ינואר 2025

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

<u>הנדון: לנוויממה 4 מ"ג, 10 מ"ג- Lenvima 4 mg, 10mg, Hard Capsule</u>

חברת אסאיי ישראל בע"מ (Eisai Israel Ltd.) מבקשת להודיעכם כי העלון לרופא של התכשירים שלהלן התעדכן בינואר 2025.

Lenvima 4 mg
Lenvima 10mg

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום).

ההתוויות המאושרות לתכשיר בישראל:

LENVIMA is indicated for the treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC) refractory to radioactive iodine (RAI).
LENVIMA is indicated in combination with everolimus for the treatment of adult patients with advanced clear cell renal cell carcinoma (RCC) following one prior vascular endothelial growth factor (VEGF)-targeted therapy.
LENVIMA is indicated as monotherapy for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have received no prior systemic therapy.
Lenvima, in combination with pembrolizumab, is indicated for the treatment of adult patients with advanced or recurrent endometrial carcinoma who have disease progression on or following prior treatment with a platinum containing therapy and who are not candidates for curative surgery or radiation.
LENVIMA is indicated in combination with pembrolizumab for the first-line treatment of adult patients with advanced RCC.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות ומצורף לפרסום זה. כמו כן, ניתן לקבל העתק מודפס באמצעות פנייה לבעל הרישום: אסאיי ישראל בע"מ, ת.ד. 3393 פתח תקווה, 4951600.

להלן העדכונים בעלון לרופא:

4.8 Undesirable effects

Paediatric population

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In patients with relapsed/refractory osteosarcoma, pneumothorax was reported at a frequency higher than that observed in adults with DTC, HCC, RCC and EC. In Study 207, pneumothorax

occurred in 6 patients (10.9%) treated with single -agent lenvatinib and 7 patients (16.7%) treated with lenvatinib in combination with ifosfamide and etoposide. Overall, 2 patients discontinued study treatment due to pneumothorax. In Study 230, pneumothorax was reported in a total of 14 patients (11 patients [28.2%] treated with lenvatinib plus ifosfamide and etoposide, and 3 patients [7.7%] treated with ifosfamide and etoposide).

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5.1 Pharmacodynamic properties

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The OLIE study (Study 230) was a Phase 2, open-label, multi-centre, randomized, controlled trial in patients (aged 2 to ≤25 years) with relapsed or refractory osteosarcoma. A total of 81 patients were randomized in a 1:1 ratio (78 treated; 39 in each arm) to lenvatinib 14 mg/m2 in combination with ifosfamide 3000 mg/m2 and etoposide 100 mg/m2 (Arm A) or ifosfamide 3000 mg/m2 and etoposide 100 mg/m2 (Arm B). Ifosfamide and etoposide were administered intravenously on Days 1 to 3 of each 21-day cycle for a maximum of 5 cycles. Treatment with lenvatinib was permitted until RECIST v1.1-defined disease progression as verified by Blinded Independent Central Review (BICR) or unacceptable toxicity. The primary efficacy outcome measure was progression-free survival (PFS) per RECIST 1.1 by BICR. The trial did not demonstrate a statistically significant difference in median PFS: 6.5 months (95%CI: 5.7, 8.2) for lenvatinib in combination with ifosfamide and etoposide versus 5.5 months (95%CI: 2.9, 6.5) for ifosfamide and etoposide (HR=0.54 [95%CI: 0.27, 1.08]). Study 230 was not powered to detect a statistically significant difference in OS. At the end of study analysis, the HR was 0.93 (95% CI: 0.53, 1.62) for the comparison of lenvatinib in combination with ifosfamide and etoposide versus ifosfamide and etoposide, with median OS 12.4 months (95% CI 10.4, 19.8) versus 17.2 months (95% CI 11.1, 22.3), respectively, and median follow-up time 24.1 months and 29.5 months, respectively.

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בברכה,

אלינה ורמן,

רוקחת ממונה

אסאיי ישראל בע"מ