

## NEWS RELEASE

### IX BIOPHARMA OBTAINS APPROVAL AND REGISTRATION OF WAFESIL FOR THE TREATMENT OF MALE ERECTILE DYSFUNCTION IN AUSTRALIA

- *First sublingual wafer sildenafil product for male erectile dysfunction available in Australia*
- *First product in iX Biopharma's pharmaceutical pipeline utilising WaferiX to receive approval and registration*

Singapore, 19 June 2018 – iX Biopharma Ltd. (“iX Biopharma” or, together with its subsidiaries, “the Group”) is pleased to announce the approval by Therapeutic Goods Administration (“TGA”), the regulatory authority in Australia, for WAFESIL (sublingual sildenafil wafer) formerly referred to as PheoniX, for the treatment of male erectile dysfunction. WAFESIL is a new dose form of sildenafil delivered using iX Biopharma’s proprietary drug delivery technology, WaferiX, which consists of a fast-dissolving wafer placed sublingually (under the tongue), allowing sildenafil to be administered safely, conveniently and rapidly into the blood stream. WAFESIL is the Group’s first pharmaceutical product utilising WaferiX to reach approval and registration.

Approximately 20% of Australian men greater than 40 years suffer from male erectile dysfunction with a significantly increased risk with aging and cardiovascular disease<sup>1</sup>. “*The launch of WAFESIL will provide new treatment options to doctors to help them serve an estimated one million men in Australia who are diagnosed with male erectile dysfunction, especially those who have an aversion to swallowing tablets*”, said Ms Eva Tan, Commercial Director. “*There is tremendous opportunity for us to establish an important new market for WAFESIL, given its status as a halal product and the only sublingual sildenafil product in Australia*”.

“*The approval of WAFESIL affirms the utility of our WaferiX drug delivery technology and demonstrates our ability to bring our products from clinical development to registration and launch*,” said Dr Janakan Krishnarajah, Chief Medical Officer.

WAFESIL is available in dosage strengths of 25 mg and 50 mg in pack sizes of 4, 8 and 12 wafers. WAFESIL will be supplied to the market via wholesaler and pharmacy channels.

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<sup>1</sup> Australian Government Department of Health, Therapeutic Goods Administration, 31 October 2017, *Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health*, accessed on 18 June 2018, <https://www.tga.gov.au/sites/default/files/final-decision-and-reasons-for-decision-by-delegate-october-2017.pdf>.

The Advisory Committee on Medicines Scheduling (“ACMS”) in Australia will be convening this month to consider the proposed reclassification of sildenafil drugs from prescription to non-prescription status, in oral preparations containing 50 mg of sildenafil per dosage unit in packs of not more than 8 dosage units. If the proposal is approved, sildenafil will be rescheduled from Schedule 4 to Schedule 3 of the Poisons Standard and be available for purchase over the counter (“OTC”) without a doctor’s prescription. Consumer-targeted advertisements of sildenafil drugs will also be allowed in Australia. Sildenafil is already available for OTC purchase in New Zealand, United Kingdom and Poland. In the event of a rescheduling of sildenafil, the market and commercial potential for WAFESIL will increase as OTC availability plus consumer advertising will enable WAFESIL to reach many men with erectile dysfunction who do not currently seek help from a doctor, and direct them away from unregulated and counterfeit supplies of erectile dysfunction drugs.

In addition to the successful registration of WAFESIL on the Australian Register of Therapeutic Goods (“ARTG”), 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.

### **About male erectile dysfunction and sildenafil**

Erectile dysfunction is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. Problems with erections may be related to a wide variety of factors. Erectile dysfunction is common among older men and is often associated with chronic illnesses including atherosclerosis, diabetes and depression. It is also associated with certain prescription medications and alcohol consumption.

Sildenafil is used to treat erectile dysfunction in adult men. It restores impaired erectile function in the aroused state by increasing blood flow to the penis. This is achieved through its inhibition of the enzyme PDE-5 ultimately resulting in relaxation of the smooth muscle surrounding the penile blood vessels.

### **About iX Biopharma and WaferiX**

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 leverages its patented sublingual drug delivery technology, WaferiX, to develop proprietary products that incorporate pharmacologically active compounds that have been approved by regulatory bodies. WaferiX is a fast-dissolving, proprietary wafer formulation that

allows pharmacologically active compounds including sildenafil to be administered sublingually (i.e., placed under the tongue) and delivered safely, conveniently and rapidly into the blood stream. The technology offers a non-invasive, pain-free alternative to traditional routes of drug administration such as intravenous drips and injections. Key advantages of WaferiX include the reduction of the effect of first-pass metabolism, rapid onset of action, better side effect profile, easy administration, improved patient compliance and a better storage profile.

iX Biopharma's pipeline of products under development includes Wafermine (Ketamine wafer) and BnoX (Buprenorphine wafer) for pain management, and XCalibur (Sildenafil capsule) for erectile dysfunction.

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.

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