
**ix BIOPHARMA REPORTS POSITIVE RESULTS FROM
WAFERMINE PHASE 2 MULTI-DOSE CLINICAL EFFICACY TRIAL (KET010)**

- ✓ Results demonstrate Wafermine's strong analgesic efficacy with strong and consistent effect sizes across both abdominoplasty and bunionectomy cohorts
- ✓ Wafermine's safety and tolerability confirmed

"Even with a relatively small number of subjects, Wafermine demonstrated strong, consistent effect sizes in Phase 2 clinical trials. This Phase 2 program not only provided evidence that Wafermine is effective for acute postoperative pain, but also contributed guidance on the best experimental design choices to demonstrate Wafermine's efficacy in both bunionectomy and abdominoplasty moving forward. This program paves the way for a strong likelihood of success in Phase 3 pivotal trials."

- Dr Neil Singla¹, Chief Scientific Officer at Lotus Clinical Research

Singapore, 5 September 2018 – Specialty pharmaceutical company iX Biopharma Ltd. ("iX Biopharma" or, together with its subsidiaries, "the Group") is pleased to announce positive top-line results for the Phase 2 study of its sublingual ketamine wafer, Wafermine. The study results demonstrate strong analgesic efficacy, safety and tolerability in participants experiencing moderate to severe acute, post-operative pain after undergoing either abdominoplasty or bunionectomy surgery.

Efficacy

The Group is pleased to report the following results:

- Based on a primary efficacy measure of the summed pain intensity difference over 12 hours (SPID12), the Wafermine 75mg (high dose) group showed a strong and clinically meaningful pain-suppressing effect and provided the strongest effect and separation from placebo compared to the other dose strengths of 25mg and 50mg.
- The standardised effect size, which is a comparable measure of the magnitude of a drug's effectiveness, for Wafermine 75mg, was 0.76 for the abdominoplasty cohort [n=10; p=0.10] and 0.73 for the bunionectomy cohort [n=20; p=0.06]. An effect size >0.7 indicates a large treatment effect.
- A dose response was observed, with the Wafermine 75mg group outperforming the Wafermine 50mg group, which in turn outperformed the Wafermine 25mg group.
- Consistent with the strong analgesic effect observed, a lower proportion of participants required rescue medication in the Wafermine 75mg group compared to placebo in both abdominoplasty and bunionectomy cohorts.

¹ Dr. Neil Singla, a board-certified anesthesiologist, is the founder and Chief Scientific Officer of Lotus Clinical Research. Dr Singla is a nationally recognized key opinion leader in analgesic protocol design and implementation. He has published extensively and is a frequent lecturer for physicians, pharmaceutical companies and medical research institutes throughout the country. He currently chairs the Analgesic Clinical Trials Shared/Special Interest Group at both the American Pain Society (APS) and the International Association for the Study of Pain (IASP). He chairs the annual APS Conference on Analgesic Clinical Trials (APS-CAT), which aims to help experts advance best practices in analgesic drug development.

Based on the reported effect sizes in the Wafermine 75mg group, an estimated cohort size of approximately 40 participants per treatment arm for abdominoplasty and approximately 50 participants per treatment arm for bunionectomy would be required in Phase 3 studies to achieve a P value <0.05 with 90% statistical power.

Safety and Tolerability Wafermine administration was safe and tolerable with no serious adverse events. Adverse events (AEs) considered related to study drug were expected and consistent with the known side-effects of ketamine. The majority of AEs were considered only of mild severity, were of short duration and resolved spontaneously.

