Antengene Receives U.S. FDA Clearance of IND Application for Phase I Trial of Small Molecule ERK1/2 Inhibitor ATG-017 in Patients with Advanced Solid Tumors

- *ATG-017 is **a small molecule ERK1/2 inhibitor** and Antengene has obtained **exclusive global rights** to develop, commercialize and manufacture ATG-017.*
- *IND clearance enables Antengene to initiate the combination portion of the Phase I "ERASER" clinical trial in the United States (U.S.) to evaluate the safety, pharmacokinetics, and preliminary efficacy of ATG-017 combination therapy with nivolumab **in patients with advanced solid tumors.***
- *To date, **the ATG-017 monotherapy dose escalation has been ongoing in Australia,** which will continue to participate in the combination therapy portion of the trial. In addition to Australia and the U.S., Antengene also plans to conduct this **Multi-Regional Clinical Trial(MRCT)** in China.*

Shanghai and Hong Kong, PRC, October 31, 2022 — Antengene Corporation Limited (**"Antengene"** SEHK: 6996.HK), a leading innovative, commercial-stage global biopharmaceutical company

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dedicated to discovering, developing and commercializing first-in-class and/or best-in-class therapeutics in hematology and oncology, today announced that **the Investigational New Drug (IND) application for ATG-017 has received clearance from the U.S. Food and Drug Administration (FDA).** The IND clearance enables Antengene to initiate the combination portion of the Phase I "ERASER" clinical trial in the United States (U.S.) **to evaluate the safety, pharmacokinetics, and preliminary efficacy of ATG-017 combination therapy with nivolumabin patients with advanced solid tumors.**

ATG-017 is an oral, potent, and selective inhibitor of extracellular signal-regulated protein kinase 1 and 2 (ERK1/2). Nivolumab is a human programmed death receptor-1 (PD-1) blocking antibody that binds to the PD-1 receptor expressed on activated T-cells. The clinical collaboration between Antengene and Bristol Myers Squibb to evaluate ATG-017 in combination with nivolumab builds on Antengene's preclinical data. **The data, including studies presented at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting & Pre-conference Programs in November 2021, has demonstrated that the combination of an ERK1/2 inhibitor and an immune checkpoint inhibitor (ICI) worked synergistically to produce improved efficacy in preclinical ICI-resistant *in vivo* mice models.**

"We are excited to have received IND clearance for activation of the ERASER study in the U.S. Preclinical results with ATG-017 have been very promising both as a monotherapy and in combination with ICIs in aggressive and resistant malignancies. We are very pleased that the further clinical exploration will involve multiple geographies as we attempt to define the potential role of ATG-017 as a novel cancer treatment," said **Dr. Kevin Lynch, Antengene's Chief Medical Officer. "**Every day, we see advanced cancer patients with limited treatment options. We intend to initiate the study in the U.S. soon, and hope that ATG-017 will eventually offer a safe and effective new treatment option to those patients in need."

"The development of new therapies for cancer patients with refractory, relapsed, or advanced diseases is a cornerstone of Antengene's work. ATG-017 is an exciting compound because of its attractive pharmacology, impressive preclinical activity on the RAS-MAPK pathway and the potential ability to synergize with ICIs. These attributes provide the rationale for evaluating ATG-017 as a monotherapy and in combination with ICIs such as nivolumab in patients with resistant or relapsed disease," said **Dr. Jay Mei, Antengene's Founder, Chairman and CEO.** "We are very encouraged by this IND clearance from the U.S.

FDA as it paves the way for one of Antengene's first studies in the U.S. and marks an important milestone in the global clinical development of ATG-017. We look forward to initiating patient enrollment of the ERASER trial in the U.S."

About ATG-017

ATG-017 is an oral, potent, and selective small molecule extracellular signal-regulated kinases 1 and 2 (ERK1/2) inhibitor. ERK1/2 are related protein-serine/threonine kinases that function as terminal kinases in the RAS-MAPK signal transduction cascade. This cascade regulates a large variety of cellular processes, including proliferation. The RAS-MAPK pathway is dysregulated in more than 30% of human cancers with the most frequent alterations being observed in RAS or BRAF genes across multiple tumor types. An ERK inhibitor enables the targeting of both RAS and BRAF mutant diseases.

Antengene presented data at the Society for Immunotherapy in Cancer (SITC) 36th Annual Meeting & Pre-conference Programs in November 2021 detailing compelling preclinical results showing the combination of ATG-017 and an anti-PD-L1 monoclonal antibody (atezolizumab) in an aggressive immune checkpoint resistant murine cancer model rendered "cold" tumors "hot". To date, ATG-017 has been approved in Australia

and the United States to enter clinical studies in patients with advanced solid tumors or hematologic malignancies.

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 25 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, 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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