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IX BIOPHARMA REPORTS POSITIVE RESULTS FROM PHARMACOKINETIC STUDY OF BNOX

Singapore, 15 May 2017 – Homegrown specialty pharmaceutical company **iX Biopharma Ltd.** ("iX Biopharma" or, together with its subsidiaries, "the Group") is pleased to announce the results of BUP001, a pharmacokinetic study of its novel sublingual buprenorphine wafer, BnoX. BnoX, which uses the Group's patented sublingual drug delivery technology, WaferiX, is one of the Group's products under development for pain management.

The primary objective of the study was to investigate the absolute bioavailability and tolerability of BnoX. (It is generally known that the oral bioavailability of buprenorphine is very low and variable, leading to unpredictable clinical effects).

The absolute bioavailability of BnoX was 45.4% with time to maximum plasma concentration (Tmax) of 1 hour. This compares favourably to the only marketed sublingual formulation for pain, Temgesic® which has a reported bioavailability of 35% and Tmax of 2-4 hours[1]. BnoX wafers were safe and well-tolerated.

Dr Janakan Krishnarajah, Chief Medical Officer said: "We are very pleased with the outcomes from BUP001 study. The results suggest that BnoX appears to have a superior pharmacokinetic profile compared to the marketed Temgesic® sublingual tablet, and may provide enhanced clinical utility in the management of both acute and chronic pain."

Dr Krishnarajah will be presenting this exciting study result at the Annual Scientific Meeting of the Australian and New Zealand College of Anaesthetists to be held in Brisbane, Australia on Monday, 15 May 2017. This is the premier annual conference for anaesthetists in Australia and New Zealand, and 1,800 attendees are expected.

[1] Temgesic® Product Information

About iX Biopharma Ltd

iX Biopharma Ltd is a Singapore public-listed specialty pharmaceutical company, with manufacturing and laboratory testing 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. The Company leverages its patented sublingual drug delivery technology, **WaferiX**, to develop proprietary products that incorporate pharmacologically active compounds that have been approved by regulatory bodies. Its pipeline of products under development includes **Wafermine** and **BnoX** for pain management; it is also in the process of commercialising **PheoniX** for erectile dysfunction and **WafeRest** for improved sleep quality.

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The pharmacokinetics, absolute bioavailability and tolerability of a novel sublingual formulation of buprenorphine (BnoX™)

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BACKGROUND

Buprenorphine is approved for use in pain management and opioid addiction. Sublingual administration of buprenorphine is a simple and non-invasive route of administration and has been available for many years. Current approved sublingual formulation is limited by slow disintegration and low bioavailability. An improved formulation may lead to increased utilization of this useful drug for acute and chronic pain management.

AIM

The principal study objective was to investigate the pharmacokinetic characteristics and determine the absolute bioavailability and tolerability of a novel sublingual buprenorphine wafer.

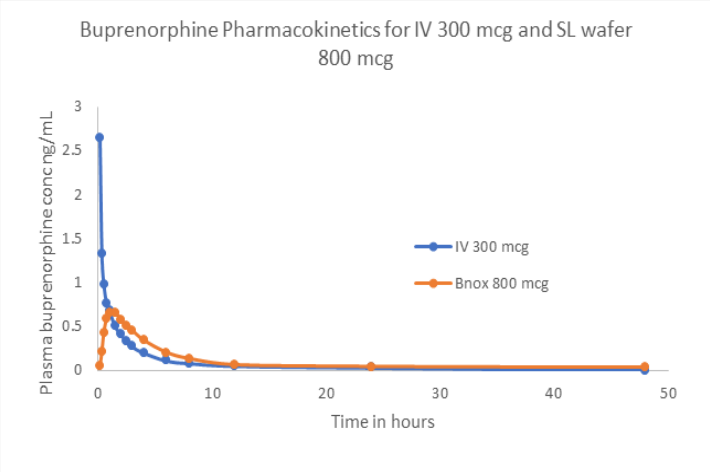
METHODS

The study was of open label, two-way randomised crossover design in fourteen fasted healthy male and female volunteers. Each participant, following a naltrexone block, received either a single 300 microgram intravenous dose of buprenorphine as a constant infusion over five minutes or a 800 microgram sublingual dose of buprenorphine (BnoX™) in two treatment periods, separated by a seven day washout. Blood sampling for plasma drug assay was taken at intervals up to 48 hours post dosing. The pharmacokinetic parameters were determined by non-compartmental analyses of the buprenorphine plasma concentration-time profiles. Local tolerability was assessed using modified Likert scales.

RESULTS

The absolute bioavailability of SL buprenorphine was 45.4% (37.8% -54.3%; 90% CI). Tmax, time to peak plasma concentration, was 10 minutes and 60 minutes after IV and SL administration, respectively. Cmax, peak plasma concentration, was 2.65 ng/mL and 0.74 ng/mL after IV and SL administration, respectively.

Elimination half-life, $t_{1/2}$, was 9.1 hours and 11.2 hours after IV and SL administration, respectively.



No serious adverse events were reported. There were no participants withdrawn due to adverse events (AEs). A total of 24 AEs were reported in 11 participants during the study: in 8 of 14 participants (57%) following dose administration with BnoX™ wafer 800 mcg and 8 of 14 participants (57%) following dose administration with IV Buprenorphine 300 mcg. Most AEs (19 of 24, 79% of all AEs) were classified as mild, with AEs of moderate severity being one each of diarrhoea, nausea, migraine, presyncope, and catheter site pain. Commonly occurring AEs, reported in at least 2 participants (> 10%) were nausea, headache, tension headache, oral hypoaesthesia, and catheter site pain. It is noted that nausea was reported only following IV Buprenorphine 300 mcg, in 3 of 14 participants (21%). Good oropharyngeal tolerability was observed with the BnoX™ wafer with no abnormal findings of oral cavity examination and no sublingual irritation or burning sensation reported on oral symptom questionnaire.

CONCLUSION

This novel sublingual buprenorphine wafer has high bioavailability (45.4%) and reduced Tmax (1 hour) compared to other SL tablet formulations of buprenorphine (Temgesic® bioavailability 35%, Tmax 2-4 hours)[1]. The wafer displayed good local tolerability. The results suggest this novel buprenorphine wafer may provide enhanced clinical utility in the management of both acute and chronic pain.

[1] Temgesic® Product Information (Australia)

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