BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Novartis gets EU nod for combination therapy for skin cancer

27 July 2015 | News | By BioSpectrum Bureau

Novartis is hopeNovartis gets EU nod for combination therapy for skin cancerful with combination therapy for skin cancer

Singapore: European Medicines Agency (EMA) has given a positive indication to Novartis' combination therapy of Tafinlar (dabrafenib) and Mekinist (trametinib) for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

US Food and Drug Administration (FDA) has also granted priority review for the same combination therapy.

"The Committee for Medicinal Products for Human Use (CHMP) positive opinion and FDA priority review of Tafinlar and Mekinist validate the importance of this targeted therapy combination for patients with the most serious form of skin cancer,"

said Mr Bruno Strigini, president, Novartis Oncology. "This good news for the combination of Tafinlar and Mekinist in metastatic melanoma follows on the FDA's recent Breakthrough Therapy designation for the combination in BRAF V600 mutation-positive non-small cell lung cancer. We look forward to working with the US and EU regulatory authorities to help bring this targeted therapy combination to more patients who may benefit."

The European Commission will review the CHMP recommendation and is expected to deliver its final decision within three months. The decision will be applicable to all 28 EU member states plus Iceland, Norway and Liechtenstein.

The FDA Breakthrough Therapy designation in BRAF V600 mutation-positive non-small cell lung cancer (NSCLC) is based on interim analysis results from an ongoing single-arm, two-stage, Phase II trial investigating the Tafinlar and Mekinist combination in patients with metastatic NSCLC who had the BRAF V600E mutation and failed at least one line of chemotherapy.