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Singapore approves AffaMed Therapeutics drug for Ocular Inflammation

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New Drug Application(NDA) approved for DEXTENZAÃ?Â® for Treatment of Ocular Inflammation and Pain Following Ophthalmic Surgery, and Ocular Itching Associated with Allergic Conjunctivitis



China's AffaMed Therapeutics, has obtained New Drug Application (NDA) from Singapore Health Sciences Authority (HSA) for DEXTENZA® (0.4 mg dexamethasone ophthalmic insert) for the treatment of ocular inflammation and pain following ophthalmic surgery, and ocular itching associated with allergic conjunctivitis.

DEXTENZA is approved in the U.S. and listed in Macau for the treatment of ocular inflammation and pain following ophthalmic surgery, and ocular itching associated with allergic conjunctivitis.

AffaMed is developing DEXTENZA, the first physician-administered sustained-release intracanalicular insert available to patients in ASEAN countries and Greater China. DEXTENZA delivers a preservative-free dose of dexamethasone for up to 30 days with a single administration, thereby offering patients significant benefit and convenience versus current treatments which require multiple administrations of eye-drops per day.

"As the first NDA filing by AffaMed, the acceptance of our DEXTENZA NDA in Singapore represents an important milestone in our company's journey to successfully advance much-needed therapeutic candidates through regulatory pathways across multiple regions in Asia," said Vijay Karwal, Chief Executive Officer of AffaMed.

AffaMed has initiated a registrational trial in Mainland China to evaluate the safety and efficacy of DEXTENZA versus a placebo vehicle in the treatment of inflammation and pain following cataract surgery, and anticipates sharing topline data from this study in Q3 2024.