Professor Stephan Schug², renowned Pain Specialist and Scientific Advisor to iX Biopharma Ltd stated: *“Wafermine provides a sublingual route of administration for ketamine, which was previously only available as a parenteral medication. This new route of administration for an ‘old’ drug offers new opportunities for the use of ketamine in multiple settings of acute pain management. The convincing efficacy of Wafermine demonstrated in two classical models of post-operative pain with acceptable and mainly minor adverse effects confirm the usefulness of this new approach. Besides post-operative pain, this medication offers new possibilities in the management of procedural pain (e.g. burns dressing changes), in the emergency department and for pre-hospital care.”*

Following the successful results of the Phase 2 study, preparations are now being made towards an End-of-Phase-2 (EOP2) meeting with the US FDA where the Phase 3 Wafermine programme will be discussed. The EOP2 meeting is anticipated to be held in the first quarter of 2019.

Dr Janakan Krishnarajah, Chief Medical Officer of iX Biopharma Ltd said, *“We are delighted with the top-line results from the KET010 study. These results represent a major step forward in the programme and we are looking forward to presenting the study results at the BioEurope conference in Copenhagen, Denmark in early November 2018.”*

The Phase 2 study was a randomised, double-blind, placebo-controlled trial in a total of 125 female and male participants who underwent either abdominoplasty or bunionectomy surgery. The study was conducted under United States Food and Drug Administration (FDA) IND #121098 at Lotus Clinical Research, a premier analgesic research clinical trial facility located in Pasadena, California.

About Wafermine

Wafermine, our lead product in clinical development, utilises iX Biopharma's proprietary WaferiX sublingual wafer technology to effectively deliver ketamine in sub-anaesthetic doses for the treatment of moderate to severe pain. This makes Wafermine the world's first oral-sublingual ketamine used for pain relief – a breakthrough in pain management. The sublingual delivery avoids the requirement (and associated logistical issues) of administering ketamine intravenously, yet still delivers the drug rapidly and predictably to the bloodstream. Wafermine may be used as an effective alternative to, or in conjunction with, opioids that are

² Prof Stephan Schug is currently Professor and Chair of Anaesthesiology and Pain Medicine in the Medical School of the University of Western Australia and Director of Pain Medicine at the Royal Perth Hospital, Australia. As the Director of Pain Medicine in the Department of Anaesthesia and Pain Medicine of Royal Perth Hospital his clinical responsibilities include the running of a Comprehensive Inpatient Pain Service at this hospital as well as a multidisciplinary Pain Medicine Centre under the auspices of the WA State-wide Pain Service. Professor Schug is an active member of several pain and anaesthesia societies including Chair of the SIG Acute Pain of IASP and Chair of the SIG Acute Pain of ACE (ANZCA, ASA, NZSA), Secretary General of Asian & Oceanic Society of Regional Anaesthesia (AOSRA) and is a Fellow of the Australian and New Zealand College of Anaesthetists (ANZCA) and its Faculty of Pain Medicine (FPMANZCA), where he is a member of the Board of the Faculty.

commonly used in the management of moderate to severe pain. With the use of Wafermine and its well-established opioid-sparing effects, patients may be able to avoid developing opioid tolerance and dependency, along with a reduced risk of opioid-induced respiratory depression.

About iX Biopharma Ltd

iX Biopharma is a Singapore public-listed specialty pharmaceutical and nutraceutical company, operating a fully integrated business model from drug development to laboratory testing, manufacturing and supply, with facilities in Australia. The Group is focused on the development and commercialisation of innovative therapies for improving the quality of life of those suffering from pain and other health conditions.

iX Biopharma's pipeline of products under development includes Wafermine (ketamine wafer) and BnoX (buprenorphine wafer) for pain management. iX Biopharma's drugs for the treatment of erectile dysfunction, Wafesil, a sublingual sildenafil wafer, and Silcap, have been registered in Australia.

The Group's nutraceuticals division, Entity Health Limited, recently launched its Entity line of nutraceutical products and is engaged in the development and commercialisation of nutraceutical products that address specific conditions and improve quality of life. In addition to the successful registration of Wafesil and Silcap, the Group's nutraceutical arm, Entity Health, has also applied for assessment by TGA for quality and safety of its nutraceutical products. To date, the Group has successfully obtained 15 product listings on the ARTG with 8 listings for domestic sales and 7 listings for export sales on the ARTG.

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