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 AND MENARINI ESTABLISH LICENSE AND COLLABORATION AGREEMENT FOR ORSERDU® 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 board of directors of the Company is pleased to announce that the Company and Berlin-Chemie AG, Menarini Group ("**Menarini**"), have entered into a license and collaboration agreement (the "**License Agreement**") granting the Group the exclusive right to develop and commercialize Orserdu® (Elacestrant) ("**Orserdu®**") in China, under Menarini's head license agreement with Radius Health, Inc. ("**Radius**"). Orserdu® is the "first and only" treatment specifically indicated for patients with ESR1 mutations in ER+, HER2- advanced or metastatic breast cancer ("**mBC**") with the approval from the U.S. Food and Drug Administration ("**FDA**") under its priority review and fast track designation in January 2023, and subsequently from the European Commission in September 2023. The transaction contemplated under the License Agreement aims to bring this innovative treatment to China, pending local regulatory approval.

Breast cancer has overtaken lung cancer as the world's mostly commonly-diagnosed cancer and China accounted for 18% of the total number of new breast cancer cases worldwide, according to statistics released by the International Agency for Research on Cancer of World Health Organization in December 2020. Approximately 70% of breast cancer cases are HR+, HER2- and up to 40% of ER+, HER2- advanced or mBC cases present with ESR1 mutations. Sequential endocrine therapy ("**ET**") is considered the mainstay treatment for premenopausal and postmenopausal women with HR+/HER2– mBC without extensive visceral involvement. However, ESR1 mutations are a known driver of resistance to standard ET, and so far, have been difficult to treat. Orserdu®, an oral selective estrogen receptor degrader ("**SERD**") developed as a once-daily treatment for ER+, HER2- tumors that harbor ESR1 mutations, represents the first innovation in ET in nearly 20 years.

The approval of Orserdu® by the FDA and European Commission is supported by data from a Phase 3 trial called EMERALD, which demonstrated statistically significant progression-free survival ("**PFS**") with Orserdu® versus standard-of-care ("**SOC**"), defined as investigator's choice of an approved endocrine monotherapy. The primary endpoints of the study were PFS in the overall patient population and in patients with ESR1 mutations. In the group of patients whose tumors had ESR1 mutations, Orserdu® achieved a median PFS of 3.8 months versus 1.9 months on the SOC, and reduced the risk of progression or death by 45% (PFS HR=0.55, 95% CI: 0.39, 0.77) versus SOC.

A post hoc subgroup analysis of the EMERALD PFS results, which was presented at the San Antonio Breast Cancer Symposium 2022, demonstrated that the duration of prior CDK4/6i treatment was positively associated with longer PFS on Orserdu® but not with SOC. For patients with ESR1 mutations who were treated with CDK4/6i for ≥12 months prior to randomization on EMERALD, Orserdu® achieved a median PFS of 8.6 months versus 1.9 months on SOC, with a 59% reduction in the risk of progression or death (HR=0.41 95% CI: 0.26–0.63).

Under the License Agreement, SciClone will utilize its development capability to proceed with clinical trials and employ its sales, marketing and regulatory expertise to distribute Orserdu®, upon approval in China. SciClone will pay Menarini an upfront fee in cash and make additional payments upon various regulatory and sales milestones. Menarini will also be eligible to receive tiered royalties based on net sales of Orserdu® in China.

In July 2020, Menarini entered into an agreement with Radius, under which Menarini acquired the global exclusive rights to commercialize Orserdu®.

To the best knowledge and belief of the Company, as of the date of this announcement, Menarini and its ultimate beneficial are not connected persons (as defined in the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") of the Company. The transactions contemplated under the License Agreement therefore do not constitute connected transactions of the Company under the Listing Rules.

The Group cannot guarantee that Orserdu® will ultimately be approved or successfully commercialized in China. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

About Orserdu®:

Orserdu® has been approved by the FDA in the U.S. for the treatment of postmenopausal women or adult men, with ER+, HER2-, ESR1-mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. It has also been approved by European Commission as a monotherapy for the treatment of postmenopausal women, and men, with ER+, HER2-, locally advanced or metastatic breast cancer with an activating ESR1 mutation who have disease progression following at least one line of endocrine therapy including a CDK4/6i.

Safety data of Orserdu® is consistent with the other endocrine therapies. Most of the adverse events, including nausea and musculoskeletal pain were grade 1 and 2. No hematological safety signal was observed and none of the patients in either of the two treatment arms of EMERALD had sinus bradycardia.

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 differ entiated 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
"CDK4/6i"	the cyclin-dependent kinases 4 and 6 inhibitors are a class of medicines used to treat certain types of HR+, HER2-negative breast cancer; these medicines interrupt the process through which breast cancer cells divide and multiply by targeting specific proteins known as CDK4/6
"ER"	estrogen receptor, one of the most informative biomarkers in breast cancer
"ESR1"	estrogen receptor 1; high ESR1 expression is associated with metastasis in breast cancer
"HER2"	human epidermal growth factor receptor; some breast cancer cells have a higher than normal level of HER2 on their surface, which helps them to grow
"HR"	hormone receptors are proteins found on breast cells; they pick up the estrogen or progesterone signals that promote cell growth, including cancer cell growth if they contain the receptors for those hormones; the growth of HR+ breast cancer cells is often driven by ER
"U.S."	the United States of America

By order of the Board
SciClone Pharmaceuticals (Holdings) Limited
ZHAO Hong
Executive Director, Chief Executive Officer and President

Hong Kong, November 7, 2023

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*