DAWNRAYS PHARMACEUTICAL (HOLDINGS) LIMITED
東瑞製葯(控股)有限公司*

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2348)

BUSINESS UPDATE
INITIATION OF PHASE III CLINICAL TRIAL FOR PRIMARY HYPERCHOLESTEROLEMIA AND MIXED HYPERLIPIDEMIA OF AK102 AND INCREASE IN CAPITAL CONTRIBUTION IN JOINT VENTURE

Reference is made to the announcements ("Announcements") of Dawnrays Pharmaceutical (Holdings) Limited (the "Company") dated 14 December 2016, 16 March 2017 and 24 June 2020 in relation to formation of the joint venture company, namely 康融東方(廣東)醫藥有限公司 (AD Pharmaceuticals Co., Ltd.) ("AD Pharmaceuticals"), between Dawnrays Biotechnology Capital (Asia) Limited ("Dawnrays Biotech"), a wholly-owned subsidiary of the Company, and 中山康方生物醫藥有限公司 (Akeso Biopharma Co., Ltd.)("Akeso Biopharma"), a wholly-owned subsidiary of Akeso, Inc. (Stock Code: 9926), pursuant to the JV Agreement dated 14 December 2016. Terms defined in the Announcements shall have the same meanings when used herein unless the context requires otherwise.

INITIATION OF PHASE III CLINICAL TRIAL OF AK102

The Company has been informed by AD Pharmaceuticals that approval obtained to initiate a controlled Phase III clinical trial of randomized, double-blind, placebo to evaluate the long-term efficacy and safety of Ebronucimab (AK102) in patients with primary hypercholesterolemia and mixed hyperlipidemia.

INCREASE IN CAPITAL CONTRIBUTION IN JOINT VENTURE

On 9 September 2021, Dawnrays Biotech and Akeso Biopharma entered into a supplemental agreement to the JV Agreement ("Supplemental JV Agreement") to increase the registered capital of AD Pharmaceuticals (owned as to 65% by Akeso Bioparma and 35% by Dawnrays Biotech) from RMB143.80 million (equivalent to approximately HK$173.16 million) to RMB 243.80 million (equivalent to approximately HK$293.58 million). The additional registered capital of RMB100 million is to be contributed in cash in proportion to their shareholding in AD Pharmaceuticals, as to RMB35 million (equivalent to approximately HK$42.15 million) by Dawnrays Biotech and RMB65 million (equivalent to approximately HK$78.27million) by Akeso Biopharma respectively, by 31 December 2023. As a result, the total investment amount of AD Pharmaceuticals will be increased from RMB243.47 million to RMB343.47 million, comprising registered capital of RMB243.80 million and capital reserve of RMB99.67 million.

The additional capital contribution does not constitute a discloseable transaction for the Company under Chapter 14 of the Listing Rules. The terms of the Supplemental JV Agreement was agreed between the parties to the JV Agreement, taking in account the capital requirement of AD Pharmaceuticals to proceed to phase III clinical trial of AK102 and phase II clinical trial of AK 109 with a view to enhancing the value of the Group's investment in AD Pharmaceuticals. In view of the above, the Board is of the view that the terms of the Supplemental JV Agreement are fair and reasonable and in the interests of the Company and the Shareholders as a whole.

ABOUT EBRONUCIMAB (PCSK9 INHIBITORS) (AK102)

Ebronucimab (AK102) is primarily used for the treatment of primary hyperlipidemias, including homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH) and other primary hypercholesterolemia patients. When used in addition to or in substitution of statin drugs, PCSK9 inhibitors (Amgen's Repatha (evolocumab) and Sanofi/Regeneron's Praluent (alirocumab)) have demonstrated efficacy in dramatically reducing cholesterol and decreasing the incidence of heart attack or stroke in patients. Ebronucimab (AK102) has the same target as evolocumab and alirocumab. According to Frost & Sullivan, Repatha (evolocumab) and Praluent (alirocumab) collectively experienced a rapid increase in global sales from US$20 million in 2015, when they were launched, to US$858 million in 2018, representing a CAGR of 250.2%.

ABOUT VEGFR-2 MONOCLONAL ANTIBODY (AK109)

VEGFR-2 monoclonal antibody (AK109) is a new all-human VEGFR-2 monoclonal antibody drug developed by AD Pharmaceuticals, which can be used for the treatment of various malignant tumors. AK109 does not activate ADCC and can bind specifically to human VEGFR-2 protein with high affinity, which blocks VEGF binding to VEGFR-2 and effectively inhibits the proliferation of vascular endothelial cells induced by VEGF/VEGFR-2 binding, thus interfering with tumor angiogenesis and inhibiting the occurrence and development of tumors.

This announcement is made on a basis to keep shareholders and potential investors of the Company informed of the latest development of the Group. There is no assurance that Ebronucimab (PCSK9 INHIBITORS) (AK102) and VEGFR-2 monoclonal antibody (AK109) will be successfully developed and ultimately marketed. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By Order of the Board of
Dawnrays Pharmaceutical (Holdings) Limited
Li Kei Ling
Chairman

Hong Kong, 9 September 2021

As at the date of this announcement, the Board of the Company comprises three executive directors, namely Ms. Li Kei Ling, Mr. Hung Yung Lai and Mr. Chen Shaojun; one non-executive director, namely Mr. Leung Hong Man; three independent non-executive directors, namely Mr. Lo Tung Sing Tony, Mr. Ede, Ronald Hao Xi and Ms. Lam Ming Yee Joan.

In this announcement, conversion of RMB into HK$ is based on the exchange rate of RMB1.00 to HK$1.2042. The exchange rates have been used, where applicable, for the purposes of illustration only and do not constitute a representation that any amounts in RMB or HK$ were or may have been exchanged at this or any other rates or at all.

** for identification purpose only*