Working to improve your health

2 March 2023

Maxigesic Rapid® tablets gain US FDA approval.

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) today announces the US Food and Drug Administration has approved a rapid release tablet form of Maxigesic for the management of mild to moderate acute pain in the US.

The approval for Maxigesic Rapid® - a unique, patented combination of 325 mg of paracetamol and 97.5 mg of ibuprofen that deploys a patented rapid release technology[1] – opens an analgesic market to AFT in the US that is worth around US$7.16 billion and is expected to grow by 5.8% a year between now and 2027[2].

AFT Managing Director Dr Hartley Atkinson says: "We are delighted with the FDA approval of this prescription medicine and excited about the growth opportunities it opens for the company. We have held talks with potential US licensees for the medicine and are evaluating US market entry plans to maximise its commercial potential. We also importantly see this as a therapeutic option to help doctors battle the opioid epidemic in the US.

Dr Atkinson said the FDA approval for Maxigesic Rapid release tablets represents the first step for the family of medicines in the important US market. The company is awaiting approval for the intravenous form of the patented medicine Maxigesic IV and is also considering the release of other dose forms in the market.

The US approval follows on other commercial successes with Maxigesic. Maxigesic Oral Liquid, a patented unique combination of 160mg paracetamol and 48mg ibuprofen per 5ml oral suspension for children, has recently received approval in an additional 12 European countries via the European Union's decentralized registration procedure.

The approval clears the way for registration approvals of the medicine in Estonia; Hungary; Lithuania; Latvia; Slovenia; Bulgaria; Cyprus; the Czech Republic; Romania; Slovakia; Greece and Poland.

[1] The patent for the dose ratio expires in 2025 and the patent on the rapid release expires in 2039. Rapid release technology has been in-licensed from US company Formul8IP.
[2] US OTC analgesic market: https://www.statista.com/outlook/cmo/otc-pharmaceuticals/analgesics/united-states

AFT Managing Director Dr Hartley Atkinson says: "The Maxigesic commercialisation programme continues to make steady progress and the increasing regulatory approvals and consequent launches will contribute to our international sales going forward."

For and on behalf of AFT Pharmaceuticals Limited by Malcolm Tubby, Chief Financial Officer.

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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 over 125 countries around the world. For more information about the company, visit our website www.aftpharm.com.