BioSpectrum the business of Bio & Health Sciences

Pierre Fabre gets EU approval for BRAFTOVI+ MEKTOVI

21 September 2018 | News

BRAFTOVI + MEKTOVI now has marketing authorisation from the European Commission in all 28 EU member states plus Liechtenstein, Iceland and Norway -

Pierre Fabre, the 2nd largest dermo-cosmetics laboratory in the world, announced that the European Commission (EC) has granted marketing authorisation for the combination of BRAFTOVI® (encorafenib) and MEKTOVI® (binimetinib) for the treatment of adult patients with unresectable or metastatic melanoma with a *BRAF*^{V600} mutation, as detected by a validated test. The EC decision is applicable to all 28 European Union (EU) member states plus Liechtenstein, Iceland and Norway.

"We are extremely pleased that European patients with advanced *BRAF*-mutant melanoma will now have the combination of BRAFTOVI and MEKTOVI as a new treatment option", said Frédéric Duchesne, President & CEO of the Pierre Fabre Pharmaceuticals Division. "All of us at Pierre Fabre are driven to make a real difference for patients. Bringing more than 30 years of oncology experience and our heritage in dermatology to our partnership with Array, we have been able to harness our expertise in order to help men and women living with this devastating disease. Today's news inspires us to continue pursuing new innovations that will benefit patients".

The EC decision, which follows the positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in July, is based on results from the Phase 3 COLUMBUS trial.

This trial demonstrated that the combination of BRAFTOVI 450 mg once daily and MEKTOVI 45 mg twice daily significantly improved median progression-free survival (PFS), compared with vemurafenib alone 960 mg twice daily (14.9 months versus

7.3 months, respectively: hazard ratio [HR] 0.54, 95% confidence interval [CI], 0.41-0.71; two-sided p<0.0001).

Treatment with BRAFTOVI and MEKTOVI achieved a median overall survival (OS) of 33.6 months, compared with 16.9 months for patients treated with vemurafenib as a monotherapy (HR 0.61, 95% CI, 0.47-0.79; p<0.0001) in the planned analysis of OS in the COLUMBUS trial.