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ASIA EDITION

Taiwan-based Formosa Pharma receives US FDA approval for ophthalmic steroid

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Represents the first US FDA-approved ophthalmic clobetasol propionate product

Taiwan-based Formosa Pharmaceuticals and AimMax Therapeutics (United States) have announced that the US Food and Drug Administration (FDA) has approved clobetasol propionate ophthalmic suspension 0.05% (APP13007), for the treatment of post-operative inflammation and pain following ocular surgery.

Utilising a super potent corticosteroid, clobetasol propionate ophthalmic suspension 0.05% is derived from Formosa Pharma's proprietary APNT nanoparticle formulation platform. This innovative formulation represents the first US FDA-approved ophthalmic clobetasol propionate product and the first new steroid in over 15 years on the ophthalmic market, offering patients a convenient and straightforward dosing regimen (twice daily for 14 days without tapering).

Two Phase 3 clinical trials demonstrated rapid and sustained clearance of inflammation and pain relief that was statistically and clinically superior to its matching placebo ($p<0.001$).

This novel eyedrop enters a $1.3 billion dollar market for topical ophthalmic steroids and steroid combinations, driven by an estimated seven million ocular surgeries performed annually in the United States.