Endurance RP Limited

壽康集團有限公司 *

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 575)

OPERATIONAL UPDATE ON FORTACIN™ / SENSTEND™

This announcement is made by Endurance RP Limited (the "**Company**" and collectively with its subsidiaries, the "**Group**") in compliance with the disclosure requirements under Rule 13.09 of The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

The board (the "**Board**") of directors (the "**Directors**", each a "**Director**") of the Company wishes to inform the shareholders of the Company and potential investors of the following update in respect of its operations.

Fortacin™ / Senstend™

The Company has been provided with an update from Wanbang Biopharmaceutical Co., Ltd. ("**Wanbang Biopharmaceutical**") in respect of its clinical study for seeking approval of an import licence for Senstend™ (the marketing name of Fortacin™ in China) from the National Medical Products Administration ("**NMPA**") of The People's Republic of China ("**PRC**" or "**China**").

We are pleased to inform shareholders and potential investors that of the three drug trials that Wanbang Biopharmaceutical registered in December 2021 with the Centre of Drug Evaluation (http://www.chinadrugtrials.org.cn/clinicaltrials.searchlist.dhtml), 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 Company, its regulatory consultant and Wanbang Biopharmaceutical have commenced the preparatory phase for preparing the New Drug Application ("**NDA**") to NMPA with the aim of submitting the NDA by the end of Q2 2023.

A brief summary of the key points of the study are:

Registration of study:	December 2021
Study type:	Phase 3 clinical trial, multi-centre, randomised, double-blinded placebo controlled study
Estimated enrolment:	285 subjects (177 enrolled and 88 subjects have been randomised as of 1 July 2022)
Primary endpoint:	To determine the effects of Senstend™ on the Index of Premature Ejaculation and the Intra-vaginal Ejaculation Latency Time
Secondary endpoint:	To evaluate the safety and tolerability of Senstend™ in Premature Ejaculation subjects and their sexual partners
Estimated completion of enrolment:	November 2022
NMPA submission:	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.

To this end, the Company remains pleased with the progress to date and looks forward to working together with Wanbang Biopharmaceutical and its regulatory consultant to achieving these important milestones.

United States Approval and Commercialisation Progress

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 (the "**PEBEQ**™") 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 (Qualitative Exit Interviews in a Randomized, Double-Blind Multicentre Study Comparing the Proportion of Responders to PSD502 and to Placebo Using the PEBEQ™ in Subjects with Premature Ejaculation) 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

As previously announced, in mid-December 2021 the Company's regulatory consultant submitted a variation for widening the specification of PGAK-1 and total impurities. In this respect, we are pleased to report that on 25 April 2022, the Medicines and Health products Regulatory Agency ("**MHRA**") 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™. We are pleased to report that 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

Once commercial supply has resumed, Orient EuroPharma Co., Ltd. ("**OEP**") will be in the position to place new orders and continue sales in Taiwan, Hong Kong and Macau. 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.

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.

Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

Note: Unless otherwise specified herein, the amounts dominated into US$ have been translated, for the purpose of illustration only, into HK$ using the exchange rate of US$1.00 = HK$7.80.

By Order of the Board
Endurance RP Limited
Jamie Gibson
Executive Director

Hong Kong, 4 July 2022

As at the date of this announcement, the Board comprises six Directors**:**

Executive Director:
Jamie Gibson *(Chief Executive Officer)*

Non-Executive Directors:
James Mellon *(Chairman)*
Jayne Sutcliffe

Independent Non-Executive Directors:
David Comba
Julie Oates
Mark Searle

* For identification purposes only