



(Incorporated in the Cayman Islands with Limited Liability)

Stock Code: 0575

18 June 2020

ANNOUNCEMENT

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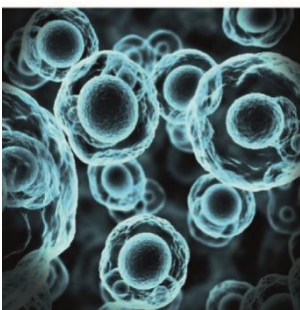
OPERATIONS UPDATE FORTACIN™

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 updates in respect of its operations in relation to Fortacin™.

Unless the context otherwise requires, capitalised terms used in this announcement shall have the same meaning given to them in the Company’s annual results announcement of 31 March 2020.

US Approval and Commercialisation Progress

Despite the difficulties experienced with COVID-19 and the recent antiracism demonstrations in the US and elsewhere, the Group has continued to make steady progression with the approval process with the US FDA with regards to its Phase II validation study of Fortacin™. In this respect, as of 14 June 2020, 23 further subjects entered screening and received a diary as part of the Phase II study, with one subject being randomised. The Group’s target is to enrol a further 44 to 47 subjects by 1 August 2020 with the aim of randomising 53 additional and completed subjects, bringing the total to 100 randomised and completed subjects for the validation study. If the site centres are successful in completing the randomisation, as mentioned,



the Group remains on target to complete the Phase II validation study of Fortacin™ by the end of 2020. However, any delay in recruiting and randomising the required subjects, whether as a result of COVID-19 or other reasons, would delay the completion of the study. On the assumption that the trial is sufficient to convince the US FDA that the Premature Ejaculation Bothersome Evaluation Questionnaire (PEBEQ) serves as an appropriate measure for support of a label claim, the pivotal Phase III work could commence in the latter half of 2020, with NDA submission possible in the first half of 2021, giving a PDUFA date in Q1 2023. These dates remain as stated in the Company's Annual Report for 2019 and our recently announced annual results announcement dated 31 March 2020. Despite the difficulties presented by COVID-19, 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.

Formal registration 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, its most significant potential market.

PRC Approval and Commercialisation Progress

The Group is continuing to progress regulatory approval with Wanbang Pharmaceutical, its commercial strategic partner for China. In this respect, Siegfried Evionnaz SA ("**Siegfried**"), the manufacturer of prilocaine, one of the API of Fortacin™, has completed the API structural identification and chemical characterization together with the M7 genotoxic assessment. Siegfried is now completing the DMF redaction work and the translation of the file into Chinese with a submission date with the National Medical Products Administration in mid-August 2020, which is a month behind schedule due to work issues it has faced as a result of COVID-19 as Siegfried's manufacturing site in Switzerland is hampered by off-site working.

However, despite this slight delay we understand that Wanbang Pharmaceutical remains on course for submitting the IND application for CTA by the end of Q3 2020 Fortacin™ as it has already completed the application and is just waiting for Siegfried to file its DMF as that will then trigger and allow Wanbang Pharmaceutical to file the CTA (as its requires the DMF file number for prilocaine) to commence clinical trials in China. On the assumption that the IND can be filed per this timeframe, the CTA could be obtained between Q4 2020 and Q1 2021. As per the terms of the licence agreement executed with Wanbang Pharmaceutical, and announced on 3 December 2018, a payment of US\$4 million (or approximately HK\$31.20 million) is payable to the Group upon obtaining Chinese regulatory approval to conduct a human clinical trial of a licensed product.

Progress re Change of Status of Fortacin™ to OTC from Rx

Recordati has informed the Company that its application to change the status of Fortacin™ to OTC from Rx is progressing well. Recordati will shortly submit the response to the final outstanding questions on the Rx to OTC switch to the Committee for Medicinal Products for Human Use, which is the European Medicinal Agency's committee responsible for elaborating the agency's opinions on all issues regarding medicinal products for human use (“CHMP”) and a draft assessment report is expected on or around 8 July 2020 from CHMP, which should give an indication of approvability. If it should proceed to CHMP opinion this would be expected on or around 23 July 2020 with a European Commission Decision (which is required for OTC launch) around October 2020. If this approval process is achieved, Recordati has mentioned that it would look to start the OTC launch from January 2021 provided that PSNW, the manufacturer, can meet the anticipated increased demand and that COVID-19 does not further complicate or impede the planned launch.

Taiwanese, Hong Kong and Macau Approval and Commercialisation Progress

Orient Europharma, the Group’s commercial strategic partner for Taiwan, Hong Kong, 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. TFDA has recently approved the DMFs for lidocaine and prilocaine the active pharmaceutical ingredients 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 annual results announcement of 31 March 2020, we remain hopeful that Orient Europharma can launch Fortacin™ in Hong Kong and Macau in 2020 but this is very much dependent on whether COVID-19 further complicates or impedes the planned launch and whether PSNW is able to deliver product to Orient Europharma from Recordati’s batch orders, 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.

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 of note 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, 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
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, 18 June 2020