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)

VOLUNTARY ANNOUNCEMENT

THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION HAS ACCEPTED THE NEW DRUG APPLICATION FOR EBRONUCIMAB INJECTION (ANTI-PCSK9 MONOCLONAL ANTIBODY, AK102) DEVELOPED BY AD PHARMACEUTICALS

This is a voluntary announcement made by Dawnrays Pharmaceutical (Holdings) Limited (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, 9 September 2021 and 22 December 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 Co., Ltd.*) ("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.

The Company has been informed by AD Pharmaceuticals that the National Medical Products Administration ("NMPA") of the People's Republic of China ("China") has accepted the New Drug Application ("NDA") for ebronucimab injection (anti-PCSK9 monoclonal antibody, research and development code: AK102), developed by AD Pharmaceuticals, for the treatment of two indications: (i) primary hypercholesterolemia and mixed hyperlipidemia, and (ii) heterozygous familial hypercholesterolemia ("HeFH").

The acceptance of NDA is based on the results of four pivotal registration trials, including three pivotal registration trials for the treatment of primary hypercholesterolemia and mixed hyperlipidemia, and one pivotal registration trial for the treatment of HeFH.

The results showed that:

- For the treatment of those two indications, the lipid-lowering efficacy of 12-week treatment was maintained over 52-week long-term treatment, demonstrating ebronucimab could deliver a consistent and lasting benefit to patients.

- Based on the background treatment of statin drug combined with or without ezetimibe, ebronucimab significantly lower serum low-density lipoprotein cholesterol ("LDL-C") relative to the baseline levels. In each administration cycle, the maximum decrease exceeds 65%.

- Ebronucimab can effectively reduce total cholesterol ("TC"), non-high density lipoprotein cholesterol ("non-HDL-C") and apolipoprotein B ("ApoB"), while increase high-density lipoprotein cholesterol ("HDL-C") and apolipoprotein A-I ("ApoA-I"). Ebronucimab dosage is expected to reduce the risk of cardiovascular events.

- Ebronucimab is safe and well tolerated. No safety signals were observed in aged population.

PCSK9 is widely recognized as the safest and most effective lipid-lowering target drug after Statins. According to the estimation made by an authoritative organization, the compound annual growth rate of China's PCSK9 market size will reach 36.9% from 2023 to 2030. As a new lipid-lowering drug to effectively reduce the level of LDL-C, anti-PCSK9 monoclonal antibody has been recommended in the guidelines of lipid management in China and overseas, and is widely recognized by clinicians.

About ebronucimab (AK102, PCSK9)

Ebronucimab is developed by 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., whose shares are listed on the Stock Exchange (stock code: 9926)).

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 (AK102, PCSK9) will continuously 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
Dawnrays Pharmaceutical (Holdings) Limited
Li Kei Ling
Chairman

Hong Kong, 2 June 2023

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

**for identification purpose only*