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AFT Pharma Reaches Licensing Agreement for *Pascomer*® in North America

Key points:

- *Clinical trials to commence in research centres in five countries, including the world-renowned Mayo Clinic.*
- *The drug is a treatment for Facial Angiofibromas in Tuberous Sclerosis; a market which could potentially be worth US$300+ million in the USA.*
- *AFT takes 100% control of Dermatology Specialty Limited Partnership (DSLP) the joint venture set up to develop Pascomer as part of the agreement.*

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) has reached an out-licensing and development agreement with US-based Timber Pharmaceuticals [Timber] for the USA, Canada & Mexico for its orphan drug[i] *Pascomer*.

Pascomer (Active ingredient, Rapamycin) is a topical treatment for Facial Angiofibromas in Tuberous Sclerosis. The disease affects over 30,000 patients in the US alone which could potentially be worth US$300+ million in the USA - if clinical studies are successful.

The first of AFT's two planned clinical studies in 120 patients is due to start in eight study centres around the world, including the world-renowned Mayo Clinic in Rochester, Minnesota in the US. Research centres in Australia, Spain, the UK and New Zealand are also taking part in the trial. Results are due in 2020.

Rapamycin is normally easily oxidised and typically has limited stability in topical formulations. However AFT has developed a formulation that uses a proprietary dermal delivery technology that has overcome these stability issues.

Extensive pre-clinical development work has been completed and an Investigational New Drug Application (IND) has been approved by US FDA. AFT will run the clinical study program in conjunction with Timber, which will cover both trial costs and direct AFT staff costs for staff involved in the *Pascomer* development program.

AFT CEO Dr Hartley Atkinson said the agreement with Timber – US based company specializing in the development and commercialization of dermatology treatments for rare diseases - represents both a significant and exciting opportunity.

"The deal we have struck with Timber, mitigates AFT's research and development risks, while still promising strong returns for the company if the clinical trials proceed successfully," Dr Atkinson said.

Timber will cover all clinical trial costs. AFT will receive signing and, provided development proceeds successfully, staged development and registration milestone payments in excess of US$10 million, potential sales milestone payments in excess of US$10 million and ongoing sales-royalty payments. At this early stage of the financial year and with the timing uncertainty of the development, AFT will leave its present operating profit guidance for FY2020 at NZ$9-12m.

"We are looking forward to the start of clinical trials. We are excited to have secured prestigious clinical trial sites such as the Mayo Clinic in the US, Children's Health Queensland in Brisbane, Clinica Universidad de Navarra in Spain and Christchurch Hospital.

"Facial angiofibromas are a disfiguring condition affecting patients from childhood. So, a successful *Pascomer* development will offer an important therapeutic option to these sufferers," Dr Atkinson said.

As part of the agreement, AFT has also taken 100% control of the original partnership set up for development of *Pascomer*, DSLP

In a series of transactions covered by the agreement, DSLP joint venture partner Tardimed (formerly named Medicas), which is the majority shareholder in Timber, transferred its share in the DSLP partnership to AFT.

Under the terms of the deal Timber, in addition to its sales of *Pascomer* in North America , will also earn a 50% share of DSLP's net royalties outside North America, Australia, New Zealand and SE Asia.

Timber President, Zach Rome said: "AFT's dermal delivery technology coupled with *Pascomer* is potentially a significant breakthrough for people with facial angiofibromas. We are delighted to be working with Hartley and his team to take this treatment to market in North America."

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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 in certain Southeast Asian markets, and to out-license our products to local licensees and distributors to the rest of the world. For more information: https://www.aftpharm.com/

About Timber

Timber Pharmaceuticals LLC (www.timberpharma.com) was founded in 2019 to develop treatments for unmet needs in medical dermatology. The company has a particular focus on rare diseases or conditions for which there are no current treatments available. Timber's lead program, TMB-001, is a novel, proprietary topical therapy in clinical development for the treatment of congenital ichthyosis, a rare, debilitating disease that involves generalized scaling of the skin

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[i] Orphan drugs are treatments for people with rare medical conditions. People with rare medical conditions often find that treatments are either unaffordable or simply do not exist. Typically, this is because drug development is costly, and companies can find it difficult to recoup their investment when the number of people suffering from a particular condition are relatively few.
To encourage companies to develop treatments for rare conditions (orphan conditions), the regulatory requirements for developing and licensing treatments can be lessened by a regulator. For example, clinical testing studies for orphan drugs may be permitted to use smaller patient groups. Tax incentives or research grants can be offered and patent protections increased. These incentives exist in the US and Europe legislation, but do not in New Zealand.