



(Incorporated in the Cayman Islands with Limited Liability)

Stock Code: 0575

4 January 2021

ANNOUNCEMENT

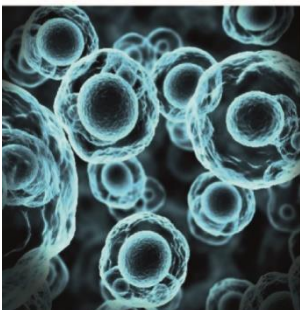


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OPERATIONS UPDATE ON FORTACIN™



The directors (the “**Directors**” or the “**Board**”) of Regent Pacific Group Limited (the “**Company**” and collectively with its subsidiaries, the “**Group**”) wish to inform the shareholders of the Company and potential investors of the following update in respect of its operations in relation Senstend™/Fortacin™.



Further to the last two operations updates issued by the Company on 2 and 14 December 2020, the Directors are pleased to inform shareholders that the Group received US\$0.72 million (or approximately HK\$5.62 million) (net of 10% PRC withholding tax) from Wanbang Pharmaceutical Marketing and Distribution Co., Ltd. (“**Wanbang Pharmaceutical**”), the Company’s commercial strategic partner for China on 29 December 2020. As previously announced, the National Medical Products Administration (“**NMPA**”) will now formally review for Clinical Trial Approval (“**CTA**”), and the Company has been advised by Wanbang Pharmaceutical that the CTA will be obtained from the Center of Drug Evaluation within 60 working days (approximately 3 months) from the date of submission, i.e. by the end of Q1 2021. Upon the successful approval from NMPA to commence the clinical trial, a payment of US\$3.20 million (or approximately HK\$24.96 million) before deduction of PRC withholding tax, or



US\$2.88 million (or approximately HK\$22.46 million) net of PRC withholding tax, will be due.

Jamie Gibson, the Chief Executive Officer of the Company, said “We are delighted by this step toward full commercial approval of Senstend™ in China. Achieving this is a significant milestone which lays a solid foundation for marketing Senstend™ there in the near future.

“We are confident that this successful China initiative not only secures the world’s largest market for Senstend™, but will also help us and our strategic partners to expand into other major markets such as the Middle East, India, North America and the Latin America (LATAM) region.

“Using the income generated by Senstend™ in China, we aim to further grow Senstend™’s market share in other markets to maintain a stable income for the Group and generate better returns for our shareholders.”

The Company has been advised by Wanbang Pharmaceutical of the indicative summary details of the clinical study for seeking approval of an import licence for Senstend™ from the NMPA:

Start date:	April/May 2021 (subject to approval from NMPA)
Study type:	Clinical trial, multi-center, randomised, double-blinded placebo controlled study
Estimated enrolment:	150
Primary endpoint:	To determine the effects of Senstend™ on the Index of Premature Ejaculation (IPE) and the Intra-vaginal Ejaculation Latency Time (IELT)
Secondary endpoint:	To evaluate the safety and tolerability of Senstend™ in Premature Ejaculation subjects and their sexual partners
Estimated study completion date:	12 months

If the clinical study meets its endpoints and NMPA has granted an import licence for Senstend™, then US\$5 million (or approximately HK\$39 million before deduction of PRC withholding tax) will be payable to the Group from Wanbang Pharmaceutical. In addition, upon first commercial sale of Senstend™ in China, US\$2 million (or approximately HK\$15.6 million before deduction of PRC withholding tax) shall be payable to the Group from Wanbang Pharmaceutical.

The Group has been informed by Wanbang Pharmaceutical that it has ordered clinical supplies (both active and placebo) from Pharmaserve (North West) Limited (“**PSNW**”), the manufacturer of Senstend™/Fortacin™, with the aim of supplies being ready for the commencement of the clinical trial. In addition, the Group has contracted PSNW to commence development on the commercial scale up to increase the current batch size per each manufacturing run to 50,000 units from 15,000 units. This is designed, if successful, to meet Wanbang Pharmaceutical’s requirements for China and Recordati’s over-the-counter’s requirements in the European Union and the United Kingdom.

United States Approval and Commercialisation Progress

Further to our operations announcement of 17 November 2020, the Group has completed the Phase II validation study with a total of 87 subjects being randomised, close to the target of 100.

The Group remains on target to submit the study to the United States Food and Drug Administration (“**FDA**”) during the first half of 2021. On the assumption that the trial is sufficient to convince the FDA that the Premature Ejaculation Bothersome Evaluation Questionnaire serves as an appropriate measure for support of a label claim, the pivotal Phase III study could commence in the latter half of 2021, with New Drug Application submission possible in late 2022, giving a Prescription Drug User Fee Act date at the end of 2023. Despite the difficulties presented by the COVID-19 pandemic, particularly as it relates to securing face-to-face meetings, the Group’s strategy remains to continue negotiations with potential commercial strategic partners for the United States market, while we complete the submission of the study to the FDA, with the aim of securing a partner just ahead of or while we conduct the Phase III trial.

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.

On Behalf of the Board of
Regent Pacific Group Limited

Jamie Gibson
Executive Director

Directors of the Company:

James Mellon (*Chairman*)*

Jamie Gibson (*Chief Executive Officer*)

David Comba[#]

Julie Oates[#]

Mark Searle[#]

Jayne Sutcliffe*

* *Non-Executive Directors*

Independent Non-Executive Directors

Hong Kong, 4 January 2021