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iX BIOPHARMA REPORTS SUCCESS OF SINGLE-DOSE WAFERMINE™ CLINICAL TRIALS

- ✓ **Results of two Phase 2 clinical trials confirm rapid onset of action with good tolerability**
- ✓ **Positive results place iX Biopharma in good position to complete clinical development programme**

Singapore, 17 September 2015 – Specialty pharmaceutical company **iX Biopharma Ltd.** ("iX Biopharma" or, together with its subsidiaries, "the Group") is pleased to announce that its Phase 2a and 2b clinical trials for its lead product, Wafermine™, have proven successful. The results confirmed a rapid onset of pain relief, along with good tolerability. Wafermine™, is one of three iX Biopharma products currently under development and the world's first oral-sublingual analgesic employing ketamine as its active compound.

The clinical trials, conducted over the past one year, were designed to demonstrate the effectiveness and rapid onset of action of Wafermine™, and to determine the dosage scheme for the pivotal Phase 3 clinical trials.

The Phase 2 clinical study protocols were approved by the US Food & Drug Administration and the two studies were conducted in the US with 200 patients. Five groups of 30 patients each who had just undergone the extraction of impacted wisdom teeth were administered 25mg, 35mg, 50mg, 70mg or 100mg of Wafermine™ in a single dose, while 50 patients (divided into two control groups) were each administered a placebo.

Prior to the drug/placebo administration, the patients were requested to rate their pain at intervals to see if a greater pain relief or longer duration of action could be achieved with higher doses. The results showed that all doses rapidly reduced pain within 10 minutes of administration and were well-tolerated by the patients, This was consistent with the large number of scientific studies demonstrating the efficacy and safety of low-dose ketamine administration in pain management.

Dr Paul Rolan, Director of Drug Development at iX Biopharma, said, "As a pain specialist, I am excited to see rapid and clinically important pain relief from Wafermine™, especially at low doses that are well-tolerated. These results put us in an excellent position to complete the clinical development programme, which will deliver a new alternative in management of severe pain."

On the back of the positive results of the above single-dose studies, the Group has commenced preparations to conduct a limited study for Wafermine™ that is designed for multiple dosing before embarking on the Phase 3 trials next year.

An abstract of the single-dose studies is appended at the end of this press release.

About iX Biopharma Ltd

iX Biopharma Ltd is a specialty pharmaceutical company, with initial focus on the development and commercialisation of innovative therapies for pain management and men's health. The Company leverages its patented sublingual drug delivery technology, WaferiX™, to develop proprietary products that incorporate pharmacologically active compounds that have been approved by the United States Food and Drug Administration. It currently has three products under development – **Wafermine™**, **Wafernyl™** and **PheoniX™**.

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ABSTRACT

A randomised, double-blind, parallel, placebo-controlled dose-ranging study to assess the analgesic efficacy, tolerability, safety and pharmacokinetics of a sublingual wafer formulation of ketamine following removal of impacted wisdom teeth.

Background

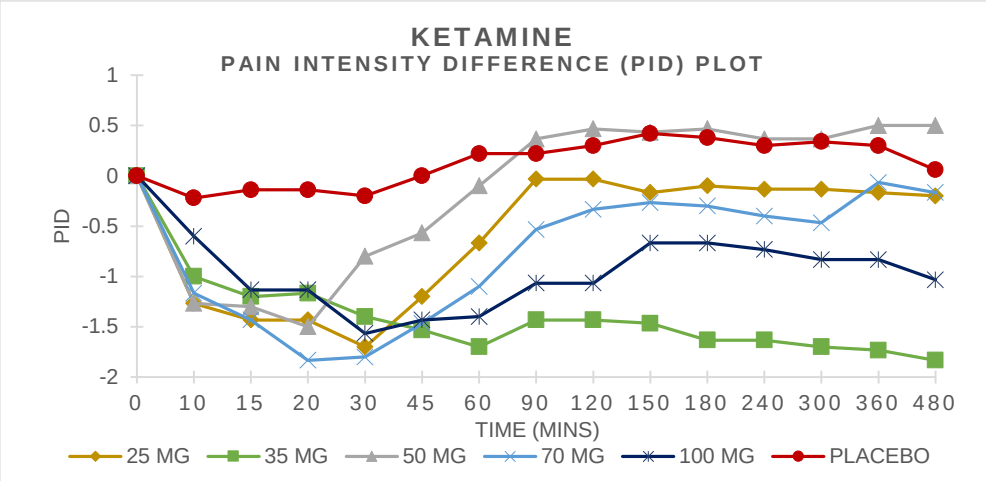
Trials KET-003 and KET-005 studied the reduction in pain and safety of single doses of Wafermine™. The purpose was to demonstrate rapid onset of pain relief and to select the dosing scheme for the pivotal phase 3 program.

Methods

Both studies examined the pain relief and safety of Wafermine™ in patients with post-operative pain following removal of impacted wisdom teeth. This is a well-accepted method of evaluating pain relief properties of single doses of drugs. In both trials, groups of 30 patients received single doses of 25, 35, 50, 70 or 100 mg of Wafermine™ with 50 patients receiving placebo. The studies were performed at specialist pain research units in the United States, using protocols approved by the US Food & Drug Administration.

Results

In both studies, Wafermine™ produced rapid onset of pain relief, usually by 10 minutes post dose, with maximum effects generally at around 30 minutes, before subsiding over 1-2 hours. The size of effects is clinically significant (see below graphs illustrating the reduction in pain).



Overall Wafermine™ was well-tolerated with most reported side effects being mild and short lived, and consistent with the expected effects of low-dose ketamine. Wafermine™ was well tolerated in the oral cavity with side effects no different from placebo.

Blood level measurement confirmed rapid absorption of Wafermine™ with levels expected for the dose.

The study results are being prepared for publication in a peer-reviewed medical journal.

Conclusion

These two studies showed rapid relief of severe pain from Wafermine™ at doses that were well-tolerated. These data are in agreement with the large number of scientific studies showing efficacy and safety of low-dose ketamine in pain management.