 2 months, and at least monthly thereafter during treatment. Monitor patients with HCC closely for signs of hepatic failure, including hepatic encephalopathy. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Renal Failure or Impairment. Serious including fatal renal failure or impairment can occur with LENVIMA. Renal impairment was reported in 14% and 7% of LENVIMA-treated patients in DTC and HCC, respectively. Grade 3-5 renal failure or impairment occurred in 3% of patients with DTC and 2% of patients with HCC, including 1 fatal event in each study. In RCC, renal impairment or renal failure was reported in 18% of LENVIMA + everolimus–treated patients (10% grade 3).

Initiate prompt management of diarrhea or dehydration/hypovolemia. Withhold and resume at reduced dose upon recovery or permanently discontinue for renal failure or impairment based on severity.

Recognize, monitor, and manage ARs that may occur with LENVIMA®

Adverse reactions in the SELECT trial

- ARs led to dose reductions in 68% of patients receiving LENVIMA in the SELECT trial[1]
- Treatment discontinuation due to ARs occurred in 18% of patients receiving LENVIMA in the SELECT trial[1]

Most common ARs (≥30%) observed in LENVIMA-treated patients

- Hypertension (73%), fatigue (67%), diarrhea (67%), arthralgia/myalgia (62%), decreased appetite (54%), decreased weight (51%), nausea (47%), stomatitis (41%), headache (38%), vomiting (36%), proteinuria (34%), palmar-plantar erythrodysesthesia syndrome (32%), abdominal pain (31%), and dysphonia (31%)[1]

Most common serious ARs (≥2%) in the LENVIMA arm

- Pneumonia (4%), hypertension (3%), and dehydration (3%)[1]

Most common grade 3-4 ARs (≥5%)[1]

Adverse reaction	LENVIMA 24 mg (n=261)	Placebo (n=131)
Hypertension[a]	44%	4%
Decreased weight	13%	1%
Fatigue[b]	11%	4%
Proteinuria	11%	0%
Diarrhea	9%	0%
Decreased appetite	7%	1%
Arthralgia/myalgia[c]	5%	3%
Stomatitis[d]	5%	0%

No grade 4 diarrhea, hand-foot skin reaction, fatigue, or proteinuria.[6]

CI=confidence interval; AR=adverse reaction; SELECT=**S**tudy of (**E**7080) **LE**nvatinib in Differentiated **C**ancer of the **T**hyroid.

[a]Includes hypertension, hypertensive crisis, increased blood pressure diastolic, and increased blood pressure.
[b]Includes asthenia, fatigue, and malaise.
[c]Includes musculoskeletal pain, back pain, pain in extremity, arthralgia, and myalgia.
[d]Includes aphthous stomatitis, stomatitis, glossitis, mouth ulceration, and mucosal inflammation.

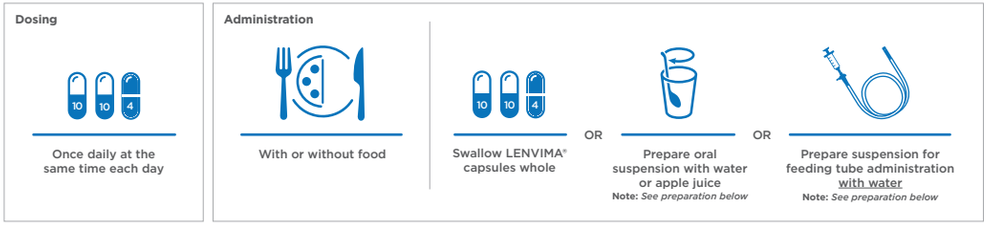
Please see Table 1 in the full Prescribing Information for Recommended Dosage Modifications for Adverse Reactions.

SELECTED SAFETY INFORMATION

Warnings and Precautions (cont'd)

Proteinuria. In DTC and HCC, proteinuria was reported in 34% and 26% of LENVIMA-treated patients, respectively. Grade 3 proteinuria occurred in 11% and 6% in DTC and HCC, respectively. In RCC, proteinuria occurred in 31% of patients receiving LENVIMA + everolimus (8% grade 3). Monitor for proteinuria prior to initiation and periodically during treatment. If urine dipstick proteinuria ≥2+ is detected, obtain a 24-hour urine protein. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Once a day. Every day. With or without food[1]



Capsules pictured are not actual size.

