

*[Press Release – For Immediate Release]*

## **Regent Pacific Announces Important Progress On FORTACIN™ / SENSTEND™ - Solution to Premature Ejaculation**

### **CHINA**

- Regent Pacific to receive a total payment of US\$4 million upon the receipt of approval from the National Medical Products Administration (NMPA) for conducting human trial
- China is expected to be the single largest market for Sendstend™

### **UNITED STATES**

- The Phase II validation study of Fortacin™ in the US and submission to the FDA are expected to complete by the end of 2020 and first half of 2021 respectively
- The pivotal Phase III study in US is expected to commence in late 2021

### **TAIWAN, HONG KONG, MACAU**

- Approval from the Taiwan FDA is expected in early 2021
- Fortacin™ is expected to launch in Hong Kong and Macau in 2021

*(17 November 2020, Hong Kong)* – **Regent Pacific Group Limited (“Regent Pacific” or the “Company” and together with its subsidiaries, the “Group”**; stock code: 0575.HK), a specialist healthcare, wellness and life sciences investment group is pleased to announce several important progress on Fortacin™/ Senstend™, the first solution to premature ejaculation (PE) that does not act on the central nervous system in China, US, Taiwan, Hong Kong and Macau respectively.

### ***Accelerates the participation in the potentially single largest market for Senstend™***

The investigational new drug (IND) for Clinical Trial Approval (CTA) has been submitted to the Center of Drug Evaluation of the National Medical Products Administration by Wanbang Pharmaceutical Marketing and Distribution Co., Ltd. (“Wanbang Pharmaceutical”), a wholly controlled company of Shanghai Fosun Pharma, Regent Pacific’s commercial strategic partner in China to seek marketing approval of Senstend™ (the marketing name of FORTACIN™ in China) in China. It is expected that the approval

would be obtained by the end of Q1 2021. Upon receiving the approval, Regent Pacific will receive a total payment of US\$4 million (approximately HK\$31.2 million) from Wanbang Pharmaceutical as per the terms of the licence agreement. The payment will be divided into two terms, US\$800,000 (approximately HK\$6.24 million) will be received upon the approval from NMPA to submit IND application for human clinical trial of a licensed product at NMPA. The remaining US\$3.20 million (HK\$24.96 million) will be received upon the receipt of the approval from the NMPA 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.

***Crucial step towards acquiring necessary regulatory approvals in the United States***

In the United States, The Phase II validation study of Fortacin™ by the U.S. Food and Drug Administration (“US FDA”) is expected to be completed by the end of 2020, followed by the submission to the FDA in the first half of 2021. The pivotal Phase III study is expected to 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 and contribute to the acquisition of all necessary regulatory approvals needed to commercialise Fortacin™ in the United States.

***Steady progress in Taiwan, Hong Kong and Macau***

In Taiwan, the Taiwan FDA (“TFDA”) has recently approved the Drug Master Files for lidocaine and prilocaine, the active pharmaceutical ingredients of Fortacin™; and also, the plant master file application for the manufacturer of Fortacin™. It is anticipated that the approval could be obtained from TFDA by early 2021 which will trigger a payment of US\$300,000 (or approximately HK\$2.34 million) to the Group.

In addition, Fortacin™ is expected to be launched in Hong Kong and Macau in 2021, a delay as a result of the COVID-19 pandemic which significantly affected the number of orders.

***Product sales in the European market gradually resume to normal despite the impact of COVID-19 continues***

Since Regent Pacific's European marketing and distribution partner for Fortacin™ is based in Italy, it has been affected by the COVID-19 pandemic. During Q3 2020, the European markets continued to be affected by the pandemic due both to the restrictions imposed to limit contagion in all territories, as well as from a cautious management of stocks by wholesalers. It is expected that the COVID-19 pandemic will continue to affect sales in Q4 2020, but with the sales activities gradually resuming to normal in the latter half of 2021. Necessary measures have been adopted so that the production and distribution activities of the product would not be affected.

**Jamie Gibson, Chief Executive Officer of Regent Pacific**, said, "We are glad to witness that Fortacin™ / Sendstend™ has received remarkable progress in different markets despite the impacts of the COVID-19 pandemic. We will continue to work closely and diligently with our current and prospective commercial partners and will keep shareholders and potential investors informed of any new developments as and when they occur."

**-END-**

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For media inquiries, please contact:

Joanne Chan	Tel: (852)3679 3671	Email: <a href="mailto:jchan@lbs-comm.com">jchan@lbs-comm.com</a>
Jason Ho	Tel: (852)3752 2675	Email: <a href="mailto:jho@lbs-comm.com">jho@lbs-comm.com</a>
Raimie Siu	Tel: (852)3752 2674	Email: <a href="mailto:rsiu@lbs-comm.com">rsiu@lbs-comm.com</a>



## **About Regent Pacific**

Regent Pacific 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 21 years of financial reporting since its initial public offering in May 1997.

## **About Fortacin™ / Sendstend™**

Fortacin™ / Sendstend™ is the first solution to premature ejaculation (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.