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## SciClone Pharmaceuticals (Holdings) Limited 賽生藥業控股有限公司\*

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 6600)

## VOLUNTARY ANNOUNCEMENT BUSINESS UPDATE

## SciClone Announces Phase III Clinical Trial of Vaborem® Completed Subject Enrollment in China

This announcement is made by SciClone Pharmaceuticals (Holdings) Limited (the "Company" or "SciClone", together with its subsidiaries, the "Group") on a voluntary basis. The purpose of this announcement is to keep the shareholders of the Company (the "Shareholders") and potential investors informed on the latest business development of the Group.

The Company is pleased to announce that the Phase III clinical trial (the "**Trial**") of Vaborem® (Meropenem and Vaborbactam for injection) ("**Vaborem**®"), a new antibacterial drug, has completed subject enrollment in China.

This study is a Phase III, randomized, double-blind, double-dummy, active-controlled, multi-center clinical trial being conducted in China to evaluate the efficacy and safety of Vaborem® for patients with complicated urinary tract infections ("cUTI") including pyelonephritis. Led by Principal Investigators Professor Wang Minggui from Huashan Hospital affiliated to Fudan University and Professor Zheng Junhua from Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine, the Trial includes 108 subjects across 27 clinical trial sites throughout China. The results of this study and a concurrent study in healthy volunteers in China to evaluate the pharmacokinetic profile of Vaborem®, are meant to bridge the foreign clinical trial data and eventually support the New Drug Application ("NDA") of Vaborem® in China.

Vaborem® is a fixed-dose combination of a carbapenem and a novel boronic acid  $\beta$ -lactamase inhibitor of class A and Class C serine  $\beta$ -lactamase. Vaborbactam can inhibit various class A and class C  $\beta$ -lactamases, so it protects meropenem from degradation by serine

carbapenemases, restoring meropenem's activity against carbapenem-resistant strains. Vaborem® has been specifically developed to inhibit carbapenem-resistant enterobacterales ("CRE") including the commonly found Klebsiella pneumoniae carbapenemase ("KPC")-producing bacteria. Currently, Vaborem® has been approved in the European Union for the treatments of a variety of indications including cUTI, complicated intra-abdominal infections ("cIAI") and hospital-acquired pneumonia ("HAP") and has been approved in the United States of America for the treatment of cUTI.

Pursuant to the License and Collaboration Agreement entered into between SciClone Pharmaceuticals and A. Menarini Asia-Pacific Holdings Pte. Ltd., part of The Menarini Group ("Menarini"), in August 2022, the Company has the exclusive right to develop and commercialize Vaborem<sup>®</sup> in China, under Menarini's head license agreement with Melinta Therapeutics, Inc.. In March 2023, the National Medical Products Administration (the "NMPA") in China officially approved the Company's Investigational New Drug (the "IND") application for Vaborem<sup>®</sup>. In July 2023, the first subject was dosed in the Trial.

The successful completion of the Trial subject enrollment for Vaborem® in China marks another important milestone in the clinical development progress of Vaborem®, reaffirming the strength of SciClone's clinical development team. The Company sincerely thanks every investigator and patient involved in the Trial, as well as our collaborating partners, and look forward to providing more effective and safer treatment options as soon as possible for patients in China suffering from life threatening and multidrug-resistant infections.

The Group cannot guarantee that the above mentioned clinical studies of Vaborem® will ultimately be successfully completed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

#### **About the Company:**

SciClone is a global biopharmaceutical company with an integrated platform for the development and commercialization of innovative therapies for cancer and severe infection. With an innovation-driven strategic transformation, SciClone has established a product portfolio with differentiated advantages, including a number of first-in-class and best-in-class potential products/pipelines. Staying true to the Group's original aspiration of "SciClone gives life hope", SciClone is dedicated to improving patients' health by providing top-tier healthcare products and services with global standards of care. For more information about the Company, please visit www.sciclone.com.

#### **DEFINITIONS**

"China"

the People's Republic of China; for the purposes of this announcement only and except where the context requires otherwise, excludes Hong Kong, Macau and Taiwan

# By order of the Board SciClone Pharmaceuticals (Holdings) Limited ZHAO Hong

Executive Director, Chief Executive Officer and President

### Hong Kong, February 1, 2024

As at the date of this announcement, the Board comprises Mr. Zhao Hong and Ms. Pan Rongrong as executive directors, Mr. Li Zhenfu, Dr. Daniel Luzius Vasella, Ms. Lin Shirley Yi-Hsien and Ms. Wang Haixia as non-executive directors, and Dr. Liu Guoen, Dr. Chen Ping, Mr. Gu Alex Yushao and Ms. Wendy Hayes as independent non-executive directors.

\* for identification purpose only