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ASIA EDITION

Taiwan's Formosa Pharma signs deal with Apotex to commercialise ophthalmic medicine in Canada

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Commercialisation of Clobetasol Propionate Ophthalmic Suspension for ocular surgery relief and recovery



Taiwan-based Formosa Pharmaceuticals has entered into an exclusive licensing agreement with Canadian firm Apotex Inc., for exclusive rights in Canada to the commercialisation of clobetasol propionate ophthalmic suspension, 0.05% (APP13007), a patented innovative medicine for the treatment of inflammation and pain following ocular surgery.

Clobetasol propionate ophthalmic suspension, 0.05% (APP13007) was approved by the US Food and Drug Administration (FDA) on March 4, 2024.

The licensing deal will include certain payments, including an upfront payment and milestone payments upon achievement of certain regulatory and sales milestones.

APP13007's active ingredient is the superpotent corticosteroid, clobetasol propionate, and is derived from Formosa Pharma's proprietary APNT nanoparticle formulation platform. The novel formulation enables a convenient and straightforward dosing regimen (twice daily for 14 days) while providing rapid and sustained relief of inflammation and pain, which in Phase 3 trials proved statistically and clinically superior to its matching placebo ($p<0.001$).

APP13007 will enter a ~$C 50 million market for topical ophthalmic steroids and steroid combinations, growing at around 5% annually, driven by an estimated ~500,000 ocular surgeries annually in Canada.