Antengene Receives CDE Endorsement to Initiate Pivotal Phase III CLINCH-3 Study of ATG-022 in CLDN18.2+ Advanced Gastric/GEJ Cancer

Shanghai and Hong Kong, PRC, May 28, 2026 — Antengene Corporation Limited （**"Antengene"**，SEHK: 6996.HK), a leading innovative, commercial-stage global biotech company dedicated to discovering, developing and commercializing first-in-class and/or best-in-class medicines for autoimmune diseases, solid tumors and hematological malignancies indications, today announced that following review by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA), the company has received CDE endorsement to conduct the pivotal Phase III CLINCH-3 study of ATG-022, a Claudin 18.2 (CLDN18.2) antibody-drug conjugate (ADC), for the treatment of CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma. The study is expected to be initiated in China first and is planned as a multi-regional clinical trial (MRCT).

"Receiving CDE endorsement to conduct the pivotal Phase III CLINCH-3 study represents a defining milestone for Antengene." said **Dr. Jay Mei, Founder, Chairman and Chief Executive Officer of Antengene**. "This achievement underscores Antengene's fully integrated R&D capabilities,

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

from the design and discovery of novel molecules to clinical translation and registrational development. The Breakthrough Therapy Designation previously granted by CDE provided an important basis for our regulatory discussions on this pivotal study and enabled efficient feedback from CDE. We are highly encouraged by the potential of ATG-022 to address the significant unmet medical needs of patients with CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma, and we look forward to working closely with investigators to advance this important study."

The CLINCH-3 study will be led by Prof. Lin Shen from Peking University Cancer Hospital as the principal investigator. This is a randomized, controlled, open-label, multicenter Phase III clinical study designed to evaluate the efficacy and safety of ATG-022 versus treatment of investigator's choice in patients with CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma. As a pivotal registrational study, CLINCH-3 is intended to support a future marketing approval application for ATG-022 as monotherapy for the treatment of CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma. The primary endpoints of the study are progression-free survival as assessed by independent review committee (PFS by IRC) and overall survival (OS). Secondary endpoints include objective

response rate (ORR), duration of response (DOR), disease control rate (DCR), safety, and other measures. The initiation of this pivotal study is supported by encouraging results from the Phase I/II CLINCH study, which showed that ATG-022, as monotherapy, demonstrated a differentiated efficacy and safety profile in patients with advanced gastric or gastroesophageal junction adenocarcinoma. As of December 25, 2025, among patients whose tumors had CLDN18.2 expression of IHC 2+ >20%, ATG-022 achieved ORRs of 46.7% and 40.0% at 1.8 mg/kg and 2.4 mg/kg, respectively, with corresponding DCRs of 86.7% and 90.0%. Median PFS (mPFS) was 6.97 months and 5.09 months, respectively, while median OS (mOS) was not yet reached in the 1.8 mg/kg cohort and was 14.72 months in the 2.4 mg/kg cohort. In the 1.8 mg/kg cohort, the incidence of Grade 3 or higher treatment-related adverse events (TRAEs) was 19.4%, highlighting a highly differentiated safety profile for an ADC. Together with its robust antitumor activity, encouraging survival outcomes and favorable tolerability, these data position ATG-022 as a potential best-in-disease therapy for gastric cancer or gastroesophageal junction adenocarcinoma.

"Advanced gastric and gastroesophageal junction adenocarcinoma remains one of the most difficult solid tumors to treat, and the challenge is particularly acute in the 3L setting, where current options, including

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

chemotherapy, anti-angiogenic agents and immunotherapy, provide limited efficacy, low objective response rates and insufficient survival benefit," said **Professor Lin Shen of Peking University Cancer Hospital, principal investigator of the CLINCH-3 study**. "ATG-022 has shown a compelling clinical profile as monotherapy at 1.8 mg/kg, with strong anti-tumor activity, meaningful survival benefit and a favorable safety profile. The CDE endorsement to conduct this pivotal Phase III study represents an important step toward potentially transforming the treatment landscape for patients with CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma. I am pleased to lead CLINCH-3 and look forward to working with Antengene to bring this promising therapy to more patients."

Antengene will continue to advance a comprehensive clinical development strategy for ATG-022 across multiple settings, including its pivotal monotherapy study in advanced gastric or gastroesophageal junction adenocarcinoma, ongoing combination studies with anti-PD-1 therapy and chemotherapy in the 1L gastric cancer setting, and further exploration in other CLDN18.2+ solid tumors, including tumor types beyond the digestive system where encouraging efficacy signals with confirmed tumor responses, have been observed. Through this strategy, the company aims to maximize the clinical potential of ATG-022

and bring innovative, impactful therapies to patients in China and around the world.

About Antengene

Antengene Corporation Limited (**"Antengene"**, SEHK: 6996.HK) is a global, R&D-driven, commercial-stage biotech company focused on developing first-in-class/best-in-class therapeutics for diseases with significant unmet medical needs. Its pipeline spans from preclinical to commercial stages, with key investigational candidates including ATG-022 (CLDN18.2 ADC), ATG-037 (oral CD73 inhibitor), ATG-101 (PD-L1 x 4-1BB bispecific antibody), ATG-125 (B7-H3 × PD-L1 bispecific ADC), ATG-207 (αCD3-TGF-β bifunctional fusion protein), as well as T cell engager (TCE) programs developed using Antengene's proprietary AnTenGager® platform.

AnTenGager®, is Antengene's proprietary TCE 2.0 platform, featuring "2+1" bivalent binding for low expressing targets, steric hindrance masking, and proprietary CD3 sequences with fast on/off kinetics to minimize cytokine release syndrome (CRS) and enhance efficacy. These characteristics support the platform's broad applicability across autoimmune disease, solid tumors and hematological malignancies, with programs targeting CD19 x CD3 (ATG-201 for B cell-related

autoimmune diseases; partnered with UCB), CDH6 x CD3 (ATG-106 for ovarian cancer and kidney cancer), ALPPL2 x CD3 (ATG-112 for gynecological tumors, digestive system malignancies, bladder cancer and NSCLC), LY6G6D x CD3 (ATG-110 for microsatellite-stable colorectal cancer), GPRC5D x CD3 (ATG-021 for multiple myeloma), LILRB4 x CD3 (ATG-102 for acute myeloid leukemia and chronic myelomonocytic leukemia) and FLT3 x CD3 (ATG-107 for acute myeloid leukemia).

To date, Antengene has obtained 32 investigational new drug (IND) approvals in the U.S. and Asia, and obtained new drug application (NDA) approvals in 10 Asia Pacific markets. Its lead commercial asset, XPOVIO® (selinexor), is approved in the Mainland of China, Taiwan China, Hong Kong China, Macau China, South Korea, Singapore, Malaysia, Thailand, Indonesia and Australia, and has been included in the national insurance schemes in five of these markets (Mainland of China, Taiwan China, Australia, South Korea and Singapore).

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, please see the other risks and uncertainties described in the Company's Annual Report for the year ended December 31, 2025, and the documents subsequently submitted to the Hong Kong Stock Exchange.