



(Incorporated in the Cayman Islands with Limited Liability)

Stock Code: 0575

17 November 2020

ANNOUNCEMENT



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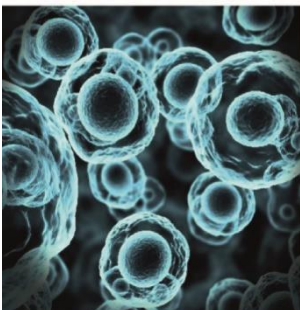
OPERATIONS UPDATE ON FORTACIN™



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 to Fortacin™ / Senstend™.

Further to the last operations update issued by the Company on 3 September 2020 and the preliminary announcement on its interim results for the six months ended 30 June 2020, issued on 24 August 2020, the Directors are pleased to inform shareholders of the following:

Chinese Approval and Commercialisation Progress



As mentioned in our interim results announcement of 24 August 2020, the Group is continuing to progress regulatory approval with Wanbang Pharmaceutical Marketing and Distribution Co., Ltd. (“**Wanbang Pharmaceutical**”), its commercial strategic partner for China and a wholly controlled company of Shanghai Fosun Pharma. The Company believes that China is potentially the single largest market for Senstend™ (the marketing name of Fortacin™ in China), a view supported by Wanbang Pharmaceutical.



We are pleased to inform shareholders that Wanbang Pharmaceutical has submitted the investigational new drug (“**IND**”) for Clinical Trial Approval (“**CTA**”) on 16 November 2020, being the first step in seeking marketing approval of Senstend™ in China. We have been advised by Wanbang Pharmaceutical that the CTA will be obtained from the Center of Drug Evaluation of the National Medical Products Administration (“**NMPA**”) within 3 months from the date of submission i.e. by end of Q1 2021. As per the terms of the licence agreement executed with Wanbang Pharmaceutical, and announced on 3 December 2018, a payment of:

- US\$800,000 (or approximately HK\$6.24 million) upon receipt from the NMPA of approval to submit the IND application for human clinical trial of a licensed product at NMPA; and
- US\$3.20 million (or approximately HK\$24.96 million) upon the receipt from the NMPA of the approval to conduct a human clinical trial of a licensed product or written NMPA acceptance as sufficient of provided data without need for conducting a further clinical trial.

United States Approval and Commercialisation Progress

Further to our interim results announcement of 24 August 2020, the Group has continued to make steady progression with the approval process with the Food and Drug Administration (the “**FDA**”) of the United States (the “**US**”) with regards to its Phase II validation study of Fortacin™. In this respect, we are pleased to report that the study has completed its enrollment of patients in early October 2020, with only 2 subjects remaining active post-randomisation in the study at this time.

The Group remains on target to complete the Phase II validation study of Fortacin™ by the end of 2020 with submission to the FDA in 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 (“**NDA**”) 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 US market, while we undertake the clinical work with the aim of securing a partner just ahead of or while we conduct the Phase III trial.

Completion of the enrollment of the Phase II validation study of Fortacin™ in the US is a critical and positive step towards making the NDA submission and ultimately achieving all necessary FDA and other US regulatory approvals needed to commercialise Fortacin™ in the US which, together with China, represent potentially its most significant potential markets.

Taiwanese, Hong Kong and Macau Approval and Commercialisation Progress

Further to our results announcement of 24 August 2020 Orient EuroPharma Co., Ltd. (“**Orient EuroPharma**”), the Group’s commercial strategic partner for Taiwan, Hong Kong Special Administration Region (“**Hong Kong**”), Macau Special Administrative Region (“**Macau**”) and certain other countries in South East Asia, has received the first deficiency letter from the Taiwan FDA (“**TFDA**”) in respect of its application for Fortacin™ and it has completed and sent back its response and supporting documents on 16 June 2020, with further follow up requests being answered by the Group. TFDA has recently approved: (i) the Drug Master Files for lidocaine and prilocaine, the active pharmaceutical ingredients of Fortacin™; and (ii) the plant master file application for the manufacturer of Fortacin™. On the assumption that TFDA does not have any further questions / deficiencies, Orient EuroPharma anticipates approval around January 2021, which would trigger a payment of US\$300,000 (or approximately HK\$2.34 million) to the Group.

Further to our interim results announcement of 24 August 2020, Orient EuroPharma now expects to launch Fortacin™ in Hong Kong and Macau in 2021. Such delay was resulted from the complications caused by the COVID-19 pandemic impeding the planned launch subject to Orient EuroPharma being able to receive their launch orders from the batch orders of Recordati S.p.A. (“**Recordati**”), as the minimum purchase order is 13,000 units per batch order and Orient EuroPharma requires significantly less than that for its launch.

Other Out-Licensing Opportunities

The Company remains in discussions with our commercial strategic partners for the Middle East, India, North America and Latin America (LATAM) region. However, it is not possible to determine with accuracy the timing of completion of such agreements, and no assurance can be given that negotiations will lead to a binding licencing agreement(s) in the aforementioned jurisdictions or at all.

Since the Group’s European marketing and distribution partner for its lead product, Fortacin™, is based in Italy, the Group has been in dialogue with Recordati to assess the situation resulting from the COVID-19 pandemic and its impact on the continued roll-out of Fortacin™. In this respect, Recordati has informed the Group that during the third quarter of 2020, its reference markets continued to be affected by the COVID-19 pandemic due both to the restrictions imposed to limit contagion in all territories, as well as from a cautious management of stocks by wholesalers. Recordati advised that the persistence of the COVID-19 pandemic will continue to affect its sales in the fourth quarter of 2020. As we all know, restrictions were imposed on the movement of people, transport, production and commerce, some of which may be in place in certain of its countries in which it operates. While Recordati’s pharmaceutical operations were allowed to continue in order to ensure the availability of drugs for patients, all its affiliates had to cease

activities engaged by their sales representatives during the “lock down”, with such sales activities now going back to normality. While complying with all the measures necessary to ensure the health and safety of its employees, Recordati did not interrupt its production and distribution activities and adopted all necessary measures to guarantee the continued availability on the market of its products.

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, 17 November 2020