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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 SEVIPROTIMUT-L

CK Life Sciences Int'l. (Holdings) Inc. (the “Company”) refers to the Company’s announcements dated 6 November 2019 and 14 May 2020 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’s application for Fast Track designation of seviprotimut-L has been granted by the U.S. Food and Drug Administration (the “FDA”). Fast Track is designed to facilitate the development and expedite the review of drugs which treat serious or life-threatening conditions and fill an unmet medical need. The FDA defines filling an unmet medical need as “providing a therapy where none exists or providing a therapy which may be potentially better than available therapy”, based on criteria such as showing superior effectiveness or improved effect on serious outcomes, avoiding serious side effects of an available therapy, decreasing a clinically significant toxicity of an available therapy that is common and causes discontinuation of treatment, and the ability to address anticipated public health need. The benefits of Fast Track designation include more frequent communication with the FDA, a rolling submission of the marketing application, and eligibility for Priority Review and Accelerated Approval, if the relevant criteria are met.

Polynoma considers that the Fast Track designation by the FDA provides further validation of seviprotimut-L as a potential new and important cancer vaccine for patients with localized melanoma.

As noted in the Company’s 2019 annual report, the Company considers that the milestone progress made by Polynoma to be very encouraging. The Company is committed to bringing the research and development initiatives to fruition, and is regularly reviewing deployment of appropriate funds to them.

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, 23 June 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).