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Taiwan's Formosa Pharmaceuticals marks first entry into EU market for ophthalmic therapies

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Licensing agreement for Clobetasol Propionate Ophthalmic Suspension for the treatment of post-operative inflammation and pain

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

DÁVI is a trusted partner of Pharmathen Global Holding B.v., AZAD Pharma AG, NTC S.r.l. and Pfizer through marketing and promotion of Xalacom (Latanoprost + Timolol) and Xalatan (Latanoprost) for more than 12 years. DÁVI is one of the key players in the Portuguese Market, with over 100 years' history in the distribution and promotion of branded ophthalmology products.

Clobetasol propionate ophthalmic suspension, 0.05% (APP13007), approved by the US Food and Drug Administration (FDA) in March, 2024, was recently launched in the United States in September, 2024. The DÁVI licensing agreement includes upfront, commercialisation milestones, and sales milestones, 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.

In a recent survey of 100 ophthalmic surgeons, rapid resolution of pain (~80% pain-free four days post-surgery) and low incidence of adverse events (<2%) were highlighted as key drivers to prescribing APP13007. APP13007 anticipates significant potential in Portugal, which has around 90,000 cataract surgeries, annually, as reported by Eurostat.