



(Incorporated in the Cayman Islands with Limited Liability)

Stock Code: 0575

13 July 2018

ANNOUNCEMENT



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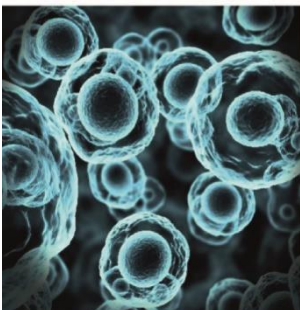
FORTACIN™ UPDATE US FOOD AND DRUG ADMINISTRATION PROGRESS



SUMMARY

The Directors of the Company are pleased to inform the shareholders of the Company and potential investors that the Phase II validation study of Fortacin™ in respect of the FDA approval process in the US was officially registered on 6 July 2018. Recruitment of subjects (100) for the study is expected to commence next month, with the study estimated to complete by October 2019.

On the assumption that the trial is sufficient to convince the FDA that the PEBEQ serves as an appropriate measure for support of a label claim, pivotal Phase III work could commence in the second half of 2019, with NDA submission possible in the second half of 2020, giving a PDUFA date in 2021. These dates are the most recent guidance received and update all previous estimates on the FDA process set out by the Company in its announcements, annual and interim reports and investor presentations.



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.

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

The directors (the “**Directors**” or the “**Board**”) of Regent Pacific Group Limited (the “**Company**”) are pleased to inform the shareholders of the Company and potential investors that the Phase II validation study of Fortacin™ in respect of The Food and Drug Administration of the United States (the “**US**”) Department of Health and Human Services (the “**FDA**”) approval process was officially registered on 6 July 2018. Recruitment of subjects (100) for the trial is expected to commence next month, with the study estimated to complete by October 2019.

The study is being conducted to test the effect of Fortacin™ (the study medication) compared to placebo in subjects with premature ejaculation. Fortacin™ is a topical (applied to skin) anaesthetic spray containing a mixture of two drugs called lidocaine and prilocaine that will be applied to the penis. Half of the subjects will receive Fortacin™ and half will receive placebo. The study will also measure the effect of Fortacin™ on the Intravaginal Ejaculatory Latency Time (IELT).

On the assumption that the trial is sufficient to convince the FDA that the Premature Ejaculation Bothersome Evaluation Questionnaire (the “**PEBEQ**”) serves as an appropriate measure for support of a label claim, pivotal Phase III work could commence in the second half of 2019, with New Drug Application (“**NDA**”) submission possible in the second half of 2020, giving a Prescription Drug User Fee Act (the “**PDUFA**”) date in 2021. These dates are the most recent guidance received and update all previous estimates on the FDA process set out by the Company in its announcements, annual and interim reports and investor presentations.

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.

The Company will continue to keep shareholders and potential investors updated with any significant 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.

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, 13 July 2018