

[Press Release – For Immediate Release]



Endurance RP Limited

(SEHK:0575.HK)

**Operational Update on the PE Prevention Drug Fortacin™ /
Senstend™**

Phase 3 Study in China is Estimated to Complete in November 2022

(4 July 2022, Hong Kong) – **Endurance RP Limited (“Endurance Longevity” or the “Company” and together with its subsidiaries, the “Group”;** stock code: 0575.HK) is pleased to provide updates on the PE prevention drug - Fortacin™ / Senstend™ (the marketing name of Fortacin™ in China).

China

Regarding the clinical study for seeking approval of an import licence for Senstend™ from the National Medical Products Administration (“NMPA”) of The People’s Republic of China (“China” or “PRC”), among the three drug trials that Wanbang Biopharmaceutical Co., Ltd. (“Wanbang Biopharmaceutical”), the Company’s commercial strategic partner for China and a wholly controlled company of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. registered in December 2021 with the [Centre of Drug Evaluation](#), the two Phase 1 studies have been successfully completed and the remaining Phase 3 study remains ongoing. Despite certain COVID-19 lockdowns and restrictions being experienced in China, the Phase 3 study has commenced with 177 patients having signed informed consent forms to enter the study (approximately 62% complete) and 88 subjects having been randomised into the study (approximately 31% complete) as of 1 July 2022. Wanbang Biopharmaceutical has advised the Company that even with the aforementioned COVID-19 lockdowns and restrictions, enrolment and randomisation is estimated to complete in November 2022.

The preparatory phase for preparing the New Drug Application (“NDA”) to NMPA have been commenced with the aim of submitting the NDA by the end of Q2 2023. All costs of the clinical trials, including all other associated regulatory and submission costs are being met by Wanbang Biopharmaceutical.

If the clinical study meets its endpoints and the NMPA grants an import licence for Senstend™, US\$5 million (or approximately HK\$39 million before deduction of PRC withholding tax) will be payable to the Group from Wanbang Biopharmaceutical. In addition, upon first commercial sale of Senstend™ in China, US\$2 million (or approximately HK\$15.60 million before deduction of PRC withholding tax) shall be payable to the Group from Wanbang Biopharmaceutical.

United States

On 22 December 2021, the Company submitted the Phase 2 study results entitled: “A Pilot, Randomized, Double-Blind Study Comparing the Proportion of Responders to PSD502 and Placebo Using the Premature Ejaculation Bothersome Evaluation Questionnaire in Subjects with Premature Ejaculation” to The Food and Drug Administration of the United States (the “FDA”). The FDA reviewed our qualitative and quantitative summary reports and provided comments regarding the Final Qualitative Exit Interview Report on 13 April 2022. The Company, after consulting with its regulatory consultants, submitted its reply to the FDA’s advice and information request letter on 4 June 2022.

After incorporating the FDA’s suggestions and recommendations into the Phase 3 protocol, the Company’s clinical research organisation has also completed the Phase 3 Study protocol, together with a ‘Type C’ meeting request, with the FDA for the product development of Fortacin™. This meeting between the Company and the FDA should occur by mid to late September 2022 (being within 75 days of receipt by the FDA of the meeting request). We are hopeful that after providing a fulsome reply to the FDA’s advice and request letter and incorporating the FDA’s recommendations and suggestions into the Phase 3 study protocol, that the Company can proceed with its Phase 3 study shortly after the ‘Type C’ meeting.

Manufacturing and Resumption of Commercial Supply

On 25 April 2022, the Medicines and Health products Regulatory Agency (“HRMA”) approved the Company’s variation submission on behalf of Senstend™ to (i) to widen the PGAK-1 impurity to 1%, from 0.5%, and total impurities to 2%, from 1%, and (ii) to increase the shelf life of Senstend™ to 24 months, from 18 months. In light of MHRA’s approval, Recordati S.p.A (“Recordati”) is now considering whether it will submit the same variations on behalf of Fortacin™ to the European Medicines Agency (“EMA”). Notwithstanding this, Recordati has engaged with an alternative European third-party

manufacturer for manufacturing Fortacin™ over the last 18 months to source alternative commercial supply for Fortacin™. This manufacturer has completed the necessary process validation batches and at the 3-month time point the product remained within specification. Recordati has on 28 June 2022 submitted a type II variation to the EMA for adding the European manufacturer to the marketing dossier as an alternative manufacturer with approval expected by Q3 2022. Once the new manufacturer is approved, commercial supply will resume for Recordati's territories. We are hopeful that this new manufacturer will be able to offer continuous supply of Fortacin™ to Recordati and our other commercial strategic partners bringing in royalty revenue for the Group.

Other Territories

Orient EuroPharma Co., Ltd. ("OEP") will be in the position to place new orders and continue sales in Taiwan, Hong Kong and Macau once commercial supply has resumed. OEP is proceeding with obtaining marketing authorisation approval in Singapore, Philippines, Malaysia, Brunei, Thailand and Vietnam.

In Q2 2022, K.S. KIM International (SK-Pharma) Ltd ("SK-Pharma") submitted its marketing authorisation in Israel and is hopeful that it will receive approval by Q4 2023. The Company, its regulatory consultant and SK-Pharma are now preparing the marketing authorisation for the Balkan region.

Moreover, the Group is in discussions with a Japanese pharmaceutical company for 'out licencing' the rights to Fortacin™ in Japan.

The Group will continue to work closely and diligently with its current and prospective commercial partners and will keep shareholders and potential investors informed of any new developments as and when they occur.

Jamie Gibson, Chief Executive Officer of the Company said "We are pleased that among the three drug trials of Senstend™. registered with the Centre of Drug Evaluation, the remaining Phase 3 study remains ongoing. We are also delighted by the progress of the relevant clinical study in the United States and the manufacturing of commercial supply in Europe. We will continue to work closely with our current and prospective commercial partners and will generate considerable returns for shareholders in the medium and long term."

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About Endurance Longevity (Stock code: 0575.HK)

Endurance Longevity is a diversified investment group based in Hong Kong currently holding various corporate and strategic investments focusing on the healthcare, wellness and life sciences sectors. The Group has a strong track record of investments and has returned approximately US\$298 million to shareholders in the 21 years of financial reporting since its initial public offering.

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