

NEWS RELEASE

IX BIOPHARMA ANNOUNCES APPROVAL OF FIRST CAPSULE SILDENAFIL DRUG FOR TREATMENT OF MALE ERECTILE DYSFUNCTION IN AUSTRALIA

- First capsule sildenafil product for male erectile dysfunction available in Australia
- Approval closely follows the successful registration of WAFESIL in June 2018

Singapore, 6 August 2018 – iX Biopharma Ltd. ("iX Biopharma" or, together with its subsidiaries, "the Group") is pleased to announce that it has received the approval by Therapeutic Goods Administration ("TGA"), the regulatory authority in Australia, for a sildenafil drug delivered using an oral capsule for the treatment of male erectile dysfunction. The product, which was formerly referred to as XCalibur, will be available under the brand name SILCAP in Australia.

SILCAP is a generic version of Viagra[®] and will compete in the growing generic male erectile dysfunction market. Unlike existing sildenafil options in the market which are delivered in tablet form, SILCAP is delivered using a novel, small capsule and gives patients who dislike or are unable to swallow tablets an alternative dose form. SILCAP is the first capsule sildenafil product to obtain marketing approval in Australia.

SILCAP represents iX Biopharma's second drug for the treatment of male erectile dysfunction and the second drug in its product development pipeline that has been approved and registered successfully. On 19 June 2018, the Company announced that it had obtained the approval and registration of WAFESIL with TGA. WAFESIL is the only sublingual sildenafil product approved in Australia and represents a new dose form of sildenafil as opposed to being a generic version of Viagra[®].

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

As previously announced by the Company, the Advisory Committee on Medicines Scheduling ("ACMS") in Australia will be convening 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. Consumertargeted 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 SILCAP and WAFESIL will increase as OTC availability plus consumer advertising will enable SILCAP and 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.

About male erectile dysfunction and sildenafil

Approximately 20% of Australian men greater than 40 years suffer from male erectile dysfunction with a significantly increased risk with aging and cardiovascular disease¹. 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

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. In addition to SILCAP, iX Biopharma has also registered WAFESIL, a sublingual sildenafil wafer for the treatment of erectile dysfunction, with TGA.

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 SILCAP and 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.

¹ 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.



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