Recommended LENVIMA dose: **24 mg (two 10-mg capsules and one 4-mg capsule)**.[1]

Preparation of suspension:

- Place the required number of capsules, up to a maximum of 5, in a small container (approximately 20 mL capacity) or syringe (20 mL). Do not break or crush capsules
- Add 3 mL of liquid to the container or syringe. Wait 10 minutes for the capsule shell (outer surface) to disintegrate, then stir or shake the mixture for 3 minutes until capsules are fully disintegrated and administer the entire contents
- Next, add an additional 2 mL of liquid to the container or syringe using a second syringe or dropper, swirl or shake and administer. Repeat this step at least once and until there is no visible residue to ensure all of the medication is taken
- If 6 capsules are required for a dose, follow these instructions using 3 capsules at a time

If LENVIMA suspension is not used at the time of preparation, LENVIMA suspension may be stored in a refrigerator at 36°F to 46°F (2°C to 8°C) for a maximum of 24 hours in a covered container. If not administered within 24 hours, the suspension should be discarded.

Note: Compatibility has been confirmed for polypropylene syringes and for feeding tubes of at least 5 French diameter (polyvinyl chloride or polyurethane tube) and at least 6 French diameter (silicone tube).

SELECTED SAFETY INFORMATION

Warnings and Precautions (cont'd)

Diarrhea. Of the 737 LENVIMA-treated patients in DTC and HCC, diarrhea occurred in 49% (6% grade 3). In RCC, diarrhea occurred in 81% of LENVIMA + everolimus–treated patients (19% grade 3). Diarrhea was the most frequent cause of dose interruption/reduction, and diarrhea recurred despite dose reduction. Promptly initiate management of diarrhea. Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Fistula Formation and Gastrointestinal Perforation. Of the 799 patients treated with LENVIMA or LENVIMA + everolimus in DTC, RCC, and HCC, fistula or gastrointestinal perforation occurred in 2%. Permanently discontinue in patients who develop gastrointestinal perforation of any severity or grade 3-4 fistula.

QT Interval Prolongation. In DTC, QT/QTc interval prolongation occurred in 9% of LENVIMA-treated patients and QT interval prolongation of >500 ms occurred in 2%. In RCC, QTc interval increases of >60 ms occurred in 11% of patients receiving LENVIMA + everolimus and QTc interval >500 ms occurred in 6%. In HCC, QTc interval increases of >60 ms occurred in 8% of LENVIMA-treated patients and QTc interval >500 ms occurred in 2%.

Continue LENVIMA until disease progression or unacceptable toxicity.[1]

Recommended dose of LENVIMA® for severe renal or hepatic impairment[1]

In patients with:	Recommended dose:
Severe renal impairment (CrCl <30 mL/min)[a]	**14 mg (one 10-mg capsule + one 4-mg capsule) once daily**
Severe hepatic impairment (Child-Pugh C)	**14 mg (one 10-mg capsule + one 4-mg capsule) once daily**

- No dose adjustment is recommended in patients with mild or moderate renal or hepatic impairment.* LENVIMA has not been studied in patients with end-stage renal disease

*Mild renal impairment is defined as CrCl 60-89 mL/min and moderate renal impairment is defined as CrCl 30-59 mL/min.
[a]As calculated by the Cockcroft-Gault equation.

Missed doses of LENVIMA[1]

- LENVIMA should be taken at the same time each day
- If a dose is missed and cannot be taken within 12 hours, skip that dose and take the next dose at the usual time of administration

CrCl=creatinine clearance.

SELECTED SAFETY INFORMATION

Warnings and Precautions (cont'd)

QT Interval Prolongation (cont'd). Monitor and correct electrolyte abnormalities at baseline and periodically during treatment. Monitor electrocardiograms in patients with congenital long QT syndrome, congestive heart failure, bradyarrhythmias, or those who are taking drugs known to prolong the QT interval, including Class Ia and III antiarrhythmics. Withhold and resume at reduced dose upon recovery based on severity.

Hypocalcemia. In DTC, grade 3-4 hypocalcemia occurred in 9% of LENVIMA-treated patients. In 65% of cases, hypocalcemia improved or resolved following calcium supplementation with or without dose interruption or dose reduction. In RCC, grade 3-4 hypocalcemia occurred in 6% of LENVIMA + everolimus–treated patients. In HCC, grade 3 hypocalcemia occurred in 0.8% of LENVIMA-treated patients. Monitor blood calcium levels at least monthly and replace calcium as necessary during treatment. Withhold and resume at reduced dose upon recovery or permanently discontinue depending on severity.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS). Across clinical studies of 1823 patients who received LENVIMA as a single agent, RPLS occurred in 0.3%. Confirm diagnosis of RPLS with MRI. Withhold and resume at reduced dose upon recovery or permanently discontinue depending on severity and persistence of neurologic symptoms.

