Antengene Announces Clearance of U.S. IND for the Phase I Trial of First-in-Class Anti-CD24 Monoclonal Antibody ATG-031

- *ATG-031, **discovered and developed in-house by Antengene**, is **the world's first anti-CD24 antibody to advance to the clinic in oncology** and Antengene's **third drug candidate to enter clinical studies in the U.S.***
- *The Phase I **"PERFORM" study** will evaluate the safety and tolerability, pharmacology, immunogenicity, and preliminary efficacy of ATG-031 in patients with **advanced solid tumors or B-cell non-Hodgkin's lymphoma (B-NHL)***

Shanghai and Hong Kong, PRC, May 18, 2023 — 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 Investigational New Drug**

上海市长宁区中山西路 1065 号 SOHO 中山广场 B 座 1206-1209 室
Suite 1206-1209, Building B, SOHO Plaza, 1065 West Zhongshan Road, Shanghai 200051, China
Tel: (86) 021 3250 1095
Fax: (86) 021 3250 1062
www.antengene.com

(IND) for a Phase I study of the first-in-class anti-CD24 monoclonal antibody ATG-031 has received clearance from the U.S. Food and Drug Administration (FDA).

The PERFORM trial is a first-in-human, multi-center, open-label, Phase I dose-finding study of ATG-031 in patients with advanced solid tumors or B-NHL. The primary objective of the study is to evaluate the safety and tolerability of ATG-031 as a monotherapy, and to determine the appropriate dose for Phase II studies. The secondary objective is to characterize the pharmacology, evaluate the immunogenicity, and assess the preliminary efficacy of ATG-031.

ATG-031 is a first-in-class humanized anti-CD24 monoclonal antibody which inhibits the "don't eat me" signal in the tumor microenvironment (TME). ATG-031 was designed to specifically bind with the CD24 expressed on cancer cells with high affinity and block the interaction between CD24 and the Siglec-10 receptor expressed on the surface of tumor associated

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macrophages (TAMs), to enhance the macrophage-mediated phagocytosis of cancer cells and promote cytotoxic T-cell function in the tumor microenvironment.

"Targeting the so-called 'don't eat me' signal is a promising therapeutic strategy for cancer treatment. **In comparison to existing 'don't eat me' blockers such as anti-CD47 monoclonal antibodies, ATG-031 demonstrated a wider therapeutic window and the ability to overcome the on-target-off-tumor toxicities observed with CD47 inhibitors,**" said **Dr. Bing Hou, Antengene's Executive Director of Drug Discovery and a co-inventor of ATG-031**. "CD24 is a small and highly glycosylated protein that makes the development of antibodies particularly challenging. Through our persistent experimental efforts and by adopting unique discovery and screening strategies as well as leveraging our deep expertise on the target's biology, Antengene's discovery scientists successfully advanced ATG-031, an antibody with optimal characteristics, into clinical development in just three years. We are thrilled to see our in-

house developed first-in-class drug entering the clinic and taking a major step towards benefiting patients."

"We believe that therapies that can effectively mobilize the macrophage activity in the tumor microenvironment will be a very important element of cancer care," said **Dr. Bo Shan, Antengene's Chief Scientific Officer**. "**The potential role of ATG-031 is supported by robust preclinical data that showed potent single agent *in vivo* efficacy and synergistic effects with chemotherapy or checkpoint inhibitors (CPIs).** Therefore, we are very optimistic about the clinical development of ATG-031 and look forward to initiating the patient enrolment as early as possible."

"**In this clinical program for ATG-031, we will deploy an in-house developed companion diagnostic (CDx) antibody, thus adding a precision-medicine element to the program,**" said **Dr. Amily Zhang, Antengene's Chief Medical Officer.** "In addition to serving as a patient selection tool, the CDx antibody will help us to better understand the CD24 expression in normal and

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cancerous tissue. We are excited to learn more about the safety, tolerability and efficacy of ATG-031 through the clinical program and **look forward to sharing the first data from this study in 2024.**"

"**ATG-031 is the world's first anti-CD24 antibody to be advanced to the clinic in oncology and Antengene's third drug candidate cleared to enter clinical studies in the U.S.,**" said **Dr. Jay Mei, Antengene's Founder, Chairman and CEO.** "I am very proud of the entire R&D organization, for innovating and advancing this proprietary asset, from bench to patient, in such a robust and efficient manner. We believe that targeting CD24 could represent a major oncological advancement and anticipate more exciting progress with this clinical program."

About ATG-031

ATG-031 is a first-in-class humanized CD24 monoclonal antibody which inhibits the "don't eat me" signal and enhances macrophage-mediated phagocytosis of cancer cells. Tumor cells evade the surveillance of the human immune system

by over-expressing "don't eat me" surface proteins that signal macrophages to prevent the detection and phagocytosis of cancer cells. CD24 (cluster of differentiation 24) is a prominent "don't eat me" signal that plays a significant role in tumor immune evasion by suppressing macrophage-mediated phagocytosis. Compared to CD47, another well-known "don't eat me" target, CD24 has more restricted distribution in normal tissue and higher expression in cancerous tissue. In addition, unlike CD47, CD24 is not expressed on human red blood cells, allowing for a wider therapeutic window and minimal on-target-off-tumor toxicity as a CD24-targeted therapy.

As a novel innate immune checkpoint, CD24 orchestrates immune evasion through its interaction with the inhibitory receptor called Siglec-10 (sialic-acid-binding Ig-like lectin 10) expressed on tumor-associated macrophages (TAMs). Preclinical data presented in 2023 at the American Association for Cancer Research Annual Meeting (AACR 2023) demonstrated that ATG-031 can specifically bind to CD24 with nM affinity and block the interaction of CD24 and Siglec-10. Furthermore, ATG-

31 induces efficient phagocytosis with a picomolar EC_{50} and stimulate the pro-inflammatory cytokines production by macrophages.

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 28 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 10 new drug applications (NDAs) in multiple Asia Pacific

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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 other risks and uncertainties described in the Company's Annual Report for year-end December 31, 2022, and subsequent filings with the Hong Kong Stock Exchange.

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