

## NEWS RELEASE

### **iX BIOPHARMA REPORTS POSITIVE RESULTS FROM MULTI-DOSE WAFERMINE™ CLINICAL TRIAL**

- ✓ **Preliminary Results of Phase 2c clinical trial confirm safety and good tolerability**

**Singapore, 7th March 2016** – Homegrown specialty pharmaceutical company **iX Biopharma Ltd.** (“iX Biopharma” or, together with its subsidiaries, “the Group”) is pleased to announce the success of KET009, a multi-dose, placebo-controlled clinical study of its lead product, Wafermine™, which confirmed its safety and good tolerability. Wafermine™ is one of three products currently developed by iX Biopharma, and the first ever oral-sublingual analgesic employing ketamine as its active compound.

The study objective was to demonstrate the safety and tolerability of Wafermine™ when administered alone and in combination with opioids through three different dosing regimens of Wafermine™ in subjects undergoing bunionectomy. The opioid used in the trial was oxycodone, a common prescription drug for pain management.

The study was conducted at a single centre in the United States of America which has expertise in undertaking bunionectomy studies. The study recruited 72 participants (6 participants each for the placebo and oxycodone groups and 12 participants each for the remaining five Wafermine™ groups) randomised to seven treatment groups. Participants received either a placebo, Wafermine™ alone, oxycodone alone or in combination with Wafermine™.

The results of the study confirmed that Wafermine™ was well-tolerated with no serious adverse effects at the maximum accumulated dosage of 315mg over a 14-hour period. The most frequent adverse events reported were nausea, vomiting and dizziness which are common in post-operative populations. It was noted that the same adverse events occurred with similar frequency in all treatment groups.

Dr Paul Rolan, Director of Drug Development said, “KET009 was successfully completed on time and within budget. This study was conducted in a single centre in USA (under the FDA IND #121098) where Wafermine™ was administered over 14-hours; making this study, to the

best of our knowledge, the longest duration of administration of a non-injected ketamine product ever studied clinically. I'm pleased to report that the safety and tolerability of Wafermine™ was excellent, establishing such treatment as suitable for multiple dose administration in clinical trials that would be required for international registration and approval. Reduction in pain scores was correlated with blood levels of ketamine, further supporting our development program with Wafermine™ for treatment in post-operative pain.”

KET009 comes on the back of successful single-dose studies that have established Wafermine™ analgesic efficacy, safety and tolerability.

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### **About iX Biopharma Ltd**

iX Biopharma Ltd is a Singapore public-listed 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™** and **Wafernyl™** for pain management, and **PheoniX™** for erectile dysfunction.

### **Contact for media:**

**Ms Alvina Tan**

DID: +65 6221 2123

H/P: +65 9787 7267

Email: [alvina.tan@arkadvisors.com.sg](mailto:alvina.tan@arkadvisors.com.sg)

**Ms Karin Lai**

DID: +65 6221 0081

H/P: +65 9837 8136

Email: [karin.lai@arkadvisors.com.sg](mailto:karin.lai@arkadvisors.com.sg)

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The contact person for the Sponsor is Mr Tony Toh, Director, Investment Banking, CIMB Bank Berhad, Singapore Branch. The contact particulars are 50 Raffles Place, #09-01 Singapore Land Tower, Singapore 048623, telephone: (65) 6337-5115.