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NEWS RELEASE

iX Biopharma receives positive EMA Scientific Advice for Wafermine

- ✓ EMA has endorsed iX Biopharma's proposed Phase 3 clinical development programme for Wafermine
- ✓ EMA Scientific Advice provides clarity on registration pathway in Europe

Singapore, 10 November 2020 – Specialty pharmaceutical company **iX Biopharma Ltd** (SGX:42C) ("iX Biopharma" or, "the Company") is pleased to announce that it has received positive feedback from the European Medicines Agency (EMA) in its scientific advice to the Company regarding its Phase 3 clinical development programme for Wafermine, its sublingual ketamine wafer, for registration in Europe (the "EMA Scientific Advice").

In the EMA Scientific Advice, the EMA endorsed the Company's proposed design of the pivotal Phase 3 studies. The Phase 3 programme, which has been similarly agreed by the US FDA, 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). 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. The Phase 3 studies will use the same pain models and primary endpoint that was successfully evaluated in Wafermine's Phase 2b clinical study.

With the successful outcome of the EMA Scientific Advice and End-of-Phase 2 meeting with the US FDA, the Company has now reached consensus with the regulators of the major markets of Europe and the United States on the remaining clinical development required to support the approval of Wafermine for the treatment of acute moderate to severe pain in those markets.

Dr. Janakan Krishnarajah, Chief Operating Officer and Chief Medical Officer of iX Biopharma said: "EMA's endorsement of the proposed Phase 3 programme design is an exciting achievement that affirms the robustness of our clinical development approach. The EMA response confirms that our development strategy will satisfy the clinical study requirements for both US and European approval, and provides clarity to programme cost and timelines. This makes Wafermine a very attractive late stage partnering opportunity for both US and European markets."

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. It is estimated that there were approximately 120 million acute pain cases in the US, EU5 countries (Germany, France, Italy, Spain, and the United Kingdom) and Japan in 2017. Moderate to severe pain accounted for the largest share of the acute pain cases[1].

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

[1] *Acute Pain - Market Insights, Epidemiology and Market Forecast to 2028, Research and Markets, 30 September 2019*

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.

- **The End -**

About iX Biopharma Ltd

iX Biopharma is a specialty pharmaceutical and nutraceutical company listed on the Catalist board of the Singapore Exchange Securities Trading Limited (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 and Singapore. iX Biopharma has developed Xativa, the world's first freeze-dried sublingual medicinal cannabis wafer.

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 in Australia through more than 250 pharmacies and health food shops, in China through its flagship stores on Tmall Global and JD Worldwide, and globally through its online store.

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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. The contact person for the Sponsor is Mr. Yee Chia Hsing, Head, Catalist. The contact particulars are 50 Raffles Place, #09-01 Singapore Land Tower, Singapore 048623, telephone: (65) 6337-5115.