Antengene Announces Claudin 18.2 Antibody-Drug Conjugate ATG-022 Granted Orphan Drug Designations by the U.S. FDA for the Treatment of Gastric and Pancreatic Cancers

Shanghai and Hong Kong, PRC, May 23, 2023 — Antengene Corporation Limited (**"Antengene"** SEHK: 6996.HK), a leading commercial-stage innovative, global biopharmaceutical company dedicated to discovering, developing and commercializing first-in-class and/or best-in-class medicines for hematology and oncology, today announced that **ATG-022, a Claudin 18.2 antibody drug conjugate (ADC) in-house discovered and developed by Antengene, has been granted two Orphan Drug Designations (ODD) consecutively by the U.S. Food and Drug Administration (FDA) for the treatment of gastric cancer and pancreatic cancer. To date, Antengene has received 3 ODDs from the FDA for two of its in-house products.**

Orphan Drugs, also known as Rare Disease Drugs, refers to pharmaceutical products developed for the prevention,

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diagnosis, and treatment of rare diseases or conditions. Orphan Drug Designations by the U.S. FDA are meant to support the development of drug candidates that could potentially bring substantial therapeutic benefits to patients with rare diseases (a condition with a prevalence of less than 200,000 in the U.S.), and to provide incentives to the subsequent development, registration and commercialization to designated drugs. Those incentives include tax credit on expenditures incurred in clinical studies, a waiver of the New Drug Application (NDA) fee, and 7-year market exclusivity in the U.S. regardless of the patent status of the designated drug.

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. **The Phase I CLINCH study of ATG-022 in patients with advanced**

or metastatic solid tumors, already approved by the China National Medical Products Administration (NMPA) and Bellberry Human Research Ethics Committee (HREC) in Australia, is currently ongoing in China and Australia.

"We believe the that Orphan Drug Designation represents an important regulatory milestone for ATG-022, recognizing the significant and urgent unmet need for new treatments to help patients who are fighting difficult to treat and devastating diseases such as pancreatic and gastric cancers," said **Dr. Amily Zhang, Antengene's Chief Medical Officer.** "We are enthusiastic about the potential for ATG-022 to treat gastric and pancreatic cancers. Moving forward, Antengene will work closely with regulators and clinical investigators to advance the CLINCH trial and fully assess ATG-022's therapeutic potential for solid tumors."

About Gastric cancer

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Gastric cancer is s malignancy arises in the gastric epithelium. According to the statistic for 2019 of the World Health Organization's (WHO), gastric cancer was ranked the ninth by mortality among all cancers. In 2022, there were an estimated 26,000 gastric cancer diagnoses and 11,000 gastric cancer-related death in the U.S. The current 5-year survival of patients with metastasized and local gastric cancers are 70% and 32%, respectively[1].

About Pancreatic cancer

Pancreatic cancer is a highly malignant type of gastrointestinal cancer. According to the statistics of the World Health Organization (WHO), pancreatic cancer was ranked 13th and 7th globally by its incidence rate and mortality rates in 2012. In 2018, the U.S. reported over 55,000 newly- diagnosed pancreatic cancer cases and 44,330 related deaths. Whereas pancreatic cancer is still defined as an orphan disease currently, it is projected that by 2030, pancreatic cancer will become the second most common cause of cancer-related deaths.

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About ATG-022

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Data from preclinical studies, including results from gastric cancer-patient derived xenograft models presented at the 2022 American Association for Cancer Research (AACR 2022), 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.

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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 10 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

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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 subsequent filings with the Hong Kong Stock Exchange.

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1. Statistics of Stomach Cancer, published in Cancer.net at: https://www.cancer.net/cancer-types/stomach-cancer/statistics

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