



Antengene Announces First Patient Dosed in Pivotal Phase III CLINCH-3 Study of ATG-022

Shanghai and Hong Kong, PRC, September 21, 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, today announced that **the first patient has been dosed in China in the pivotal Phase III CLINCH-3 study of ATG-022. ATG-022 is a CLDN18.2 antibody-drug conjugate (ADC) being evaluated for the treatment of CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma.**

ATG-022 was previously granted **Breakthrough Therapy Designation (BTD)** by the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA). This designation has facilitated efficient regulatory communications and supported the rapid advancement of the CLINCH-3 study. **Initiated in China with the first patient dosed and planned for expansion into a multi-regional clinical trial (MRCT), the CLINCH-3 study is intended to generate robust clinical evidence to support a future marketing approval application for ATG-**



022 as monotherapy for CLDN18.2+ advanced gastric or gastroesophageal junction adenocarcinoma.

The CLINCH-3 study is 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. The initiation of this pivotal study is supported by encouraging results from the Phase I/II CLINCH studies, which showed that ATG-022, as monotherapy, demonstrated a differentiated robust efficacy and well tolerated safety profile in patients with advanced gastric or gastroesophageal junction adenocarcinoma. As of June 26, 2026, among **patients with moderate to high CLDN18.2 expression (IHC 2+ $\geq$ 20%), in the 1.8 mg/kg dose cohort**, the recommended phase 2 dose (RP2D), the ORR was 46.7% (14/30) with confirmed ORR of 40% (12/30), the DCR was 86.7% (26/30), and the mOS had not yet been reached after a median follow-up of 14.03 months. **Among patients with low/ultra-low CLDN18.2 expression treated at the efficacious dose range of 1.8-2.4 mg/kg**, the ORR was 28.6% (6/21) and the DCR was 52.4% (11/21). In addition, multiple patients achieved complete responses (CR). **In terms of safety**, compared with the data

cutoff of December 25, 2025, the incidence of Grade ≥ 3 treatment-related adverse events (TRAEs) in the 1.8 mg/kg dose cohort increased slightly from 19.4% to 21.0%, with only 9.7% of patients experiencing dose reduction due to TRAEs. Despite more than six additional months of treatment exposure and follow-up, the incidence of Grade ≥ 3 TRAEs remained broadly stable in the 1.8 mg/kg dose cohort. 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.

“The dosing of the first patient in CLINCH-3 marks an important step in the clinical evaluation of ATG-022.” said **Professor Lin Shen of Peking University Cancer Hospital, principal investigator of the CLINCH-3 study.** “Patients with advanced gastric or gastroesophageal junction adenocarcinoma continue to face substantial unmet medical needs, particularly after disease progression on existing therapies. The antitumor efficacies and manageable safety profile observed in the Phase I/II study demonstrate therapeutic potential, supporting advancement of ATG-022 into the pivotal Phase III clinical study. CLINCH-3 will provide important evidence regarding whether ATG-022 can improve clinical outcomes for patients with CLDN18.2+ disease. We look



forward to conducting this study with scientific rigor and working closely with participating investigators and study centers.”

Antengene will continue to advance the three complementary clinical development pathways planned for ATG-022: **CLINCH-3 provides a near-term registration pathway** for ATG-022 monotherapy at the optimized RP2D 1.8 mg/kg dose in **3L+ gastric/GEJ cancer with CLDN18.2 IHC 2+ $\geq$ 20%**, establishing ATG-022 in gastric cancer. **CLINCH-2 is evaluating ATG-022 in 1L in combination with standard-of-care chemotherapy and anti-PD-1 therapy**, targeting the broadest CLDN18.2-positive population starting from **IHC 1+ $\geq$ 1%**, with the goal of supporting 1L registration and unlocking the full potential of ATG-022 in gastric cancer. Meanwhile, **the CLINCH basket trial is expanding ATG-022 beyond gastric cancer**, with encouraging efficacy already observed in multiple non-gastric CLDN18.2-positive solid tumors. 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 x PD-L1 bispecific ADC), ATG-207 (α CD3-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 diseases, 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; partnered with K2 Therapeutics established by MPM BioImpact), 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 35 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.