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14 July 2021

## **Maxigesic® Oral Liquid gets first regulatory approval**

*Maxigesic Oral Liquid – a non-opioid analgesic developed for children - achieves first approval in Europe to set up the first global launch and a pathway for further registrations and launches.*

AFT Pharmaceuticals (NZX; AFT, ASX; AFP) today announces that it has successfully gained its first regulatory approval of Maxigesic Oral Liquid in Europe (Italy and Malta) with further regulatory approvals now expected.

Maxigesic Oral Liquid is a novel non-opioid treatment for pain in children between the ages of 2-12 years. It is a patented unique combination of 160mg paracetamol and 48mg ibuprofen per 5ml oral suspension and is an extension of AFT's patented Maxigesic family of medicines.

The registration follows a pivotal clinical safety study in 251 patients in Australia, New Zealand and Mexico\*<sup>1</sup> between the ages of 2-12, who were treated for up to 11 days after a tonsillectomy.

AFT Pharmaceuticals Managing Director Dr Hartley Atkinson said: "We are delighted with the registration of Maxigesic Oral Liquid. It demonstrates the significant potential of our Maxigesic intellectual property.

"The commercialisation of the tablet version of the medicine is establishing the brand and acceptance across broad populations around the world. The new dose forms such as Oral Liquid and the intravenous form Maxigesic IV ® extend the addressable market and the growth potential for AFT and its global licensee partners.

"The registration of the Oral Liquid version is also a significant achievement because of the additional regulatory challenges of gaining approval for a medicine targeted at children.

"This registration now allows an upcoming launch with our partner in Italy, Angelini Pharma SpA which is exciting as Angelini has made good progress in Italy with the tablet to date," said Dr Atkinson.

AFT Pharmaceuticals is making good progress commercialising the Maxigesic family of medicines around the world. Maxigesic tablets, Maxigesic IV ® and the Oral Liquid form, are now licensed in more than 100 countries across the globe.

The tablet and intravenous dose forms are registered in 49 and 24 countries, respectively. Further registrations of these forms as well as the Oral Liquid are expected in the coming year.

The company has also developed a hot drink sachet version of the medicine, Maxigesic Cold & Flu Hot Drink 'powder for oral liquid sachet'. This dose form gained its first registration in Australia in April 2021 in two strengths being Paracetamol 1000mg + Ibuprofen 300mg and Paracetamol 500mg + Ibuprofen 300mg as over the counter medicines.

This product has been licensed alongside other oral dose forms of Maxigesic in over 100 countries, while the first launch for this product is planned in the current financial year in Australia where Maxigesic is the largest selling paracetamol and ibuprofen combination product in units and dollars/value\*<sup>2</sup>.

For and on behalf of AFT Pharmaceuticals Limited, Malcolm Tubby, CFO

\*<sup>1</sup> Playne R et al. Analgesic effectiveness, pharmacokinetics and safety of a paracetamol/ibuprofen fixed-dose combination in children undergoing adenotonsillectomy: a randomised, single-blind, parallel group trial. *Pediatr Anesth*. <http://doi.wiley.com/10.1111/pan.13517>

\*<sup>2</sup> IRI Total Pharmacy, MAT to 6 June 2021.

#### **For more information:**

##### **Investors**

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

##### **Media**

Richard Inder  
The Project  
Tel: +64 21 645 643

#### **About Maxigesic® Oral Liquid**

Maxigesic Oral Liquid [paracetamol 160mg + ibuprofen 48mg per 5mL] is a unique combination of paracetamol and ibuprofen in the same patented synergistic 3.3:1 ratio as other Maxigesic dose forms. It is not yet approved in Australia or New Zealand.

#### **About Maxigesic® Cold & Flu Hot Drink**

Maxigesic Cold & Flu Hot Drink powder for oral liquid hot drink is a unique combination of paracetamol and ibuprofen in the same patented synergistic 3.3:1 ratio as other Maxigesic dose forms. It has two strengths being Paracetamol 1000mg + Ibuprofen 300mg and Paracetamol 500mg + Ibuprofen 300mg per sachet. It is approved in Australia but not New Zealand to date.

#### **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 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](http://www.aftpharm.com).