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Market and media release

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AFT welcomes US FDA Complete Response Letter

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) today announces it has received a US Food and Drug Administration (FDA) complete response letter (CRL) covering its application for the approval of a tablet version of its Maxigesic® pain relief medication.

In the letter, the US regulator said an FDA Good Manufacturing Practice (GMP) inspection of the tablet production facilities – delayed due to COVID-19 related travel disruptions – was the “only deficiency” with AFT’s application.

A CRL indicates the FDA has completed its review of a new drug application. The letter covered AFT’s application for prescription Maxigesic tablets, branded Combogesic® in the US, for treatment of mild to moderate acute pain.

The FDA also requested minor labelling changes and asked for updated global safety data.

AFT Managing Director Dr Hartley Atkinson said the CRL indicated AFT had cleared a significant hurdle on its path towards the commercialisation of the Maxigesic pain relief family of medicines in the world’s largest pharmaceutical market.

“This is a very pleasing result. The letter shows a prescription version of Maxigesic is approvable in the US and that AFT is well on the way to approval of its patented medicine in the US market.

“The labelling and safety data are simple to address. The GMP inspection of the manufacturing site which is located outside the US and has previously held FDA GMP approval will take longer to resolve due to present COVID19 travel bans. We will need to await lifting of these restrictions to organise the site inspection. However, a remote GMP inspection has already been requested which is an alternative solution. Presently the precise timing cannot be confirmed.”

Dr Atkinson said it was too early to say when the medicine would be approved for sale in the US. In addition to final approval from the FDA, AFT still needed to licence the medication to a distributor.

“Talks with potential licensees are ongoing, and a positive CRL was a major endpoint, we now look forward to progressing these discussions, and the one final outstanding regulatory requirement in the coming months,” 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 business with a broad range of products, both developed itself and in-licensed from third parties. AFT's products cover all major pharmaceutical distribution channels: over-the-counter, prescription and hospital. Historically, AFT's home markets have been Australia, New Zealand and South-East Asia. However, the company is out-licensing its own products to licensees and distributors to sell in an increasing number of countries around the world. The company's intensive Research and Development program forms the basis of its international sales strategy. For more information about the company, visit our website www.aftpharm.com.