



## **Antengene Initiates Phase II Dose Expansion Study of Claudin 18.2 ADC ATG-022 in China and Australia**

Shanghai and Hong Kong, PRC, March 20, 2024 — Antengene Corporation Limited (“**Antengene**” SEHK: 6996.HK), a leading innovative, commercial-stage global biopharmaceutical company dedicated to discovering, developing and commercializing first-in-class and/or best-in-class therapeutics in hematology and oncology, today announced that **it has initiated the dose expansion portion of the Phase II CLINCH study of ATG-022 (Claudin 18.2 antibody-drug conjugate[ADC]) in China and Australia.** Prior to this, the CLINCH trial has already produced promising preliminary clinical results with **partial response (PR) and complete response (CR).**

**The CLINCH trial, consists of a dose escalation portion and a dose expansion portion, is a multi-center, open-label Phase I/II study of ATG-022 monotherapy in patients with advanced or metastatic solid tumors.** The primary objective of the study is to evaluate the safety and tolerability of ATG-022 and to determine important dosing parameters including maximum tolerated dose (MTD) and recommended Phase II dose (RP2D) of ATG-022 monotherapy. The secondary objective is to

characterize the pharmacology and evaluate the preliminary efficacy of ATG-022.

**The dose expansion portion of the study will enroll patients with gastric cancer or other solid tumors.** In May 2023, the U.S. Food and Drug Administration (FDA) consecutively granted two Orphan Drug Designations (ODDs) to ATG-022 for the treatment of pancreatic cancer and gastric cancer, separately.

**Dr. Amily Zhang, Antengene's Chief Medical Officer,** said, "We are excited that the dose expansion portion of the Phase II study of ATG-022 in China and Australia. The Phase I/II CLINCH trial is supported by strong preclinical data and has already made encouraging early observations with **one PR and CR in two patients with metastatic gastric cancer.** With the trial entering its next critical phase, we will continue working closely with regulators and investigators to fully explore the clinical potential of ATG-022."

### **About ATG-022**

ATG-022 is an antibody-drug-conjugate targeting Claudin 18.2. Claudins are cell adhesion molecules normally expressed within the tight junctions between cells to form a barrier that regulates cell permeability. In cancer,



Claudins are expressed at the cell surface due to changes in cell polarity. The Claudin 18.2 is often overexpressed in various primary malignant tumors including gastric, esophageal, cholangiocarcinoma and pancreatic cancers.

Data from preclinical studies, including results from gastric cancer-patient derived xenograft models presented at the 2022 American Association for Cancer Research (2022 AACR), showed that ATG-022 binds to Claudin 18.2 with low nanomolar affinity and demonstrated potent in vitro and in vivo antitumor effects, including in vivo efficacy demonstrated in Claudin 18.2 low expression models. This could pave the way for broad clinical utility of ATG-022 in gastric cancer patients with a wide range of Claudin 18.2 expression levels. ATG-022 demonstrated an excellent safety profile in Good Laboratory Practice (GLP) toxicology studies.

### **About Antengene**

Antengene Corporation Limited ( “**Antengene**” , SEHK: 6996.HK) is a leading commercial-stage R&D-driven global biopharmaceutical company focused on the discovery, development, manufacturing and commercialization of innovative first-in-class/best-in-class therapeutics for the treatment of hematologic malignancies and solid tumors, in realizing its vision of “Treating Patients Beyond Borders” .



Since 2017, Antengene has built a pipeline of 9 oncology assets at various stages going from clinical to commercial, including 6 with global rights, and 3 with rights for the APAC region. To date, Antengene has obtained 29 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 11 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in Mainland of China, Taiwan China, Hong Kong China, Macau China, South Korea, Singapore and Australia.

### **Forward-looking statements**

The forward-looking statements made in this article relate only to the events or information as of the date on which the statements are made in this article. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this article completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this article, statements of, or references to, our intentions or those of any of our Directors or our Company are made as of the date of this article. Any of these intentions may alter in light of future development. For a further discussion of these



and other factors that could cause future results to differ materially from any forward-looking statement, please see the other risks and uncertainties described in the Company's Annual Report for the year ended December 31, 2022, and the documents subsequently submitted to the Hong Kong Stock Exchange.