Antengene Announces IND Approval for the Phase I CLINCH Trial of ATG-022 (Claudin 18.2 ADC) for the Treatment of Advanced or Metastatic Solid Tumors in China

- ***Discovered and developed in-house by Antengene's R&D team,*** *ATG-022 is* ***an antibody-drug-conjugate (ADC) targeting the Tumor Associated Antigen (TAA) Claudin 18.2.***
- *The Phase I* ***CLINCH trial*** *is designed to evaluate the safety, pharmacology, and preliminary efficacy of ATG-022 monotherapy in patients with advanced or metastatic solid tumors.* ***ATG-022 has also received the clinical trial clearance (CTN) by the Bellberry Human Research Ethics Committee (HREC) in Australia and is currently recruiting patients with advanced or metastatic solid tumors.***

Shanghai and Hong Kong, PRC, March 14, 2023 -- Antengene Corporation Limited (**"Antengene"** , SEHK: 6996.HK), a leading innovative commercial stage global biopharmaceutical company dedicated to discovering, developing and commercializing first-

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in-class and/or best-in-class therapeutics in hematology and oncology, today announced that **the China National Medical Products Administration (NMPA) has approved the Phase I study of ATG-022 for the treatment of advanced or metastatic solid tumors (the CLINCH Trial).**

The CLINCH trial is a multi-center, open-label Phase I dose-finding 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/or 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.

"Developed in-house by Antengene, ATG-022 is a potential best-in-class ADC that can target Claudin 18.2 with high affinity and recently published industry results have validated Claudin 18.2 as an important cancer target," said **Dr. Bo Shan, Antengene's Chief Scientific Officer.**

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"We believe that this IND clearance in China is an important milestone for ATG-022 because of the agent's potential role in the treatment of gastric cancer and other advanced solid tumors. We look forward to initiating patient enrolment for this study and beginning to work with our investigators to evaluate the therapeutic utility this drug as soon as possible."

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 isoform is overexpressed in various primary malignant tumors including gastric, esophageal 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 broad and expanding pipeline of 13 clinical and preclinical assets, of which 10 are global rights assets, and 3 came with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 28 investigational

new drug (IND) approvals in the U.S. and Asia, and submitted 9 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in Mainland of China, Taiwan,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, see the section titled "Risk Factors" in our periodic reports filed with the Hong Kong Stock Exchange and the other risks and uncertainties described in the Company's Annual Report for year-end December 31, 2021, and subsequent filings with the Hong Kong Stock Exchange.

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