



Working to improve your health

18th October 2023

AFT welcomes US FDA approval for sale of Maxigesic IV®

AFT Pharmaceuticals (NZX: AFT, ASX: AFP) today announces it has been notified overnight that the US FDA has approved Maxigesic IV®, the intravenous form of its patented pain relief medicine, for sale in the US, which represents AFT's second FDA approval within one year.

The medicine is now positioned to go on sale either at the tail end of FY'24 or early in FY'25, an event that will trigger a milestone payment of US\$6 million to AFT from the US licensee of the medicine Hikma Pharmaceuticals. AFT is entitled to 65% of this under its profit share arrangements with Hyloris. AFT also qualifies for a US\$2.9 million reimbursement of regulatory fees paid to the FDA for Maxigesic IV that it expects to receive in the current financial year.

If the commercial milestone for the launch of Maxigesic IV is triggered within this financial year (FY'24) then this license income will be in addition to the current \$22-24m guidance.

AFT Co-Founder and Managing Director Dr Hartley Atkinson says: "We are delighted with the FDA approval of this prescription medicine. We are also proud of the achievement, which is the second approval in one year.

"The US analgesic market is the world's largest, worth US\$6.83 billion in 2023, and is forecast to grow by an estimated 4.89% a year until 2028¹. We now have two medicines that can begin to take a share of this market – Maxigesic IV and Maxigesic Rapid®, the rapid dissolving tablet prescription form of the medicine that was approved by the FDA in March 2023.

"The FDA approval of Maxigesic Rapid was the first time the US food and medicine regulator had given the green light for sale of a New Zealand-developed patented medicine based on clinical trial data.," Dr Atkinson said.

"It is a real credit to the determination, commitment, and capability of the AFT team and our research and development partner, Belgium's Hyloris Pharmaceuticals. We thank them all for their efforts."

Maxigesic IV is a novel, unique combination, intravenous formulation for the treatment of post-operative pain that aims to provide an effective alternative to opioid pain relief medicines, offering a significant alternative therapeutic option. Maxigesic Rapid

¹ [Statista](#)

offers similar benefits, which AFT is still working through the best way to approach the US market for this dose form of the medicine.

In the United States chronic opioid usage in patients following surgery averaging around 9%, which is a concern². Drug overdoses involving opioids meanwhile resulted in over 80,000 deaths in the US in 2021³. Patients who experienced an opioid overdose accounted for nearly US\$2 billion in annual hospital costs⁴.

Maxigesic was invented by Dr Atkinson and was first introduced in New Zealand in 2009 in tablet form. The medicine has since been licensed in more than 100 countries worldwide and is sold in a variety of dose forms in 62 countries.

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

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About AFT Pharmaceuticals www.aftpharm.com

AFT Pharmaceuticals are 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, prescription, and hospital. AFT Pharmaceutical's product portfolio comprises both proprietary and in-licensed products, and includes patented, branded, and generic drugs.

² [Chronic Opioid Usage in Surgical Patients in a Large Academic Center - PubMed \(nih.gov\)](#)

³ [Data Overview | Opioids | CDC](#)

⁴ [Premier | Opioid Overdoses Costing U.S. Hospitals an Estimated \\$11... \(premierinc.com\)](#)