

[Press Release – For Immediate Release]



Endurance RP Limited
壽康集團有限公司
(Formerly, known as Regent Pacific Group Limited)
(SEHK:0575.HK)

Fortacin™ Receives Strong Positive Results for US Phase II PRO Validation Study

(15 July 2021, Hong Kong) – **Endurance RP Limited (“Endurance Longevity” or the “Company” and together with its subsidiaries, the “Group”;** stock code: 0575.HK) is pleased to announce the successful completion of prespecified data analysis from the United States study mandated patient reported outcome (“**PRO**”) for PE. The PRO, the PE Bothersome Evaluation Questionnaire (“**PEBEQ™**”) was developed as the key final step for assessment of efficacy ahead of the Phase III randomised clinical trial (“**RCT**”) already planned for the US.

Mandated patient reported outcome (“PRO”) for PE

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 PE has been successfully completed. The PRO, the **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**”), which is already planned for the US.

In this 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.

The PRO, the PE Bothersome Evaluation Questionnaire (“PEBEQ™”)

The PRO, the PE Bothersome Evaluation Questionnaire (“**PEBEQ™**”) was developed compliant to FDA guidelines. 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 PE (“**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**”).

Jamie Gibson, Chief Executive Officer of the Company, said, “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. The 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.

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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 23 years of financial reporting since its initial public offering in May 1997.

www.endurancerp.com

About Fortacin™

Fortacin™ is the first solution to PE that does not act on the central nervous system and offers bona fide therapeutic efficacy that has been validated through extensive clinical trials in Europe, with over 23,500 doses delivered to trial participants. The solution is a topical spray containing low doses of lidocaine and prilocaine that take effect almost immediately upon application, giving users more control without reducing pleasure. Fully approved by the European Medicines Agency (EMA), Fortacin™ is now available in France, Germany, Italy, Portugal, Spain and the UK.

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