



Working to improve your health

18 April 2023

AFT submits Maxigesic IV® packaging data to the US FDA

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) today announces it has submitted to the US Food and Drug Administration (FDA) data the regulator requested as it considers registration of the company's patented intravenous pain relief medicine Maxigesic IV.

In a delay to the registration of the medicine in the US, the FDA requested in July 2022 additional data on the performance of Maxigesic IV's primary packaging (the glass vial in which the medicine is stored and the vial's stopper).

AFT along with its commercialisation partner Belgium's Hyloris Pharmaceuticals has over the last year collated the data and submitted today.

AFT Managing Director Dr Hartley Atkinson said: "We believe the data we have submitted will satisfy the FDA's requirements and remove the outstanding hurdle to registration. All going well we anticipate registration of the medicine this year and sales to follow shortly after."

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 is currently licensed in more than 100 countries across the globe. It has also been registered in 43 countries and launched in 19 countries including Australia, France, 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

Dr Hartley Atkinson
Managing Director
AFT Pharmaceuticals
Tel: +64 9488 0232

Richard Inder
The Project
Tel: +64 21 645 643

Released for and on behalf of AFT Pharmaceuticals by Malcolm Tubby, Chief Financial Officer

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: aftpharm.com