

GLAXOSMITHKLINE - Novel Combo therapy (BRAf+MEK) filed in Europe – Potential New SoC for BRAf positive metastatic melanoma patients

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Date: February 2013

Pages: 3

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Abstracts

GSK announced the filing of its BRAF and MEK inhibitors– trametinib (MEK inhibitor) as monotherapy and in combination with dabrafenib (BRAF inhibitor) as combo therapy for the treatment of metastatic melanoma with a BRAF V600 mutation. The application has been submitted for accelerated assessment with the review time of 150 days. The accelerated assessment and early filing of the combination therapy is based on extraordinary efficacy shown in PhII study which doubled the response rate and PFS (9.5mo vs.5.6mo) compared to BRAF inhibitor monotherapy. The combination should become the new standard of care in melanoma patients with BRAF+ve mutation as besides better efficacy it also lowers the dermatological toxicity associated with monotherapy Zelboraf.

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