

## **Safety and efficacy of a novel skin lightening agent for melasma**

### **Introduction**

Hydroquinone is considered the gold standard treatment for melasma. The main problem with hydroquinone based products is that there are safety concerns related to their use. A large unmet need exists for a safe and effective treatment for melasma.

### **Materials & Methods**

The purpose of this study was to evaluate the skin lightening efficacy of a novel hydroquinone free skin lightening compound (SBM-TFC-1067). The study endpoints were spectrophotometric measurement of surface reflectance, melanin quantification, morphological assessment and histological analysis of melanocytes. Compounds were topically applied daily to a 3-D human skin model from Mattek for 14 days using 3 different concentrations (0.1, 0.05 and 0.01%). Pigmentation was evaluated on days 0, 7, 11, and 14 using a chromameter to measure brightness ( $L^*D65$ ). Total melanin content was quantified after day 14.

### **Results**

Statistically significant differences in surface reflectance were observed versus vehicle control with the 0.1% concentration of SBM-TFC-1067 after 7, 11 and 14 days and with the 0.05% concentration after 11 and 14 days of topical application. A statistically significant reduction in melanin quantity was also observed versus vehicle control with the 0.1% and 0.05% concentrations (-19.03 and -9.22 micrograms respectively). Histological and morphological assessment revealed that the skin lightening effect and melanin reduction of the 0.1% concentration of SBM-TFC-1067 was likely due to some cytotoxicity in addition to inhibition of tyrosinase, whereas there was no evidence of cytotoxicity with the 0.05% concentration.

### **Discussion**

With these promising results, SBM-TFC-1067 would be very useful as a potential new treatment for melasma. Previous in vitro studies have shown an excellent safety profile with eight times the efficacy of deoxyarbutin. Further development including formulation, dose finding studies and well designed clinical trials to demonstrate safety and efficacy are needed.