Antengene Announces IND Approval for the Phase I STAMINA-001 Study to Evaluate ATG-037 (CD73 Inhibitor) for the Treatment of Locally Advanced or Metastatic Solid Tumors in China

- *ATG-037,* ***an inhouse asset developed by Antengene and with global rights,*** *has been approved to enter clinical studies in Australia and China, thus becoming* ***the first oral small molecule CD73 inhibitor entering the clinical-stage in China and the wider Asia Pacific region.*** *ATG-037 IND in Australia has been started enrolling in that phase I study.*

- *The STAMINA-001 study will evaluate ATG-037 as a monotherapy and in combination with the immune checkpoint inhibitor (ICI), pembrolizumab, to determine the safety, pharmacology, and preliminary efficacy in patients with* ***locally advanced or metastatic solid tumors.***

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Shanghai and Hong Kong, PRC, November 2, 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 the **China National Medical Products Administration (NMPA) has approved the Phase I study of ATG-037 for the treatment of locally advanced or metastatic solid tumors (STAMINA-001 Trial).**

The primary objective of the study is to evaluate the safety, pharmacology, tolerability, and preliminary efficacy of ATG-037 as monotherapy and in combination with pembrolizumab, to determine the appropriate dose for Phase II studies. Secondary objectives include characterization of the pharmacology of ATG-037.

ATG-037 is an orally available, small molecule CD73 inhibitor. CD73 generates adenosine, which leads to

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immunosuppression in the tumor microenvironment. ATG-037 has demonstrated promising preclinical efficacy as a monotherapy and in combination with ICIs and chemotherapy agents. In preclinical studies, the compound has demonstrated the ability to overcome the "hook effect" that has been observed in some anti-CD73 antibodies. In addition, GLP toxicology studies indicate the compound potentially has a wide therapeutic window.

"My Team and I have been closely tracking the emerging research on the adenosine axis and its potential role in creating an immunosuppressive tumor microenvironment. This work has identified CD73 as a promising immunotherapy target. Overexpression of CD73 has been associated with poor outcomes in a number of solid tumors and inhibitors of CD73 have demonstrated anti-tumor activity in preclinical models," said **Professor Yilong Wu, the Chief Expert of Guangdong Provincial People's Hospital, and principal investigator of the study,** "We see this as very important work and are pleased to participate in the Phase I STAMINA-001 study to evaluate the

novel, orally-available small molecule CD73 inhibitor, ATG-037, in collaboration with Antengene."

"Antengene believes that therapies that act in the tumor microenvironment will become one the most important elements of a cancer care regimen. Adopting a dual-engine strategy that leverages both inhouse R&D and partnerships, we have carefully assembled a novel portfolio of proprietary and collaborative novel programs, including the CD73 inhibitor, ATG-037, to target this segment of cancer biology," said **Dr. Jay Mei, Antengene's Founder, Chairman and CEO**. "In preclinical studies, ATG-037 demonstrated several characteristics that could position the product candidate as a best-in-class agent. We are very pleased to receive IND approval for the STAMINA-001 study from the NMPA and look forward to accelerating the further development of the exciting ATG-037 program."

About the STAMINA-001 Trial

The STAMINA-001 trial is a Phase I multi-center, open-label, dose finding study of ATG-037 monotherapy or combination

therapy with pembrolizumab in patients with locally advanced and metastatic solid tumors.

The primary objective of the study is to evaluate the safety, pharmacokinetic, pharmacodynamics and preliminary efficacy of ATG-037 monotherapy and combination therapy with pembrolizumab and to determine the maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D) and/or optimal biological dose of ATG-037 monotherapy. As a Phase I study, there will be intensive safety monitoring throughout the trial.

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, driven by its vision of **"Treating Patients Beyond Borders"**.

Since its founding in 2017, Antengene has built a broad and expanding pipeline of 15 clinical and preclinical assets, including 10 assets with global rights and 5 with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 26 investigational new drug (IND) approvals in Asia and the U.S., and submitted 6 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 document relate only to the events or information as of the date on which the statements are made in this document. Except as required by law, Antengene undertakes 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 document

completely and with the understanding that our actual future results or performance may be materially different from what we expect. In this document, 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 document. Any of these intentions may be altered 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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