Working to improve your health

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US FDA accepts Maxigesic IV® New Drug Application

US regulator filing triggers milestone payment to AFT from its US licensee Hikma Pharmaceuticals

AFT Pharmaceuticals (NZX.AFT, ASX.AFP) today announces the US Food and Drug Administration (FDA) has confirmed acceptance of the New Drug Application (NDA) for Maxigesic IV®, the intravenous form of its patented pain relief medicine which was filed in August this year.

The US regulator is expected, in due course to confirm the Prescription Drug User Fee Act (PDUFA) action date for the filing. The PDUFA date – the date at which the FDA must respond to the application will be notified later this year and is estimated to be between August and September 2022.

As disclosed in April, the licensing of Maxigesic IV to our US partner Hikma Pharmaceuticals and the filing with the FDA triggers milestone payments in aggregate of US$3.6 million, which will be recognised in the first half of the current financial year.

In total the licensing 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 of up to US$18 million and a profit share from in-market product sales.

AFT Managing Director Dr Hartley Atkinson said: "The NDA acceptance marks an important milestone for our company. It is a major step towards bringing much needed innovation in non-opioid, post-operative pain management and addressing the current opioid crisis, which is responsible for many deaths in the U.S. each year.

"Together with our EU-based development partner Hyloris Pharmaceuticals and Hikma, we are looking forward to working with the FDA and to further executing on our global commercial rollout of Maxigesic IV."

The NDA submission is based on positive data from two Phase 3 studies of Maxigesic IV: a randomised, double-blind, placebo-controlled efficacy trial in 276 patients following bunionectomy surgery and an open-label, multi-centre, single arm, multiple dose safety study in 232 patients undergoing general, orthopaedic, or plastic surgery.

Treatment with Maxigesic IV was well-tolerated, had a faster onset of action and offered higher pain relief compared to ibuprofen IV or paracetamol IV alone in the same doses.

Moreover, the superior analgesic effect of Maxigesic IV was supported by a range of secondary endpoints, including reduced opioid usage rates compared to the paracetamol IV, ibuprofen IV and placebo treatment groups (P<0.005)[2].

The open-label Phase 3 safety study demonstrated that Maxigesic IV, administered 6-hourly as a 15-minute infusion over an exposure period of 48 hours to 5 days, was well-tolerated, and was perceived positively by study participants, supporting a favourable risk benefit profile[3].

Dr Atkinson said the market for Maxigesic IV, which has been licensed in over 100 countries across the globe, is now registered in 28 countries and launched in five countries, was significant.

"In 2019, 51 million surgical procedures were performed in the U.S. Meanwhile, globally, approximately 1.2 billion vials of non-opioid IV analgesics are sold each year. Of these, greater than 260 million vials of IV paracetamol are sold representing a global market of more than US$700 million. Maxigesic IV represents an effective alternative for many of these doses.

"Meanwhile the findings of reduced opiate use among those treated with Maxigesic IV has important implications for clinicians looking to reduce the risk of opioid addiction that can follow from post-operative pain management.

"Recently released data by the Centers for Disease Control and Prevention (CDC) show that drug overdose deaths reached a record high of 93,331 in 2020, of which 57,550 (62%) were due to synthetic opioid misuse[4].

"This represented a significant increase as compared to 2015 where synthetic opioids were involved in 18% of all overdose deaths. It is gratifying to be advancing a medication in the US that can help to overcome this terrible epidemic."

We look forward to providing further detail when we release our half-year financial result in mid-November."

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

Footnotes:

[1] Hikma Product Press Release (2020)
[2] Daniels et al, 2019, Clinical Therapeutics
[3] Gottlieb et al, 2021, Biomedicine & Pharmacotherapy
[4.] The CDC estimates that the total economic burden of prescription opioid misuse in the U.S. alone is US $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

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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