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)

UPDATE ON JOINT VENTURE COMPANY

EARLY COMPLETION OF PATIENT ENROLLMENT OF EBRONUCIMAB (PCSK9 MONOCLONAL ANTIBODY, AK102) IN A PHASE III CLINICAL TRIAL FOR PRIMARY HYPERCHOLESTEROLEMIA AND MIXED HYPERLIPIDEMIA IN THE PRC

This is a voluntary announcement made by Dawnrays Pharmaceutical (Holdings) Ltd. (the "Company" together with its subsidiaries, collectively referred to as the "Group") .

Reference is made to the announcements ("Announcements") of the Company dated 14 December 2016, 16 March 2017, 24 June 2020 and 9 September 2021 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 Inc.)("Akeso Biopharma"), 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.

AD Pharmaceuticals, a joint venture company owned as to 35% by the Group and 65% by Akeso Biopharma **(**a wholly-owned subsidiary of Akeso, Inc., a biopharmaceutical company dedicated to the research, development, manufacturing and commercialization of new drugs that are first-in-class and best-in-class therapies and whose shares are listed on the Stock Exchange (stock code: 9926)**)**, is primarily engaged in the development of Ebronucimab(PCSK9 monoclonal antibody; research and development code:AK102) and AK109 (a new all-human VEGFR-2 monoclonal antibody, developed by AD Pharmaceuticals).

**for identification purpose*

The Company has been informed by AD Pharmaceuticals that Ebronucimab (PCSK9 monoclonal antibody, AK102) had been completed patient enrollment early in a pivotal registrational phase III clinical trial in the PRC for the treatment of primary hypercholesterolemia and mixed hyperlipidemia.

The clinical trial is one of the three large-scale pivotal registrational clinical trials of Ebronucimab for the treatment of primary hypercholesterolemia and mixed hyperlipidemia. The clinical trial is designed to cover the unmet clinical needs of a large number of population, aiming to evaluate the efficacy and safety of long-term administration of Ebronucimab on patients with extremely high, high and low-to-medium cardiovascular hyperlipidemia risk, and provide more basis for product launch.

Results of previous clinical trials showed that Ebronucimab demonstrated good efficacy and safety profile in treating patients with hypercholesterolemia. After 12 weeks of continuous treatment using Ebronucimab, the fasting serum level of low-density lipoprotein cholesterol (''LDL-C'') in each dose group have improved significantly compared to patients treated with placebo, demonstrating similar efficacy as the marketed products with the same target. In particular, 450 mg once every four weeks (Q4W) can reduce LDL-C by 65.48% from baseline and 65.69% from the placebo arm; 150 mg once every two weeks (Q2W) can reduce LDL-C by 63.69% from baseline and 63.90% from the placebo arm. In the clinical trials, Ebronucimab showed similar safety profile compared with marketed PCSK9 monoclonal antibody drugs with the same target, with drug-related adverse events greater than 5% and higher than placebo only included injection site adverse reactions.

AD Pharmaceuticals could complete the patient enrollment for the phase III clinical trial of Ebronucimab in the PRC early is the result of efficient clinical operation system and innovation capability. Clinical trials have shown that Ebronucimab has a more complete inhibition of PCSK9 compared to marketed products with the same target, and can significantly reduce cholesterol in all patients administered. The Company expects that Ebronucimab will be approved for marketing as soon as possible, providing more choice for a large number of cardiovascular patients in the PRC.

PCSK9 monoclonal antibody is known as the most effective lipid-lowering drug following the statin drugs. At present, two PCSK9 monoclonal antibodies, namely Evolocumab and Alirocumab, have been approved for launch globally. The global market size of PCSK9 monoclonal antibody was US$1.246 billion in 2020, and an authoritative institution forecasts that PCSK9 monoclonal antibody market in the PRC will grow at a compound annual growth rate of 36.9% from 2023 to 2030.

ABOUT EBRONUCIMAB (PCSK9 MONOCLONAL ANTIBODY, AK102)

Ebronucimab (AK102) is used for the treatment of primary hypercholesterolemia and mixed hyperlipidemia, including homozygous familial hypercholesterolemia (HoFH), heterogeneous familial hypercholesterolemia (HeFH) and hypercholesterolemia patients with atherosclerosis cardiovascular disease. By reducing the PCSK9 circulation level, Ebronucimab increases the expression of low-density lipoprotein receptors (LDLR) on the cell surface and increases the removal of LDL-C, thereby reducing the LDL-C level in the circulation. The marketed PCSK9 monoclonal antibody has demonstrated a significant reduction in cholesterol and a reduction in the incidence of heart attack or stroke in patients, based on the background treatment of statin drugs.

This announcement is made on a basis to keep shareholders and potential investors informed of the latest development of the Group. There is no assurance that Ebronucimab 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, 22 December 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.