NOVARTIS

TAF MEK melanoma - Efficacy - HCP

Prescribing information

Image

Image

Efficacy of TAFINLAR® (dabrafenib) + MEKINIST® (trametinib)

TAFINLAR in combination with MEKINIST is indicated in adult patients with unresectable or metastatic melanoma with a *BRAF* V600 mutation.[1,2]

TAFINLAR in combination with MEKINIST is indicated for the adjuvant treatment of adult patients with Stage III melanoma with a *BRAF* V600 mutation, following complete resection.[1,2]

Common adverse events include:

- TAFINLAR + MEKINIST: The most common adverse reactions (incidence ≥20%) for dabrafenib in combination with trametinib were pyrexia, fatigue, nausea, chills, headache, diarrhoea, vomiting, arthralgia and rash[1,2]

- TAFINLAR: The most common adverse reactions (incidence >15%) reported with dabrafenib were hyperkeratosis, headache, pyrexia, arthralgia, fatigue, nausea, papilloma, alopecia, rash and vomiting[1]

- MEKINIST: The most common adverse reactions (incidence ≥20%) for trametinib were rash, diarrhoea, fatigue, oedema peripheral, nausea and dermatitis acneiform[2]

For more safety information on TAFINLAR and MEKINIST, click here.

For the full safety profile, please refer to the Summary of Product Characteristics (SmPC) for TAFINLAR and MEKINIST.

Adverse event reporting: Details of how to report adverse events are available at the bottom of the page. Please refer to the respective SmPC for all licensed indications.

Durable 5-year survival responses in metastatic melanoma

Pooled data of two large Phase III trials (N=563): COMBI-v* (vs vemurafenib) and COMBI-d (vs dabrafenib)† demonstrate a long-term PFS response with TAFINLAR + MEKINIST, that is maintained over 5 years (Year 2: 31%, Year 3: 24%, Year 4: 21%, Year 5: 19%).

- COMBI-v (n=704): The mPFS was significantly higher at 11.4 months with the combination group compared with 7.3 months for vemurafenib (HR=0.56 [95% CI: 0.46–0.69]; p<0.001)[4]

- COMBI-d (n=423): The mPFS was 9.3 months in the combination group and 8.8 months in the TAFINLAR-only group (HR=0.75 [95% CI: 0.57–0.99]; p=0.03)[5]

Select the COMBI-v & -d, COMBI-v, COMBI-d and COMBI-MB options below to discover more about TAFINLAR + MEKINIST efficacy in key studies of metastatic melanoma.[3–6]

In the extended follow-up of the COMBI-AD trial (N=870),‡ adjuvant TAFINLAR + MEKINIST led to a durable relapse-free survival rate at 5 years vs placebo in eligible patients with Stage III melanoma (52% vs 36%; HR=0.51 [95% CI: 0.42–0.61])[5]

Data demonstrate that the combination of TAFINLAR + MEKINIST offers patients a chance for **durable** RFS at 5 years (52% vs 36% in the placebo arm; HR=0.51 [95% CI:

0.42–0.61]).[7,8]

Select the COMBI-AD option below to learn more about TAFINLAR + MEKINIST efficacy as an adjuvant therapy

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*__COMBI-v__ (N=704) was an open-label, randomised Phase III study that assessed patients with *BRAF* V600 mutation-positive unresectable or metastatic melanoma, the comparator *BRAF* inhibitor was vemurafenib monotherapy. Primary endpoint was OS. Secondary endpoints included PFS, ORR, DOR and safety profile.[4]
†__COMBI-d__ (N=423) was a double-blind, randomised Phase III trial that assessed 1L patients with unresectable (Stage IIIC) or metastatic (Stage IV) *BRAF* V600E/K mutation-positive cutaneous melanoma. The comparator was TAFINLAR + placebo. The primary endpoint was PFS. Secondary endpoints included OS, ORR, DOR, safety profile and pharmacokinetics.[5]
‡__COMBI-AD__ (N=870) was a double-blind, placebo-controlled, Phase III trial in patients with Stage III (Stage IIIA [lymph node metastasis ≥1 mm], IIIB, or IIIC) cutaneous melanoma with a *BRAF* V600 E/K mutation, following complete resection. Patients received either oral TAFINLAR at a dose of 150 mg twice daily plus MEKINIST at a dose of 2 mg once daily (combination therapy, 438 patients) or two matched placebo tablets (432 patients) for 12 months. The primary endpoint was relapse-free survival. Secondary endpoints included OS, DMFS, RFS, and safety profile.[7]

1L, first-line; *BRAF* V600 (E/K), mutation of the *BRAF* gene in which valine (V) is substituted at amino acid 600 with either glutamate (E) or lysine (K); DMFS, distant metastasis-free survival; DOR, duration of response; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; RFS, relapse-free survival; SmPC, summary of product characteristics.

References

1. TAFINLAR (dabrafenib) Summary of Product Characteristics.
2. MEKINIST (trametinib) Summary of Product Characteristics.
3. Robert C, et al. *N Engl J Med* 2019;381:626–636.
4. Robert C, et al. *N Engl J Med* 2015;372:30–39.
5. Long GV, et al. *N Engl J Med* 2014;371:1877–1888.
6. Davies MA, et al. *Lancet Oncol* 2017;18:863–873.
7. Dummer R, et al. *N Engl J Med* 2020;383(12):1139–1148.

8. Long GV, et al. *N Engl J Med* 2017;377:1813–1823.

Pooled COMBI-v and COMBI-d efficacy

Pooled COMBI-v and COMBI-d efficacy

See more details

Hide details

COMBI-AD efficacy

COMBI-AD efficacy

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.
