BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

GSK gets EU nod for metastatic melanoma inhibitor

24 April 2013 | Regulatory | By BioSpectrum Bureau

Singapore: GlaxoSmithKline has recieved European Commission (EC) marketing authorisation for Mekinist (trametinib) as a single agent in the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

Trametinib has not demonstrated clinical activity in patients who have progressed on a prior BRAF inhibitor therapy. Trametinib is a MEK inhibitor which blocks the activity of a protein kinase called MEK. This protein is present in the MAPK pathway, which regulates the normal growth and death of cells and plays a role in metastatic melanoma development. Some mutations in the BRAF gene can cause the MEK protein to stimulate cancer cell growth and survival; therefore, inhibiting MEK can potentially slow down the growth of tumours in BRAF-mutant metastatic melanoma.

Dr. Paolo Paoletti, President of Oncology, GSK said, "We welcome the decision of the European Commission. MEK has been pursued as a therapeutic target in cancer for more than a decade, and Mekinist is the first medicine in this class to be licensed in Europe."