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CK Life Sciences Int'l. (Holdings) Inc.
長江生命科技集團有限公司

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 0775)

BUSINESS UPDATE ON PHASE III CLINICAL STUDY OF SEVIPROTIMUT-L

CK Life Sciences Int'l. (Holdings) Inc. (the “Company”) refers to the Company’s announcement dated 6 November 2019 which provided an update on the ongoing Phase III clinical study of seviprotimut-L, an investigational melanoma vaccine candidate of Polynoma LLC (“Polynoma”), the Company’s wholly-owned U.S. immuno-oncology focused biopharmaceutical subsidiary.

The Company announces that Polynoma will be presenting final analysis of clinical data from Part B1 of MAVIS (Melanoma Antigen Vaccine Immunotherapy Study), a Phase III clinical study of seviprotimut-L, at the American Society of Clinical Oncology (ASCO)’s ASCO20 Virtual Scientific Program, to be held online from 29 to 31 May 2020. The study abstract is one of 12 abstracts selected for discussion in the Melanoma/Skin Cancers poster discussion session.

MAVIS is a multicenter, double-blind, placebo-controlled adaptive Phase III trial to assess the safety and efficacy of seviprotimut-L, with primary endpoints of recurrence-free survival (RFS) and overall survival (OS) in patients with American Joint Committee on Cancer (AJCC) Stage IIB/C, IIIA, IIIB/C melanoma at high risk of recurrence after definitive surgical resection, and is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration.

Highlights of the data to be presented include (a) improved outcomes in Stage IIB/IIC patients, with final analysis of subgroups confirming the findings of the interim analysis, suggesting enhanced RFS for seviprotimut-L in patients with AJCC Stage IIB/IIC melanoma, particularly those under age 60, and those with ulceration, whose lesions are considered more serious because they have a greater risk of metastasis, (b) for Stage IIB/IIC melanoma patients under 60, there was a trend towards improvement in overall survival for those treated with seviprotimut-L and (c) seviprotimut-L was well-tolerated with treatment-emergent adverse events (AEs) similar to patients given placebo and there were no treatment-related serious adverse events.

Polynoma considers that the final analysis of Part B1 of MAVIS reinforces the findings from the interim analysis last year, suggesting improved outcomes with seviprotimut-L in Stage IIB/IIC melanoma patients, particularly in those aged under 60 and those with disease with ulceration. Polynoma believes that seviprotimut-L will be an important new option for the adjuvant treatment of patients with localised melanoma and that these data show promise for seviprotimut-L as a vaccine-based treatment of melanoma. Polynoma will be advancing seviprotimut-L into the definitive part of the MAVIS study.

The data being presented at the ASCO20 Virtual Scientific Program are derived from the final analysis of 347 patients enrolled in Part B1 of Polynoma's ongoing Phase III clinical trial of seviprotimut-L.

It should be noted that the Phase III clinical trial for seviprotimut-L is ongoing and the data are subject to further review by the relevant regulatory authorities. There is accordingly no assurance of the outcome. Shareholders of the Company and potential investors are therefore advised to exercise caution when dealing in the securities of the Company.

By Order of the Board
CK Life Sciences Int'l., (Holdings) Inc.
Eirene Yeung
Company Secretary

Hong Kong, 14 May 2020

As at the date of this announcement, the Executive Directors of the Company are Mr. Li Tzar Kuoi, Victor (Chairman), Mr. Kam Hing Lam, Mr. Ip Tak Chuen, Edmond, Mr. Yu Ying Choi, Alan Abel and Dr. Toh Kean Meng, Melvin; and the Non-executive Directors are Mr. Peter Peace Tulloch, Mrs. Kwok Eva Lee (Independent Non-executive Director), Mr. Colin Stevens Russel (Independent Non-executive Director), Mr. Kwan Kai Cheong (Independent Non-executive Director) and Mr. Paul Joseph Tighe (Independent Non-executive Director).