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US FDA seeks more information on Maxigesic IV® application

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) announces that it has today received a Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) on its application for the US registration of Maxigesic IV®, the intravenous form of its patented pain relief medicine. The FDA have requested additional data on one remaining issue.

AFT Managing Director Dr Hartley Atkinson said: "While it is disappointing not to have received registration of Maxigesic IV as we initially expected, we are confident that we can deliver the FDA the information that it needs to approve our medicine.

"We are now discussing the FDA's request with our development and commercialisation partner Hyloris Pharmaceuticals. We will be updating the market shortly on revisions to the US commercialisation pathway and timeline for the medicine as we gain more clarity on the FDA's request."

Maxigesic® IV, is a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion, for the treatment of post-operative pain. It has been developed in collaboration with Hyloris and currently licensed in more than 100 countries across the globe. It has also been registered in 37 countries and launched in 7 countries including Australia, Germany and Korea. The medicine is protected by several granted patents and pending patent applications.

Released for and on behalf of AFT Pharmaceuticals 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