Market release
12 October 2017

Positive result from large US clinical trial for *Maxigesic* IV (*Intravenous*)

AFT Pharmaceuticals (AFT) has today announced the results of the major Phase 3 clinical trial for the intravenous (IV) form of its *Maxigesic* painkiller.

The study has found that *Maxigesic IV* provides much better pain relief than either paracetamol IV or ibuprofen IV alone in the same doses. The study was conducted in Texas and Maryland, USA at a cost of $NZ7.5 million.

Maxigesic IV (Paracetamol 1000mg + Ibuprofen 300mg solution for infusion) has been developed as a line extension to *Maxigesic* tablets primarily for use post-operatively in hospitals where patients cannot take an oral medicine.

The market for injectable analgesics is well defined and the leading non-opioid analgesic, paracetamol IV, has achieved significant sales around the world (US$622 million, Newport 2017) including North America and Europe. However paracetamol is still a relatively weak analgesic and is often supplemented with IV opioid analgesics.

CEO of AFT, Dr Harley Atkinson, says that the significance of results are two-fold. “First, this study shows the effectiveness of this form of *Maxigesic* and provides us with a strong basis for further advancing our world-wide licensing programme. Second, the fact that we can provide an opioid-free IV analgesic with improved analgesic strength compared to the market leading non-opioid analgesic, at a time when regulators

around the world are raising flags about opioid-based painkillers, is potentially significant in term of sales potential."

Dr Atkinson added that this US study has been the most expensive study ever conducted by AFT Pharmaceuticals and a key reason that AFT raised capital through the 2015 company float. "With pharma drug development, sometimes you need to crack a few eggs to make an omelette. This has been one of those cases. The sales potential for this particular form of the *Maxigesic* product line, together with the pleasing key study results, suggest that this has been a worthwhile investment. To have achieved an on-time completion and highly successful result - including multiple studies in addition to this pivotal Phase 3 study - is very satisfying. It's a credit to our research team at AFT and our collaborators in the US who conducted the study."

Maxigesic IV is currently licensed in 71 countries across Africa, and North Africa and parts of the Middle East, CIS, Italy and Turkey.

Dr Atkinson says that the results of the study are timely for the company given that licences for key higher value-markets have yet to be negotiated, and that the study results would likely help achieve more significant upfront licensing payments. He notes there will also be further regulatory work required, including filing the dossier and completion of registrations in multiple geographies around the world.

"The study results show we're continuing on the path to delivering the objectives listed in our 2015 Product Disclosure Statement. Meeting those commitments is important to both the management and board of AFT."

Trial details

The trial was carried out in the United States by Dr Ira Gottlieb, DPM (Chesapeake Research Group, LLC, Pasadena, Maryland) and Dr Stephen E Daniels, DO (Optimal Research LLC, Austin, Texas).

The study results were conducted in 276 patients after bunion surgery in Pasadena and Austin. The study was successful and met the primary endpoint demonstrating *Maxigesic IV* provided superior pain relief to either Paracetamol IV alone, Ibuprofen IV alone or placebo.

Results indicated a highly statistically significant difference between treatment groups in the primary endpoint (the key trial clinical measurement) for the improvement in sum of

the pain intensity difference scores (SPID) $p<0.001$ for *Maxigesic* IV in comparison will all other treatment groups.

End of release

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