Endurance RP Limited

壽康集團有限公司 *

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 575)

Strongly Positive Results of Fortacin™'s US Phase II PRO Validation Study

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 is pleased to announce the successful completion of prespecified data analysis from the 16 centre United States (the "**US**") study undertaken to validate the US Food and Drug Administration (the "**FDA**") mandated patient reported outcome ("**PRO**") for premature ejaculation. The PRO, the Premature Ejaculation Bothersome Evaluation Questionnaire ("**PEBEQ™**") was developed compliant to FDA guidelines as the key final step for assessment of efficacy ahead of the Phase III randomised clinical trial ("**RCT**") already planned for the US.

In this US study, PSD502, marketed as Fortacin™ in the European Union and the United Kingdom, produced substantial changes in intravaginal latency time ("**IELT**") and reduced the level of distress experienced by patients, as reflected in the PEBEQ™. These results are entirely consistent with the previous extensive Phase III RCTs that were successfully completed prior to approval by the European Medicines Agency. The changes were clinically and statistically significant both from baseline and from placebo, resulting in an eight-to-nine-fold increase from pre-treatment IELT values. Also consistent with previous RCTs, compliance with therapy and with study requirements was high (over 92% completed in this study), and side effects were minimal.

Clinically and statistically significant differences between Fortacin™ and placebo were observed in the FDA-favoured domain ("**Item 3**") of the PEBEQ™ ($p < 0.0008$). At the request of the FDA, Item 3 was designed to determine the degree of "bother" that the patients were experiencing due to the condition. For PRO validation, excellent correlations were also observed between changes in Item 3 of the PEBEQ™ and the

domains of sexual satisfaction, control and distress captured using the Index of Premature Ejaculation ("**IPE**"), one of two PROs used in previous studies. The terms such as "bother" are important because they are used in the final approved prescribing information ("**PI**").

Overall, the study confirms the safety and efficacy of Fortacin™. The new data will be used to refine the final Phase III RCT protocol, which is already prepared, and suitable clinical sites screen for expedient and good clinical practice enrolment.

Formal registration of the Phase II validation study of Fortacin™ is a critical and positive step towards making the new drug application ("**NDA**") submission and ultimately achieving all necessary FDA and other US regulatory approvals needed to commercialise of Fortacin™ in the US, its most significant potential market.

The Group anticipates that the results of the study will be submitted to the FDA by mid-August 2021. On the likely assumption that the study is sufficient to convince the FDA that the PEBEQ™ serves as an appropriate measure for support of a label or PI claim, the pivotal Phase III RCT study could commence in the latter half of 2021, with NDA submission possible in late 2022, giving a Prescription Drug User Fee Act date at the end of 2023.

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

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

Hong Kong, 15 July 2021

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