MELANOMA
Management Matters

ESMO 2014 Industry Satellite Symposium

Long-term patient outcomes with BRAF inhibitors in metastatic melanoma: Evidence and experience

Monday 29 September 2014 | 18:00–19:30

San Sebastian Auditorium, IFEMA
Madrid, Spain

Not intended for US healthcare professionals
A GSK-sponsored promotional symposium
For prescribing information, see below
Full summary of product characteristics will be available at the symposium and the booth

Faculty


Paul Nathan


Paolo Ascierto


Caroline Robert


Salvador Martin Algarra

Programme

18:00–18:05 **Chair's welcome:**
Evolution of patient-centric decision-making in metastatic melanoma
Paul Nathan, UK

18:05–18:25 **Long-term outcomes with BRAF inhibitors in metastatic melanoma: An evidence update**
Paolo Ascierto, Italy

18:25–19:10 **Talking points:**
- **How do we interpret the evidence on long-term outcomes with BRAF inhibitors?**
- **Can we predict long-term outcomes with BRAF inhibitors?**
- **What are the implications of using long-term evidence on BRAF inhibitors for treatment selection?**

Paul Nathan, UK
Caroline Robert, France
Salvador Martin Algarra, Spain
Paolo Ascierto, Italy

19:10–19:25 **Ask the experts: Your questions answered**
Paul Nathan, UK

19:25–19:30 **Summary and close**
Paul Nathan, UK

Prescribing Information

(Please refer to full SmPC before prescribing)

Tafinlar® ▼ (dabrafenib) 50mg and 75mg capsules. Each capsule contains dabrafenib mesilate, equivalent to 50mg and 75mg of dabrafenib, respectively. **Indication** In monotherapy for adults with unresectable or metastatic melanoma with a BRAF V600 mutation. **Dosage and administration** Before taking dabrafenib, patients must have confirmation of BRAF V600 mutation using a validated test. 150mg twice daily (b.d.) with interval of ~12hrs between doses (max. total daily dose 300mg), taken until patient no longer derives benefit or develops unacceptable toxicity. Take ≥1 hour before or ≥2 hours after a meal, at similar times every day. Swallow capsules whole with water; do not chew, crush or mix with food/liquids. If dose is missed, do not take if <6 hours until next dose. *Dose modification:* Management of ADRs may require treatment interruption, dose reduction or discontinuation. 1st reduction: 100mg b.d., 2nd reduction: 75mg b.d., 3rd reduction: 50mg b.d. (min. dose). Consider dose re-escalation following same dosing steps as de-escalation when ADR under effective management. *Renal impairment:* No dose adjustment required in mild or moderate impairment. Caution advised in severe renal impairment. *Hepatic impairment:* No dose adjustment required in mild impairment. Caution advised in moderate and severe hepatic impairment. *Elderly:* No initial dose adjustment required in patients >65 yrs. *Paediatrics:* Safety & efficacy not established in patients <18 yrs. **Contraindications** Hypersensitivity to active substance or excipients. **Special warnings and precautions** *Pyrexia:* Interrupt treatment if temperature ≥38.5˚C and investigate for infection. Restart once fever resolves with anti-pyretics. Restart at reduced dose if fever associated with other severe signs or symptoms as clinically appropriate. *Cutaneous squamous cell carcinoma (CuSCC) and new primary melanoma:* Examine skin prior to treatment, monthly during treatment and for up to 6 months after discontinuation. Patients should inform their physician immediately if a new lesion develops. Dose modifications/interruptions not recommended. *Non-cutaneous secondary/recurrent malignancy:* Head and neck examination and chest/abdominal scan prior to treatment. Monitor as clinically appropriate and for up to 6 months after discontinuation. *Renal failure:* Monitor serum creatinine routinely while on therapy, and interrupt treatment as clinically appropriate if creatinine increases. *Uveitis:* Monitor for signs and symptoms of ophthalmological reactions while on therapy. *Pancreatitis:* Investigate unexplained abdominal pain promptly, including serum amylase and lipase measurements. Monitor closely when re-starting dabrafenib. *QT prolongation:* Treatment not recommended in patients with uncorrectable electrolyte abnormalities, long QT syndrome or those taking medicinal products known to prolong QT interval. Monitor ECG and electrolytes before treatment, one month after therapy, and after dose modification. Permanent treatment discontinuation recommended if QTc increase is both >500msec and >60msec change from baseline. **Undesirable effects** Please refer to full SmPC before prescribing. *Very common:* Papilloma, decreased appetite, headache, cough, nausea, vomiting, diarrhoea, hyperkeratosis, alopecia, rash, PPE syndrome, arthralgia, myalgia, pain in extremity, pyrexia, fatigue, chills, asthenia. *Common:* cuSCC, seborrhoeic keratosis, skin tags, basal cell carcinoma, hypophosphataemia, hyperglycaemia, constipation, dry skin, pruritus, actinic keratosis, skin lesion, erythema, influenza-like illness, LVEF decrease. **Interactions** Avoid co-administration with strong inducers or inhibitors of CYP2C8 and CYP3A4, and agents that increase gastric pH, when possible. Exercise caution when co-administering with digoxin and with warfarin; consider additional INR monitoring. Dabrafenib may reduce efficacy of hormonal contraceptives; use alternative effective contraception and continue for 4 weeks post-discontinuation. **Pregnancy** Do not administer to pregnant women unless benefit to mother outweighs the risk to foetus. **Marketing authorisation (MA) nos.** EU/1/13/865/001; EU/1/13/865/003. **MA holder** GlaxoSmithKline Trading Services Ltd., Kinsale Road, Cork. **Legal category** POM. ONCE/BRF/0074/13. September 2013.

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For UK attendees:
– Reporting forms and information can be found at: http://www.mhra.gov.uk/yellowcard
– Adverse events should also be reported to GlaxoSmithKline on 0800 221 441
For ex-UK attendees:
– Please report adverse events via your local GSK contact or affiliate office

Further information is available from Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441.

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