



Antengene Presents Latest ATG-022 Clinical Data at ESMO 2025 Demonstrating Efficacy Across All CLDN18.2 Expression Levels and Exceptional Tolerability

Shanghai and Hong Kong, PRC, October 20, 2025 — 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 hematologic malignancies and solid tumors, today announced that **the latest results from the ongoing Phase I/II CLINCH study of ATG-022 (CLDN18.2 antibody-drug conjugate [ADC]), were presented in a Poster Presentation at the European Society for Medical Oncology Congress 2025 (ESMO 2025) in Berlin, Germany.**

Details of the Poster Presentation:

ATG-022 (CLDN18.2 antibody-drug conjugate)

Title: Phase I/II study of Claudin 18.2 ADC ATG-022 in patients with advanced gastric/ gastroesophageal junction cancer (CLINCH)

Abstract Number: 2907

Presentation Number: 2113P

ATG-022 and CLINCH Study Overview

- ATG-022 is a CLDN18.2-targeted ADC with sub-nM affinity and fast internalization. Using a VC-MMAE linker-payload (DAR 4), ATG-022 has demonstrated potent activity across tumors with high, low, and ultra-low CLDN18.2 expression.
- The ongoing Phase I/II CLINCH study consists of dose escalation and dose expansion phases. In dose escalation, patients with advanced solid tumors regardless of CLDN18.2 expression receive ATG-022 once every three weeks



(0.3-3.0 mg/kg Q3W) to evaluate the safety, tolerability, and pharmacokinetics; CLDN18.2-positive ($\geq$ IHC 1+, 1%) patients are treated at 1.8 mg/kg or 2.4 mg/kg in dose expansion to evaluate the efficacy and safety.

- ATG-022 has been granted two Orphan Drug designations (ODDs) by the U.S. Food and Drug Administration (FDA) for the treatment of gastric cancer and pancreatic cancer, and in August 2025 obtained Breakthrough Therapy Designation from China's National Medical Products Administration (NMPA) for treating CLDN18.2-positive, HER-2 negative unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) who have received at least two prior lines of therapy.

Key Results from the CLINCH Study

- **Efficacy Data**
 - **Among GC/GEJC patients with moderate/high CLDN18.2 expression (IHC 2+ > 20%), the 2.4 mg/kg dose cohort** observed 1 complete response (CR), 11 partial responses (PRs) and 15 stable diseases (SDs), resulting in an objective response rate (ORR) of 40% (12/30) and a disease control rate (DCR) of 90% (27/30). The median progression-free survival (mPFS) was 6.97 months and the 12-month overall survival (OS) rate was 66.2%. **In the 1.8 mg/kg dose cohort**, there were 1 CR, 9 PRs, and 11 SDs, resulting in an ORR of 40% (10/25) and a DCR of 84% (21/25).
 - **Among GC/GEJC patients with low/ultra low CLDN18.2 expression (IHC 2+ $\leq$ 20%),** patients treated at the efficacious dose of 1.8-2.4 mg/kg achieved 1 CR and 5 PRs, resulting in an ORR of 33.3% (6/18) and a DCR of 50% (9/18). **The patient with CR has demonstrated durable response and has been on the study for over 22 months.**
 - To date, the study has observed three CRs, one from each of the three forementioned cohorts (two dose cohorts among CLDN18.2 mid/high



expressors and the cohort of low/ultra low CLDN18.2 expressors). **This broad-spectrum antitumor activity indicates ATG-022's potential as a new treatment option for a broader population of patients).**

- **Safety Data**

- At 2.4 mg/kg in the dose expansion, 45.8% of patients had ≥ 1 treatment-emergent adverse events (TEAEs), 60.4% of patients had grade ≥ 3 TEAEs. The most common grade ≥ 3 treatment-related adverse events (TRAEs, $\geq 5\%$ of patients) were neutrophil count decrease (16.7%), decreased appetite (14.6%) and anaemia (8.3%).
- In the dose-expansion phase, the **1.8 mg/kg** cohort demonstrated excellent safety and tolerability, with **only 13.6% of patients reporting serious TEAEs and 18.2% reporting Grade ≥ 3 TEAEs**. The favorable safety profile of this dose level support its potential use in first-line combination regimens with chemotherapy and immune checkpoint inhibitors.
- No ophthalmological toxicities or interstitial lung disease have been observed.

Conclusions and Outlook

- ATG-022 demonstrated a manageable safety profile and encouraging antitumor effects in GC/GEJC adenocarcinoma patients with a broad range of CLDN18.2 expressions, thus supporting further clinical investigation in patients with variable CLDN18.2 expressions. **In addition to GC/GEJC, preliminary efficacy has been observed in other non-GI tumor types which will be reported at upcoming conferences.**
- The 2.4 mg/kg cohort showed a favorable safety profile, while the 1.8 mg/kg cohort demonstrated even better safety and tolerability. These findings provide **strong support for advancing ATG-022 in combination with immune checkpoint inhibitors and chemotherapy in first-line**



treatment settings, paving the way to significantly expand its clinical reach and commercial potential.

- The Phase II dose expansion study of ATG-022 is going smoothly in China and Australia. In parallel, Antengene is actively preparing for combination therapy studies involving ATG-022 to further advance its clinical development.

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 and includes several in-house discovered programs, including ATG-022 (CLDN18.2 ADC), ATG-037 (oral CD73 inhibitor), ATG-101 (PD-L1 × 4-1BB bispecific antibody), ATG-031 (CD24-targeting macrophage activator), and ATG-042 (oral PRMT5-MTA inhibitor).

Antengene has also developed AnTenGager™, a proprietary T cell engager 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 indications.

To date, Antengene has obtained 31 investigational new drug (IND) approvals in the U.S. and Asia, and submitted new drug applications (NDAs) in 11 Asia Pacific markets. Its lead commercial asset, XPOVIO® (selinexor), is approved in 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, 2024, and the documents subsequently submitted to the Hong Kong Stock Exchange.