Working to improve your health

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Scomara™ Tentative Approval by US FDA

AFT Pharmaceuticals (NZX: AFT; ASX: AFP), today announces that the US Food and Drug Administration (FDA) has issued a tentative approval for Scomara (rapamycin 0.5% cream) for treatment of Facial Angiofibromas in Tuberous Sclerosis (FA in TSC).

The quality, efficacy and safety data has been evaluated, and subsequent product labelling and claims have been tentatively approved but the launch and commercialisation is subject to existing 'orphan exclusivity' for another product that was granted in 2022 and expires on 22 March 2029. FA in TSC affects between 15,000 to 30,000 patients in the US.

Orphan exclusivity in some countries is a regulatory incentive granted to pharmaceutical companies to encourage the development of treatments for rare diseases. In the United States, it provides seven years of market protection during which the FDA cannot approve any other application for the same drug for the same rare disease indication.

However, the orphan exclusivity granted in the US does not apply in many other significant markets around the world, where FDA approval will support regulatory approval. These markets include Canada, Australia, New Zealand, where AFT operates directly itself, and many markets in Asia.

In these markets AFT believes Scomara will have a competitive advantage over the existing orphan product because the medicine is only applied once a day and it is stored at ambient temperature. In contrast, the competing product must be refrigerated and is applied twice per day.

AFT Managing Director Dr Hartley Atkinson said, "We are pleased to achieve this tentative approval following FDA review of our regulatory application but are disappointed that the US launch will be delayed at least until 22 March 2029. However, the tentative approval is a catalyst for AFT to develop new and significant markets for the medicine outside the US which is positive."

AFT has not forecast any revenue from the medicine in its budgets so this decision does not impact AFT's forecast for FY27. AFT receives a 65% share of the earnings from the opportunity world-wide after the recovery of development costs[1]. AFT also separately receives a royalty for the use of its proprietary technology in the medicine which is due prior to any profit share calculations.

[1]The remaining 35% of profits accrues to the 35% owner of AFT Orphan Pharmaceuticals

Released for, and on behalf of, AFT Pharmaceuticals Limited by Stuart Houliston, Chief Financial Officer.

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About AFT Pharmaceuticals

AFT is a growing New Zealand based multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over the counter (OTC), prescription, and hospital. Our product portfolio comprises both proprietary and in-licensed products, and includes patented, branded, and generic drugs[2]. Our business model is to develop and in-license products for in our markets of Australia, New Zealand, Singapore, Malaysia, Hong Kong, USA, Canada, EU ex Ireland, and UK, and to out-license our products to local licensees and distributors to over 125 countries around the world. For more information about the company, visit our website www.aftpharm.com.