Working to improve your health

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FDA confirms earlier than expected PDUFA date for Maxigesic IV®

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) today announces the US Food and Drug Administration (FDA) has confirmed an earlier than expected Prescription Drug User Fee Act (PDUFA) date for Maxigesic IV, the intravenous form of its patented pain relief medicine.

The PDUFA date – the date at which the FDA must respond to the application - will be 30 June 2022, ahead of the August to September 2022 that AFT had expected.

AFT Managing Director Dr Hartley Atkinson said: "The earlier than envisaged PDUFA date offers the potential for an earlier registration and launch of Maxigesic IV in the US with our partner Hikma Pharmaceuticals.

"The launch itself is associated with a significant milestone payment so as long as we can achieve the PDUFA date this represents a useful time saving on our timeline for the commercialisation of Maxigesic IV in the US."

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 the rest of the world. For more information: aftpharm.com