LENVIMA® (lenvatinib) capsules 10 mg and 4 mg

Selected Safety Information

Warnings and Precautions (cont'd)

Hemorrhagic Events. Serious including fatal hemorrhagic events can occur with LENVIMA®. In DTC, RCC, and HCC clinical trials, hemorrhagic events, of any grade, occurred in 29% of the 799 patients treated with LENVIMA as a single agent or in combination with everolimus. The most frequently reported hemorrhagic events (all grades and occurring in at least 5% of patients) were epistaxis and hematuria. In DTC, grade 3-5 hemorrhage occurred in 2% of LENVIMA-treated patients, including 1 fatal intracranial hemorrhage among 16 patients who received LENVIMA and had CNS metastases at baseline. In RCC, grade 3-5 hemorrhage occurred in 8% of LENVIMA + everolimus–treated patients, including 1 fatal cerebral hemorrhage. In HCC, grade 3-5 hemorrhage occurred in 5% of LENVIMA-treated patients, including 7 fatal hemorrhagic events. Serious tumor-related bleeds, including fatal hemorrhagic events, occurred in LENVIMA-treated patients in clinical trials and in the postmarketing setting. In postmarketing surveillance, serious and fatal carotid artery hemorrhages were seen more frequently in patients with anaplastic thyroid carcinoma (ATC) than other tumors. Safety and effectiveness of LENVIMA in patients with ATC have not been demonstrated in clinical trials.

Consider the risk of severe or fatal hemorrhage associated with tumor invasion or infiltration of major blood vessels (eg, carotid artery). Withhold and resume at reduced dose upon recovery or permanently discontinue based on severity.

Impairment of Thyroid Stimulating Hormone Suppression/Thyroid Dysfunction. LENVIMA impairs exogenous thyroid suppression. In DTC, 88% of patients had baseline thyroid stimulating hormone (TSH) level ≤0.5 mU/L. In patients with normal TSH at baseline, elevation of TSH level >0.5 mU/L was observed post baseline in 57% of LENVIMA-treated patients. In RCC and HCC, grade 1 or 2 hypothyroidism occurred in 24% of LENVIMA + everolimus–treated patients and 21% of LENVIMA-treated patients, respectively. In patients with normal or low TSH at baseline, elevation of TSH was observed post baseline in 70% of LENVIMA-treated patients in HCC and 60% of LENVIMA + everolimus–treated patients in RCC.

Monitor thyroid function prior to initiation and at least monthly during treatment. Treat hypothyroidism according to standard medical practice.

Impaired Wound Healing. Impaired wound healing has been reported in patients who received LENVIMA. Withhold LENVIMA for at least 1 week 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 LENVIMA after resolution of wound healing complications has not been established.

Osteonecrosis of the Jaw (ONJ). ONJ has been reported in patients receiving LENVIMA. Concomitant exposure to other risk factors, such as bisphosphonates, denosumab, dental disease, or invasive dental procedures, may increase the risk of ONJ.

Perform an oral examination prior to treatment with LENVIMA and periodically during LENVIMA treatment. Advise patients regarding good oral hygiene practices and to consider having preventive dentistry performed prior to treatment with LENVIMA and throughout treatment with LENVIMA.

Avoid invasive dental procedures, if possible, while on LENVIMA treatment, particularly in patients at higher risk. Withhold LENVIMA for at least 1 week prior to scheduled dental surgery or invasive dental procedures, if possible. For patients requiring invasive dental procedures, discontinuation of bisphosphonate treatment may reduce the risk of ONJ.

Withhold LENVIMA if ONJ develops and restart based on clinical judgement of adequate resolution.

Embryo-Fetal Toxicity. Based on its mechanism of action and data from animal reproduction studies, LENVIMA can cause fetal harm when administered to pregnant women. In animal reproduction studies, oral administration of lenvatinib during organogenesis at doses below the recommended clinical doses resulted in embryotoxicity, fetotoxicity, and teratogenicity in rats and rabbits. Advise pregnant women of the potential risk to a fetus and advise females of reproductive potential to use effective contraception during treatment with LENVIMA and for 30 days after the last dose.

Adverse Reactions

In DTC, the most common adverse reactions (≥30%) observed in LENVIMA-treated patients were hypertension (73%), fatigue (67%), diarrhea (67%), arthralgia/myalgia (62%), decreased appetite (54%), decreased weight (51%), nausea (47%), stomatitis (41%), headache (38%), vomiting (36%), proteinuria (34%), palmar-plantar erythrodysesthesia syndrome (32%), abdominal pain (31%), and dysphonia (31%). The most common serious adverse reactions (≥2%) were pneumonia (4%), hypertension (3%), and dehydration (3%). Adverse reactions led to dose reductions in 68% of LENVIMA-treated patients; 18% discontinued LENVIMA. The most common adverse reactions (≥10%) resulting in dose reductions 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 breastfed children, advise women to discontinue breastfeeding during treatment and for 1 week after the last dose. LENVIMA may impair fertility in males and females of reproductive potential.

