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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**

## GANNEX ANNOUNCES POSITIVE PHASE I CLINICAL RESULTS ON ITS THR-β AGONIST ASC41

The Board of Directors (the "Board") of Ascletis Pharma Inc. (the "Company") is pleased to announce the positive Phase I clinical results of ASC41 oral tablet, a liver-targeted prodrug of Gannex Pharma Co., Ltd. (甘萊製藥有限公司, "Gannex"), a wholly-owned subsidiary of the Company. The active metabolite of ASC41 is a selective thyroid hormone receptor beta (THR- $\beta$ ) agonist.

This Phase I trial is a randomized, double-blind, placebo controlled single- and multiple-ascending dose study in 65 subjects with elevated low-density lipoprotein cholesterol (LDL-C) (> 110 mg/dL), a population characteristic of non-alcoholic fatty liver disease (NAFLD). ASC41 has been formulated in commercially ready oral tablets developed in-house using proprietary technology. In the single-ascending dose portion of the study, preliminary data suggest that ASC41 is safe and well tolerated up to a dose of 20 mg. Furthermore, ASC41 tablet formulation showed a dose-proportional pharmacokinetic profile from 1 mg to 20 mg. In the multiple-ascending dose (MAD) portion of the study, preliminary data suggests that after 14 days of once daily oral dosing, subjects demonstrate clinically meaningful and statistically significant reduction in LDL-C and triglycerides compared to placebo, as shown in the table below.

# Placebo-adjusted relative change (mean) from baseline after 14 days of once daily oral dosing of ASC41 tablets

	1 mg (n=12)	2 mg (n=12)	5 mg (n=12)
Placebo-adjusted LDL-C reduction <i>P-value vs placebo</i>	-0.42%	-11.94%	-19.99%
	p=0.947	p=0.052	p=0.002
Placebo-adjusted triglyceride reduction <i>P-value vs placebo</i>	-39.43%	-31.06%	-34.49%
	p=0.002	p=0.029	p=0.015

ASC41 had a benign adverse event profile at all doses following 14-day treatment, with no grade 3 or above adverse events, no serious adverse events or premature discontinuations. Furthermore, ASC41 tablet formulation displayed a dose-proportional pharmacokinetic profile from 1 mg to 5 mg following once daily, 14-day dosing.

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 ASC41 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 12, 2021

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.