

Sol-Gel to treat rosacea using acne drug

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Sol-Gel achieves successful Ph II Study in rosacea



Singapore: Israel-based Sol-Gel Technologies achieved positive results for a phase II trial in the US targeting mild-to-severe rosacea using a benzoyl peroxide drug product developed by Sol-Gel.

Although benzoyl peroxide is an established treatment for acne, until now it has not been used for the treatment of rosacea because it causes a high degree of skin irritation. Sol-Gel's proprietary silica-based microencapsulation drug delivery system, successfully demonstrated in the study that it can ultimately provide a safe and effective first-in-class treatment.

"The study results, could change the way physicians treat rosacea," said Dr Alon Seri-Levy, Sol-Gel's co-founder and CEO. Noting that encapsulated benzoyl peroxide (E-BPO) is the first drug in Sol-Gel's pipeline of innovative topical dermatological drugs to complete phase II studies, he added that, "We plan to initiate phase III studies for E-BPO next year."

The double-blind, randomized, vehicle-controlled, dose-range study was carried out at eight medical centers in the US on 92 rosacea patients. The patients received one of two doses of E-BPO or a vehicle gel (control group). The length of the

treatment was 12 weeks. The primary objective of the study was to identify the lowest dose of E-BPO gel that demonstrates both safety and effectiveness in the treatment of rosacea.

There were two primary efficacy endpoints: the proportion of subjects with the primary measure of success, defined as a 2-grade improvement in the Investigator Global Assessment (IGA) relative to Baseline at week 12, with patients at Week 12 IGA being clear or almost clear of symptoms; and the change in inflammatory lesion count at week 12.