

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



Endurance RP Limited

壽康集團有限公司*

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 575)

OPERATIONAL UPDATE

Clinical Update – Fortacin™ / Senstend™ Excellent Positive Outcomes from the Phase 3 Randomised Clinical Trial in China

- Statistically and Clinically Significant Increase in all Four co-primary Efficacy Endpoints
- Well Tolerated and Devoid of Systemic Side Effects

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 Company is pleased to announce that the Phase 3 double-blind placebo-controlled study of Senstend™ undertaken in The People’s Republic of China (“**China**”) by our commercial strategic partner Wanbang Biopharmaceutical Co., Ltd. (“**Wanbang Biopharmaceutical**”) for the treatment of premature ejaculation (“**PE**”) has met all four co-primary endpoints of Intra-vaginal Ejaculation Latency Time (“**IELT**”), Index of Premature Ejaculation (“**IPE**”) Ejaculatory Control and IPE Sexual Satisfaction domains and IPE Distress. Compared to both baseline and placebo, Senstend™ produced clinically and statistically significant increases in IELT, ejaculatory control and satisfaction and reduction in distress. As in our previous studies undertaken in Europe and the United States (“**US**”), Senstend™ was well tolerated by both Chinese patients and partners and no new side effects were reported.

Jamie Gibson, CEO of the Group, said “*We are delighted with these highly significant and positive results from the Phase 3 clinical study in China, which reinforces the results from the European and US Phase 3 clinical studies. This represents an important milestone in the regulatory submission process in China. We now look forward to our commercial partner in China submitting the New Drug Application (“**NDA**”) to National Medical Products Administration (“**NMPA**”) by the end of Q3 2023 with approval expected 12 months later.*”

Phase 3 Study Design

The study was a multi-centre, randomised, double blind, placebo-controlled efficacy study that enrolled a total of 295 patients, in which 197 patients were allocated to the Senstend™ group and 98 were allocated to the placebo group. Patients were treated for a 3-month period at 11 sites in China.

The study population consisted of male subjects aged over 20 years or above with PE diagnosed according to the definition of the International Society for Sexual Medicine (ISSM).

The Primary Efficacy Endpoints and Statistical Testing consisted of

- Change in mean IELT from baseline to during 3-month double-blind treatment phase;
- Mean change in IPE domain of ejaculatory control from baseline to Month 3;
- Mean change in IPE domain of sexual satisfaction from baseline to Month 3; and
- Mean change in IPE domain of distress from baseline to Month 3

Study Results

Entirely consistent with our Phase 3 clinical studies undertaken in Europe and the US, analyses show that Senstend™ produced a highly clinically and statistically significant increase from baseline in all four co-primary study endpoints. The IELT was increased by six-fold with Senstend™ when compared to baseline ($p < 0.0001$). Likewise there were substantial clinically and statistically significant changes ($p < 0.0001$) in sexual satisfaction, control and distress.

Overall, Senstend™ was well tolerated in the majority of subjects and their sexual partners. The safety profile Senstend™ did not reveal additional abnormal safety signs and there were no systemic adverse events.

About Senstend™

Senstend™ (the brand name for Fortacin™ in China) is a proprietary formulation of two marketed drugs, lidocaine and prilocaine, dispensed by a metered dose aerosol developed for the treatment of premature ejaculation, a disorder affecting between 20% and 30% of men in China. Based on World Bank population estimates of 2022, there is a significant target male PE population base of approximately 55 million males in China (assuming 20% PE prevalence and aged between 20-59 years old). In December 2018, Plethora signed an exclusive license agreement with Wanbang Biopharmaceutical Co., Ltd., a wholly controlled company of Shanghai Fosun Pharma to market Senstend™ for premature ejaculation in China.

Jamie Gibson, further, said, *“It is estimated that Senstend™ has the potential to help an initial target market of approximately 9 million patients in China in its first year of launch, growing to over 170 million patients by its tenth year. We have a strong partner in Wanbang Biopharmaceutical, who benefits from being part of the Fosun network. This company has the marketing expertise established e-commerce platforms and an unrivalled national distribution network of hospitals, clinics and pharmacies to help ensure the commercial success of Senstend™ in China.”*

Senstend™ has the potential to help about 9 million patients in China during its first year of launch, growing to over 170 million by the tenth year. Our strong partner Wanbang Biopharmaceutical, which is part of the Fosun network, has established marketing expertise, e-commerce platforms and an unrivalled nationwide logic and distribution through Sinopharm, China’s number one pharmaceutical and healthcare distributor, through its network of hospitals, clinics and pharmacies to ensure the commercial success of Senstend™ in China.

All costs of the clinical trials, including all other associated regulatory and submission costs are being met by Wanbang Biopharmaceutical. If 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. In addition, and as disclosed on 3 December 2018, there are other significant payments payable to the Group from Wanbang Biopharmaceutical in respect of:

Commercial Milestone Payment

A possible payment of up to US\$25 million (or approximately HK\$195 million) in total upon achievement of certain annual net sales milestones, dependent on the net sales achieved by Wanbang Biopharmaceutical.

Further Payments and Royalties

- 25 percent of net receipts; and
- tiered percentage royalties on net sales, ranging from the low to high teens, except that lower payment structures will apply in certain circumstances where a generic product has successfully entered and impacted the market in China.

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 on submission of and, ultimately, achieving approval of the NDA by NMPA.

European market

The Company understands that the return of Fortacin™ to the market in certain countries in the European Union has been very positive with the first batch of units in Germany receiving strong demand from patients. The manufacturer has released 30,000 units in February 2023 and the next 30,000 units are slated for delivery in July 2023.

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, 17 April 2023

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 Sutcliff

Independent Non-Executive Directors:

David Comba

Julie Oates

Mark Searle

* For identification purposes only