BioSpectrum ASIA EDITION
the business of Bio & Health Sciences

Taiwan-based Formosa Pharma inks $86 M worth ophthalmology deal with American firm Eyenovia

August 21, 2023 | News

For the commercialisation of APP13007 for the treatment of inflammation and pain following ocular surgery



Taiwan-based Formosa Pharmaceutical has entered into a licensing agreement with Eyenovia, whereby Eyenovia obtains exclusive US rights for the commercialisation of APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%) for the treatment of inflammation and pain following ocular surgery.

APP13007 is currently under review by the US Food and Drug Administration (FDA) and has been assigned a Prescription Drug User Fee Act (PDUFA) date of March 4, 2024. The total deal package, including upfront payment and development and sales milestones, has a value of $86 million, with additional considerations throughout the term of the agreement.

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 ($p<0.001$).

If approved, APP13007 will enter a $1.3 billion market for topical ophthalmic steroids and steroid combinations, driven by an estimated seven million ocular surgeries annually in the US.