Antengene Announces IND Approval in China for Phase Ib/II Study of ATG-022 (CLDN18.2 ADC) in Combination with KEYTRUDA® (Pembrolizumab) ± Chemotherapy

Shanghai and Hong Kong, PRC, December 2, 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 autoimmune disease, solid tumors and hematological malignancies indications, today announced that the **China National Medical Products Administration (NMPA) has approved the investigational new drug (IND) application for the Phase Ib/II CLINCH-2 study evaluating ATG-022 (CLDN18.2 antibody-drug conjugate [ADC]) in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), as well as ATG-022 in combination with pembrolizumab and chemotherapy**.

CLINCH-2 is a Phase Ib/II study that will be led by its principal investigator Prof. Lin Shen at Beijing Cancer Hospital, the lead

trial center. The study is designed to evaluate two combination regimens in patients with CLDN18.2-positive, HER2-negative, and PD-L1-positive (CPS≥1) unresectable or metastatic **gastric cancer or gastroesophageal junction adenocarcinoma (GC/GEJC)**: ATG-022 in combination with pembrolizumab (A+P); and ATG-022 in combination with pembrolizumab plus the CAPOX chemotherapy regimen (A+P+C). The primary objective of the study is to assess the safety and tolerability of the two combination regimens, while the secondary objectives include evaluating the regimens' preliminary antitumor activity, assessing ATG-022's immunogenicity, and characterizing its pharmacokinetic (PK) profile.

Antengene released updated clinical data from the Phase I/II CLINCH study of ATG-022 monotherapy in patients with advanced GC/GEJC at the European Society for Medical Oncology Congress 2025 (ESMO 2025). For details of the dataset, please refer to the press release published on October 20, 2025 (https://www.antengene.com/newsinfo/449). The results demonstrated clear differentiation for ATG-022 in both safety and efficacy. **In the 1.8 mg/kg dose cohort, the incidence of grade 3 or**

higher treatment-related adverse events was only 18.2%. Moreover, the study did not observe any ocular toxicity or interstitial lung disease, and the incidence of peripheral neuropathy reported in the study was relatively low. The efficacious doses (1.8mg/kg and 2.4mg/kg) have both demonstrated an objective response rate (ORR) of 40%. This is **a strong validation of ATG-022's potential in combination with pembrolizumab and chemotherapy in the frontline setting.** In addition, **antitumor activity was observed across high, medium, and low CLDN18.2 expression levels, supporting the use of IHC 1+ ≥1% as the enrollment threshold for frontline combination therapy, indicating potential applicability to a much broader patient population compared to other CLDN18.2-targeting therapies.** Furthermore, in the basket cohort of other CLDN18.2+ tumor types, efficacy was observed in a gynecologic tumor subtype, providing early proof of concept for **potential expansion into tumor types beyond gastric cancer.**

Antengene will continue to advance both the ongoing CLINCH study and the newly approved CLINCH-2 study, with plans to share

updated results at upcoming medical conferences to further demonstrate the clinical potential of ATG-022.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About ATG-022

ATG-022 is a CLDN18.2-targeted antibody-drug conjugate (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.

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 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.

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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.

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To date, Antengene has obtained 32 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.

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