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## NEWS RELEASE

**Singapore, 10 December 2019** – Specialty pharmaceutical company **iX Biopharma Ltd** (SGX:42C) (“iX Biopharma” or, “the Company”) is pleased to announce that it has successfully concluded an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) regarding Wafermine, a sublingual ketamine wafer for the treatment of acute moderate to severe pain.

During the meeting, the Company and the FDA reached agreement on key aspects of the pivotal Phase 3 clinical trial program to support approval of Wafermine for the indication of acute moderate to severe pain. The Phase 3 program consists of two randomised, double blind, placebo-controlled studies, one in an orthopaedic pain model (bunionectomy) and one in a soft-tissue pain model (abdominoplasty). Both of these post-operative pain models were successfully evaluated in the recent Phase 2b clinical study. The primary efficacy measure for both studies will be SPID12, which is the summed pain intensity difference over 12 hours. The summed pain intensity difference over 24 hours (SPID24) and 48 hours (SPID48) will be evaluated as secondary endpoints.

**Dr. Janakan Krishnarajah, Chief Medical Officer of iX Biopharma said:** *"We are very pleased with the positive outcome of our meeting with the FDA and this is a major milestone for the iX Group. We appreciate the valuable guidance the FDA has provided and look forward to continuing a constructive relationship as we advance our Phase 3 registration program. We remain focused on bringing Wafermine to market as a new and differentiated non-opioid analgesic for patients and caregivers seeking alternatives to conventional opioids."*

The Phase 3 studies will be using the same post-operative pain models that were successfully evaluated in the recent Phase 2b clinical study. Accordingly, the Company is highly confident that the excellent results from this study can be replicated in the final pivotal studies. More importantly, confirmation of the EOP2 meeting with the FDA gives clarity to the Wafermine development program, especially costs and timeline. Further, it positions the Company well to continue licensing discussions with potential licensees.

– The End –

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## **About Wafermine**

Wafermine is a novel sublingual ketamine wafer developed using the Group's patented WaferiX sublingual delivery technology for the treatment of acute moderate to severe pain. Ketamine is a non-opioid drug which offers a valuable alternative to opioids for the treatment of pain. Ketamine is a NMDA antagonist which, unlike opioids, does not cause respiratory depression leading to death if misused. Wafermine has the potential to be used in substitution or as an adjunct to opioids addressing a large unmet clinical need.

## **About iX Biopharma Ltd**

iX Biopharma is a specialty pharmaceutical and nutraceutical company listed on the Catalist board of the Stock Exchange of Singapore (SGX-ST), operating a fully integrated business model from drug development to manufacturing and supply, with facilities in Australia. The Group is focused on the development and commercialisation of therapies for diseases of the central nervous system using novel, patent-protected formulations for sublingual delivery.

iX Biopharma's pipeline of products under development includes Wafermine (ketamine wafer) and BnoX (buprenorphine wafer) for pain management. iX Biopharma's drugs for the treatment of erectile dysfunction, Wafesil, a sublingual sildenafil wafer, and Silcap, have been registered in Australia.

The Group's nutraceuticals division, Entity Health Limited, is engaged in the development and commercialisation of nutraceutical products that address specific conditions and improve quality of life. It distributes its Entity line of nutraceutical products through more than 200 pharmacies and health food shops in Australia and online.

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This announcement has been reviewed by the Company's sponsor, CIMB Bank Berhad, Singapore Branch ("**Sponsor**") in accordance with Rule 226(2)(b) of the Catalist Rules. This announcement has not been examined or approved by the SGX-ST and the SGX-ST assumes no responsibility for the contents of this announcement, including the correctness of any of the statements or opinions made or reports contained in this announcement.

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