Antengene's ATG-022 (CLDN18.2 ADC) Granted Breakthrough Therapy Designation for the Treatment of Gastric/Gastroesophageal Junction Adenocarcinoma

Shanghai and Hong Kong, PRC, August 19, 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 **its in-house discovered CLDN18.2 ADC, ATG-022,was granted a Breakthrough Therapy designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) for the treatment of CLDN18.2-positive, HER-2 negative unresectable or metastatic gastric or gastroesophageal junction (GC/GEJ) in patients who have received at least two prior lines of therapy.**

To provide further details on the latest clinical data of ATG-022, Antengene's management team will host a conference call on

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August 20, 2025 (Wednesday), from 9:00 am to 10:00 am (Beijing Time).

Ways to Participate:

1. Webcast: https://s.comein.cn/5hgdc8k2

2. Conference Call:

(Dial-in From China)

Mainland of China: +86-4001510269

Global: +86-01021377168

(Dial-in From Overseas)

Hong Kong, China: +852-51089680

Hong Kong, China: +852-800931266

Taiwan, China: +886-277083288

Global: +86-01021377168

United States: +1-2087016888

Access Code: 303021

Management Participants:

Dr. Jay Mei	Founder, Chairman, and CEO
Mr. Donald Lung	Chief Financial Officer
Mr. Kavin Cao	Corporate Vice President and Board Secretary

Dr. Bing Hou	Vice President, Head of Discovery Science and Translational Medicine
Dr. Godfrey Guo	Vice President, Clinical Development

The Breakthrough Therapy designation, introduced by the NMPA, is a key initiative aimed at accelerating the development and approval of innovative medicines that offer significant clinical benefits. **With this designation, ATG-022 will receive priority review resources, reducing the overall research and development timeline and enabling faster access for patients in China.** This follows the U.S. Food and Drug Administration's (FDA) granting of Orphan Drug Designation (ODD) to ATG-022 for the treatment of gastric and pancreatic cancers, highlighting its strong clinical potential across multiple tumor types.

In the ongoing CLINCH Phase I/II clinical study, data show that **ATG-022 demonstrated significant antitumor activity and a favorable safety profile in patients with gastric or gastroesophageal junction adenocarcinoma across high, low, and ultra-low CLDN18.2 expression levels.**

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- **CLDN18.2 Moderate-to-high expression (IHC 2+ > 20%)**
  - **2.4 mg/kg Cohort**
    - Objective Response Rate (ORR): 40% (12/30), including 1 Complete Response (CR)
    - Disease Control Rate (DCR): 90% (27/30)
    - Median Progression-free Survival (mPFS): 6.97 months
    - 6-month PFS Rate: 51.1%
    - 9-month Overall Survival (OS) Rate: 82.7%
    - 12-month OS Rate: 66.2%
  - **1.8 mg/kg Cohort**
    - ORR: 40% (10/25), including 1 CR
    - DCR: 84% (21/25)
- **CLDN18.2 Low and Ultra-low expression (IHC 2+ ≤ 20%)**
  - **Efficacious dose range of 1.8-2.4 mg/kg**
    - ORR: 33.3% (6/18), including 1 CR
    - DCR: 50% (9/18)
    - Notably, some responding patients had CLDN18.2 expression levels below 5%, underscoring the robust antitumor activity of ATG-022 in both low- and ultra-low-expression populations.

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To date, three patients in the study have achieved CR during treatment, with one case observed in each of the three aforementioned cohorts (i.e., both dose levels in the CLDN18.2 moderate-to-high expressor cohorts and the CLDN18.2 low and ultra-low expressor cohort). **This broad-spectrum antitumor activity positions ATG-022 as a potential new treatment option for a wider patient population compared with other CLDN18.2-targeted therapies.**

Antengene is currently conducting the Phase II dose-expansion stage of ATG-022 in the Mainland of China and Australia, with the program now entering mid-to-late stage of clinical validation. The company will continue to advance the clinical development of ATG-022 in gastric cancer while exploring its potential in other CLDN18.2-positive tumors. For gastric cancer indications, the development strategy spans first- through third-line treatment:

- **First-line treatment (CLDN18.2 IHC 1+ ≥1%, PD-L1 CPS ≥1%):** ATG-022 in combination with pembrolizumab and chemotherapy (CAPOX/FOLFOX)

- **Second-line treatment (CLDN18.2 IHC 1+ ≥1%, PD-L1 CPS ≥1%):** ATG-022 in combination with pembrolizumab
- **Third-line treatment (CLDN18.2 IHC 2+):** ATG-022 monotherapy, covering patients across different CLDN18.2 expression levels, including CLDN18.2 moderate-to-high expressor (2+ >20%), and low and ultra-low expressors (2+ ≤ 20%)

In addition, the ongoing Phase II study includes a basket trial cohort covering multiple tumor types. In a certain subtype of gynecologic tumor, all 7 patients who had undergone at least one efficacy assessment demonstrated tumor shrinkage, indicating significant clinical potential for ATG-022 in other CLDN18.2-positive tumors. This cohort remains open for enrollment and follow-up, and the continued data generation is expected to further strengthen the robust value proposition of ATG-022 across multiple tumor types.

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 the Mainland of China, Taiwan China, Hong Kong China, Macau China, South Korea, Singapore, Malaysia, Thailand, Indonesia 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, 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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