

*[Press Release – For Immediate Release]*

## **Regent Pacific Announces Key Progresses On FORTACIN™ / SENSTEND™ - Solution to Premature Ejaculation**

### **CHINA**

- Regent Pacific received **US\$0.72 million** (approximately HK\$5.62 million, (net of 10% PRC withholding tax) from Wanbang Pharmaceutical on 29 December 2020
- The Clinical Trial Approval (“CTA”) will be obtained from the Center of Drug Evaluation by the end of **Q1 2021**
- Regent Pacific to receive the following payments from Wanbang Pharmaceutical:
  - **US\$3.20 million\*** (approximately HK\$24.96 million) upon the successful approval from NMPA to commence the clinical trial
  - **US\$ 5 million\*** (approximately HK\$39 million) NMPA has granted import drug licence approval for Senstend™
  - **US\$2 million\*** (approximately HK\$15.6 million) upon first commercial sale of Senstend™ in China

*\*before deduction of PRC withholding tax*

### **UNITED STATES**

- Phase II validation study has been completed with a total of 87 subjects being randomised and is target to submit the study to the United States Food and Drug Administration (“FDA”) during the first half of 2021

*(4 January 2021, 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 key updates of Fortacin™ / Senstend™, the first prescription solution to premature ejaculation (PE) that does not act on the central nervous system, in China and the United States respectively.

Regent Pacific received US\$0.72 million (approximately HK\$5.62 million) from its commercial strategic partner in China – Wanbang Pharmaceutical Marketing and Distribution Co., Ltd. (“Wanbang Pharmaceutical”), a wholly controlled company of Shanghai Fosun Pharma to seek marketing approval of Senstend™ (the marketing name of Fortacin™ in China) in China on 29 December 2020. The Clinical Trial Approval (“CTA”) of Senstend™ will be reviewed by the National Medical Products Administration (“NMPA”) and is expected to be obtained from the Center of Drug Evaluation by the end of Q1 2021. Upon the successful approval from NMPA to commence the clinical trial, Regent Pacific will receive a payment of US\$3.20 million\* (approximately HK\$24.96 million) from Wanbang Pharmaceutical.

**Jamie Gibson, Chief Executive Officer of Regent Pacific**, 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.”

Gibson added, “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.”

Regent Pacific will receive US\$ 5 million\* (approximately HK\$39 million) from Wanbang Pharmaceutical if the clinical study tentatively to be started in April/May 2021 meets its endpoints of determining the effects of Senstend™ on the Index of Premature Ejaculation (IPE) and the Intra-vaginal Ejaculation Latency Time (IELT) and to evaluate the safety and tolerability of Senstend™ in Premature Ejaculation subjects and their sexual partners,

together with an import licence for Senstend™ granted by NMPA. Regent Pacific will also receive US\$2 million\* (approximately HK\$15.6 million) upon the first commercial sale of Senstend™ in China from Wanbang Pharmaceutical with tiered percentage royalties on net sales, ranging from low to the high teens from first commercial sale.

In addition, Wanbang Pharmaceutical has ordered clinical supplies 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. Regent Pacific has also 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 to meet Wanbang Pharmaceutical’s requirements for China and Recordati’s over-the-counter’s requirements in the European Union and the United Kingdom.

### **Steady Progress in the United States**

The Phase II validation study in the United States has been completed with 87 randomised subjects. The study is targeted to submit to the United States Food and Drug Administration (“FDA”) during the first half of 2021. It is expected that the pivotal Phase III study could commence in the latter half of 2021, assuming 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; with New Drug Application (“NDA”) submission possible in late 2022, giving a Prescription Drug User Fee Act date at the end of 2023.

**-END-**

### **About Regent Pacific (Stock code: 0575.HK)**

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 23 years of financial reporting since its initial public offering in May 1997.

### **About Fortacin™**

Fortacin™ 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.

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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>