14 September 2023
EMA/CHMP/402638/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Finlee

dabrafenib

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Finlee[2], intended for the treatment of low- and high-grade glioma (LGG and HGG). The applicant for this medicinal product is Novartis Europharm Limited.

Finlee will be available as a 10 mg dispersible tablet. The active substance of Finlee is dabrafenib, a protein kinase inhibitor (ATC code: L01EC02) which inhibits RAF kinases. Oncogenic *BRAF* mutations lead to constitutive activation of the RAS/RAF/MEK/ERK pathway, and are implicated in cell cycle progression, cell proliferation and arresting apoptosis. The most commonly observed *BRAF* mutation is V600E, which has been identified in 19% of paediatric LGG and approximately 5% of paediatric HGG.

The benefits of Finlee in combination with trametinib are an increased overall response rate (ORR; 46.6% vs 10.8%) and progression free survival (PFS; 20.1 vs 7.4 months) compared to carboplatin and vincristine chemotherapy for LGG, and an ORR of 56.1% and duration of response (DOR) of 22.2 months measured in a single-arm trial for HGG. The most common side effects of dabrafenib in combination with trametinib were pyrexia, rash, headache, vomiting, fatigue, dry skin, diarrhoea, haemorrhage, nausea, dermatitis acneiform, neutropenia, abdominal pain and cough.

The full indication is:

> Low-grade glioma
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> Finlee in combination with trametinib is indicated for the treatment of paediatric patients aged 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.
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> High-grade glioma
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> Finlee in combination with trametinib is indicated for the treatment of paediatric patients aged

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1 year and older with high-grade glioma (HGG) with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment.

Finlee should be initiated and supervised by a qualified physician experienced in the use of anti-cancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.