Working to improve your health

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AFT licenses Maxigesic® IV in the US

Agreement with Hikma, the US' third largest supplier of generic injectable medications by volume[1], will see AFT benefit from upfront, regulatory and commercial milestone payments worth up to US$18.8 million and a profit share from in-market product sales.

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) today announces it has signed an exclusive License and Distribution Agreement with Hikma Pharmaceuticals USA ("Hikma") for the commercialisation of its Maxigesic IV, an intravenous, opioid free post-operative pain relief medicine, in the United States.

The agreement represents the first out license of the Maxigesic family of medicines into the US market. AFT, over the longer-term, is also targeting the US market for the tablet and liquid forms of the medication.

Under the terms of the license agreement, Hikma will have exclusive rights for the sales, marketing, and distribution of Maxigesic IV in the US.

In return AFT will be entitled to upfront, regulatory and commercial milestone payments of up to US$18.8 million as well as a profit share from in market product sales.

The milestone payments comprise US$7.5 million of payments due upon certain agreed milestones leading up to and including registration and the first commercial sale of Maxigesic IV in the US. Of these, US$3.6 million will be earned following the signing of the agreement and filing of Maxigesic IV for approval with the FDA. The further milestone payments are payable upon certain sales targets for Maxigesic IV in the US being reached.

AFT Managing Director Dr Hartley Atkinson said: "We are excited to be entering into the US market with Hikma, which has a strong and respected US hospital market presence and, in line with AFT's core values, is focused on providing cost effective therapies which improve patient care.

"The US market for post-operative pain management medication, according to independent research, was worth US$745 million in 2019 and is set to grow to US$1.7 billion by 2028.[2]

"It is satisfying to be offering a pain management medicine that gives clinicians a real alternative to opioids in the US, where addiction to these drugs has become an

epidemic. We believe, with Hikma, we can capture a significant share of this revenue."

Hikma is a global pharmaceutical company focused on complex and differentiated branded generics and generic pharmaceuticals across a broad range of indications, including respiratory, oncology and pain management.

It is the third largest US supplier of generic injectable medicines by volume, with a growing portfolio of over 100 products. Today one in every six injectable generic medicines used in US hospitals is a Hikma product.[1]

Dr Atkinson said AFT had expected to announce the agreement with Hikma in March this year and held that view right up to the last day of the 2021 financial year. However, as signalled at the start of this month the company had been hindered in achieving this goal due to unexpected delays in the negotiations.

"Had we achieved our plans to conclude the agreement with Hikma before 31 March 2021, we would have delivered FY21 earnings in the range of guidance affirmed in November 2020 for an operating profit of $14 million to $18 million. Sadly, the delays forced us to lower our guidance.

"AFT understands the importance of delivering on market expectations. We are pleased we can now provide further colour to our last earnings update and its timing, given the good faith efforts that we made to close out the commercially sensitive negotiations with Hikma before the end of our financial year, and then as soon as possible thereafter."

Maxigesic IV offers clinicians and healthcare providers a strong proposition. It is an effective alternative for the treatment of post-operative pain. It also avoids the side effects of traditional opioid-based analgesics that have fuelled an unprecedented cycle of addiction and abuse around the world.

The US agreement adds to existing Maxigesic IV agreements in Europe: Everpharm [Germany, Austria, France, and Italy]; Aguettant [Nordics, Netherlands, Portugal, and Spain]; Medochemie [Bulgaria, Cyprus, Czech Republic, Hungary, Romania, and Slovakia], Jed Pharma [Ireland] and Edge [United Kingdom], Vianex [Greece].

Outside Europe, AFT has also negotiated licensing agreements for Maxigesic IV in Ecuador [Acino], Hong Kong [DKSH] and Thailand [Alliance Pharma]. All of the agreements have been negotiated over the past year in spite of COVID-19 travel bans and are among the many steps AFT has taken to set itself up for continued growth,

Meanwhile, AFT is working to complete US FDA approval for the tablet form of the medication. In November last year, the FDA said a Good Manufacturing Practice inspection of the tablet production facilities for Maxigesic was the "only deficiency" with AFT's application for regulatory approval. The inspection is still pending due to COVID-19 related travel disruptions.

"We look forward to providing more detail when we release out audited financial results in May."

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

Notes to editors:
Maxigesic IV (Paracetamol 1000mg + Ibuprofen 300mg solution for infusion) is a patented intravenous formulation developed as a line extension to Maxigesic tablets, for use post-operatively in hospitals when patients cannot take a medicine orally. A major Phase 3 clinical trial conducted in the USA found that Maxigesic IV provided significantly better pain relief than either paracetamol (acetaminophen) IV or ibuprofen IV alone in the same doses.[3] Further, recently completed exposure trials have demonstrated the drug's efficacy and safety in an expanded population group over a longer treatment period.[4]

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.

About Hikma:
Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

About Ferghana Partners (New York, London, Boston) initiated the Hikma transaction and provided strategic/financial advisory services to AFT Pharma.

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4. Maxigesic® IV Phase 3 Exposure Study. Study ID No. AFT-MXIV-11. NCT04005755. Extending the safety profile of the post-operative administration of an intravenous acetaminophen/ibuprofen fixed dose combination: an open-label, multi-center, single arm, multiple dose study. Submitted for publication.