No dose adjustment is recommended for patients with mild (CLcr 60-89 mL/min) or moderate (CLcr 30-59 mL/min) renal impairment. LENVIMA concentrations may increase in patients with DTC, RCC, or EC (endometrial carcinoma) and severe (CLcr 15-29 mL/min) renal impairment. Reduce the dose for patients with DTC, RCC, or EC and severe renal impairment. There is no recommended dose for patients with HCC and severe renal impairment. LENVIMA has not been studied in patients with end-stage renal disease.

No dose adjustment is recommended for patients with HCC and mild hepatic impairment (Child-Pugh A). There is no recommended dose for patients with HCC with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment. No dose adjustment is recommended for patients with DTC, RCC, or EC and mild or moderate hepatic impairment. LENVIMA concentrations may increase in patients with DTC, RCC, or EC and severe hepatic impairment. Reduce the dose for patients with DTC, RCC, or EC and severe hepatic impairment.

References: 1. LENVIMA [package insert]. Nutley, NJ: Eisai Inc. **2.** Schlumberger M, Tahara M, Wirth LJ, et al. Lenvatinib versus placebo in radioiodine-refractory thyroid cancer. *N Engl J Med*. 2015;372(7):621-630. **3.** NEXAVAR [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; 2020. **4.** Eisenhauer, EA, Therasse P, Bogaerts J, et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). *Eur J Cancer*. 2009;45(2):228-247. **5.** Gianoukakis AG, Dutcus CE, Batty N, Guo M, Baig M. Prolonged duration of response in lenvatinib responders with thyroid cancer. *Endocr Relat Cancer*. 2018;25(6):699-704. **6.** Haddad RI, Schlumberger M, Wirth LJ, et al. Incidence and timing of common adverse events in lenvatinib-treated patients from the SELECT trial and their association with survival outcomes. *Endocrine*. 2017;56(1):121-128.

See how LENVIMA® can drive results for your patients with RAI-R DTC

Superior PFS benefit

18.3 months median PFS[1]*

18.3 months median PFS: (95% CI: 15.1-NE) with LENVIMA vs 3.6 months (95% CI: 2.2-3.7) with placebo (HR: 0.21 [95% CI: 0.16-0.28]; *P*<0.001)

Superior response

65% ORR† with LENVIMA (including 2% CR‡)[1,2§]

65% ORR: (95% CI: 59%-71%) vs 2% ORR (95% CI: 0%-4%) with placebo (no CR); *P*<0.001

Median OS was not estimable at data cutoff[1§] (HR: 0.73 [95% CI: 0.50-1.07]; *P*=0.10)

- 83% (109/131) of placebo-treated patients with confirmed disease progression crossed over to receive LENVIMA in the open-label extension phase (data cutoff: November 15, 2013)[1,2]

NCCN PREFERRED FIRST-LINE SYSTEMIC THERAPY OPTION (CATEGORY 1)‖

Lenvatinib (LENVIMA) is the only category 1 preferred first-line systemic therapy option by the National Comprehensive Cancer Network® (NCCN®) for locally recurrent or metastatic, progressive radioactive iodine-refractory differentiated thyroid cancer¶

*Primary endpoint.

†Objective response rate (ORR)=sum of CR and PR.[1,4]

‡Complete response (CR)=disappearance of all target and nontarget lesions.[4]

§Secondary endpoint.

‖Category 1 recommendation is based on high-level evidence. There is uniform NCCN consensus that the intervention is appropriate.

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INDICATION

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

SUMMARY OF WARNINGS AND PRECAUTIONS

Adverse reactions, some of which can be serious or fatal, may occur with LENVIMA, including hypertension, cardiac dysfunction, arterial thromboembolic events, hepatotoxicity, renal failure or impairment, proteinuria, diarrhea, fistula formation and gastrointestinal perforation, QT interval prolongation, hypocalcemia, reversible posterior leukoencephalopathy syndrome, hemorrhagic events, impairment of thyroid stimulating hormone suppression/thyroid dysfunction, impaired wound healing, osteonecrosis of the jaw, and embryo-fetal toxicity. Based on its mechanism of action and data from animal reproduction studies, LENVIMA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception. Based on the severity of the adverse reaction, LENVIMA should be interrupted, reduced, and/or discontinued.

RAI-R=radioactive iodine refractory; DTC=differentiated thyroid cancer; PFS=progression-free survival; CI=confidence interval; NE=not estimable; HR=hazard ratio; PR=partial response.

Discover more about LENVIMA

lenvimahcp.com/rai-refractory-differentiated-thyroid-cancer

Please see Selected Safety Information throughout and full Prescribing Information

Eisai

May 2023 LENV-US9388

LENVIMA® (lenvatinib) capsules 10 mg and 4 mg