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5 April 2022

## **AFT notes FDA approval for Pascomer alternative**

AFT Pharmaceuticals (NZX: AFT, ASX: AFP) today notes the US Food and Drug Administration (FDA) has approved a topical treatment indicated for facial angiofibroma (FA) associated with Tuberous Sclerosis Complex (TSC) developed by Japan's Nobelpharma<sup>1</sup>.

The active ingredient in Nobelpharma's medicine is rapamycin, which AFT and its development partner, the US-based Timber Pharmaceuticals, are also developing as a treatment for FA in TSC and other larger non orphan indications under the brand Pascomer.

Nobelpharma's medicine has also been granted orphan status for FA in TSC. This means that Nobelpharma will gain exclusivity for a period of seven years in USA which will prevent AFT filing its Pascomer for this orphan indication with the FDA during this period.

AFT notes that the clinical study results for its study of rapamycin for the FA in TSC orphan indication will be available in mid-2022. It confirms that its clinical trial program for non-orphan drug Pascomer indications will continue.

Furthermore, AFT notes it has been granted a significant formulation patent for Pascomer in Australia until November 2040 which will form the basis of further patent filings around the world<sup>2</sup>. The Nobelpharma product is only stable under refrigerated conditions for 12 months whilst the AFT proprietary formulation has resulted in a product stable at room temperature for 36 months.

AFT Managing Director Dr Hartley Atkinson said that the company does not expect that the FDA's approval of Nobelpharma's medicine will affect the \$12.5 million carrying value of the Pascomer assets in the company's accounts. He also confirmed that AFT retains its guidance for an operating profit for the year to 31 March 2022 of \$18 million to \$23 million.

AFT will report its results for the 2022 financial year in late May.

"AFT is disappointed that Nobelpharma has secured FDA approval ahead of us. As we noted in our 2021 annual report, we always maintained there were significant

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<sup>1</sup> <https://www.prnewswire.com/news-releases/fda-approves-nobelpharmas-hyffor-sirolimus-topical-gel-0-2-301516272.html>

<sup>2</sup> Australian patent (Patent Number 2020277132) Pascomer formulation patent

uncertainties associated with both conclusion of the clinical trials and the successful registration of Pascomer with orphan status," Dr Atkinson said.

"It was for these reasons that we adopted a conservative valuation of the Pascomer assets. We continue to believe Pascomer has strong potential for non-orphan indications and the potential market for these is potentially larger than the market for FA in TSC."

In 2019 AFT and Timber agreed an out-licensing and development agreement for the USA, Canada & Mexico for rapamycin under the brand Pascomer. Last year it also licensed the technology in Europe to Germany's Desitin Arzneimittel GmbH, a specialist pharmaceutical company based in Hamburg, Germany.

"AFT is consulting with its development partner and licensees to assess the implications of the FDA's approval of Nobelpharma's medicine. We will update the market as more information becomes available," Dr Atkinson said.

*For and on behalf of AFT Pharmaceuticals Limited by Malcolm Tubby, Chief Financial Officer.*

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**About AFT Pharmaceuticals**

AFT is a growing 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. Our business model is to develop and in-license products for sale by our own dedicated sales teams in our home markets of Australia and New Zealand and to out-license / distribute 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](http://www.aftpharm.com).