Antengene Announces HREC Approval in Australia for the Phase I Trial of ATG-022 (Claudin 18.2 ADC) in Patients with Advanced or Metastatic Solid Tumors

- ***Discovered in-house by Antengene's R&D team**, ATG-022 is **an antibody-drug-conjugate targeting the Tumor Associated Antigen (TAA) Claudin 18.2***
- *The Phase I trial is designed to evaluate the safety, pharmacology, and preliminary efficacy of ATG-022 as a monotherapy in patients with **advanced or metastatic solid tumors***

Shanghai and Hong Kong, PRC, December 9, 2022 -- 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 **Antengene has received approval by the Bellberry Human Research Ethics**

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Committee (HREC) in Australia to initiate the Phase I Trial of ATG-022 in patients with advanced or metastatic solid tumors (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 biologically effective dose, maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of ATG-022 monotherapy. The secondary objective is to characterize the pharmacology and evaluate the preliminary efficacy of ATG-022.

ATG-022 is an antibody-drug-conjugate (ADC) targeting Claudin 18.2. It is comprised of anti-Claudin 18.2 mAb, a toxin that induces cell apoptosis and a linker that is only cleaved inside of cells. ATG-022 demonstrates bystander effect. Claudin 18.2 is a TAA overexpressed particularly in gastric, esophageal and pancreatic cancers.

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Antengene presented data at the 2022 American Association for Cancer Research Annual Meeting (2022 AACR) which showed that ATG-022 binds to Claudin 18.2 with high affinity of low nanomolar level and demonstrated potent *in vitro* and *in vivo* antitumor effects, including stronger *in vivo* efficacy observed in Claudin 18.2 low expression gastric cancer patient-derived xenograft models compared to other benchmark compounds.

"Claudins are a major component of the tight junctions that control the intercellular space. While Claudin 18.2 is overexpressed in several types of cancers, it is generally not found on the surface of normal cells. This differential expression paves the way for Claudin 18.2-based therapies to be selective for cancer tissue and therefore combine clinical efficacy with safety." said **Dr Sarwan Bishnoi**. "ATG-022 is a high-affinity ADC directed against Claudin 18.2. We believe ATG-022 may offer new hope for patients who have failed other therapies, especially in difficult to treat gastro-intestinal tumor types with positive expression of Claudin 18.2."

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"We chose to develop Claudin 18.2 because of the target's potential to distinguish between normal and cancer cells with a wide therapeutic index" , said **Dr. Bo Shan, Antengene's Chief Scientific Officer**. "We utilized our next generation ADC discovery platforms developed through our in-house research and collaborations to create a high-affinity, potentially differentiated ADC agent, ATG-022. *In vivo* efficacy has been seen in tumors that have low levels of Claudin 18.2 expression and so we believe that ATG-022 could be a promising agent for cancer patients with a broad range of Claudin 18.2 expression levels. We look forward to collaborating with the investigators of this trial to fully evaluate ATG-022's therapeutic potential."

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

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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, with *in vivo* efficacy observed 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 15 clinical and preclinical assets, of which 10 are global rights assets, and 5 came with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 27 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 7 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in mainland 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.