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## Ascletis Pharma Inc.

## 歌禮製藥有限公司

(incorporated in the Cayman Islands with limited liability)
(Stock Code: 1672)

## **VOLUNTARY ANNOUNCEMENT**

## ASCLETIS ANNOUNCES FIRST PATIENT DOSED IN THE PHASE II CLINICAL TRIAL OF FASN INHIBITOR ASC40 FOR TREATMENT OF MODERATE TO SEVERE ACNE

- Previous clinical trials demonstrated ASC40 is safe and inhibits human facial sebum production in a dose-dependent fashion
- Excess sebum production plays a significant role in the pathogenesis of acne and suppression of sebum production reduces acne incidence and severity
- Acne is the eighth most prevalent disease in the world and affects more than 640 million people globally

The board of directors (the "Board") of Ascletis Pharma Inc. (the "Company" or "Ascletis") is pleased to announce the dosing of the first patient in the Phase II clinical trial of ASC40 for moderate to severe acne. ASC40 is an oral, selective inhibitor of fatty acid synthase (FASN), a key enzyme which regulates de novo lipogenesis. Human sebum production requires de novo lipogenesis, which is increased in acne and suppressed by the FASN inhibitor ASC40.

The Phase II trial is a randomized, double-blind, placebo-controlled, multicenter clinical trial in China to evaluate the safety and efficacy of ASC40 for the treatment of patients with moderate to severe acne. About 180 patients will be randomized into three active treatment arms or one placebo control arm at the ratio of 1:1:1:1 and receive ASC40 (25 mg, 50 mg or 75 mg) or matching placebo orally once a day for 12 weeks. The primary outcomes include percentage change of total lesion count at week 12 compared to baseline and ratio of subjects, whose Investigator's Global Assessment (IGA) grades are decreased by ≥2 grades at week 12 compared to baseline.

Acne is the eighth most prevalent disease in the world and affects more than 640 million people globally. The onset of acne often coincides with pubertal hormonal changes, and the condition affects approximately 85% of adolescents and young adults aged 12 to 25 years. However, acne can also persist into or develop during adulthood.

Current first-line treatments for acne include topical creams such as topical retinoids and androgen receptor inhibitor, oral isotretinoin, and antibiotics. A report published by Allied Market Research indicated that the global acne medication market size was US\$11.86 billion in 2019, and is projected to reach US\$13.35 billion by 2027.

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: We cannot guarantee that we will be able to ultimately commercialize ASC40 successfully.

By order of the Board Ascletis Pharma Inc. 歌禮製藥有限公司 Jinzi Jason WU Chairman

Hangzhou, the People's Republic of China January 13, 2022

As at the date of this announcement, the Board comprises Dr. Jinzi Jason WU and Mrs. Judy Hejingdao WU, as executive Directors; and Dr. Yizhen WEI, Mr. Jiong GU and Ms. Lin HUA, as independent non-executive Directors.