



## **Antengene Announces 2024 Interim Financial Results, Highlights Progress in R&D and Commercialization**

Antengene Corporation (6996.HK) today announced its interim results for the period ending June 30, 2024, along with several significant milestones achieved in recent months.

**Dr. Jay Mei, Antengene's Founder, Chairman, and CEO**, stated, "In the first half of 2024, the company has made significant progress in both R&D and commercialization. Our four global rights assets — ATG-022 (Claudin 18.2 ADC), ATG-037 (CD73 small molecule), ATG-101 (PD-L1/4-1BB bispecific antibody), and ATG-031 (CD24 monoclonal antibody) have all advanced steadily as planned. Among them, ATG-022, currently in Phase II dose expansion stage, **has demonstrated efficacy not only in gastric cancer patients with moderate-to-high Claudin 18.2 expression but also in those with low and ultra-low expression levels.** This unprecedented data reinforces our belief that ATG-022 is poised to become a globally best-in-class molecule targeting Claudin 18.2. While we remain focused on building a differentiated and innovative pipeline, the company has also established a robust self-sustaining revenue-

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](http://www.antengene.com)



generating capability. **XPOVIO® has achieved three significant milestones within the past six months, including a supplementary new drug approval (NDA) for diffuse large B-cell lymphoma (DLBCL) in the Mainland of China, National Health Insurance Service Approval for Reimbursement in South Korea, and NDA approvals for multiple myeloma (MM) in Malaysia.** To date, XPOVIO® has been approved for marketing in eight countries and regions across the Asia-Pacific markets and included in the national health insurance of four of these markets, generating product revenue of RMB 60.8 million in the first half of 2024."

**Dr. Mei continued,** "Antengene's innovative R&D capabilities, strategic approach to drug discovery and development, and rigorous cost-efficiency measures ensure the company is well positioned for sustained operations and growth in the coming years. With a cash and bank balance of RMB 1.024 billion, we have sufficient runway to provide strong support to the continuous growth, development, and operations of Antengene. We look forward to sharing more of our progress in the second half of 2024, with a key highlight being the latest research results of ATG-037, which will be presented in a mini oral presentation at the ESMO Annual Meeting on September 16."

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## 1、Global Rights Assets with Advancing Steadily at Clinical Stage

### **ATG-022 (Claudin 18.2 Antibody-Drug Conjugate, ADC): Currently at Phase II Dose Expansion Stage, Effectively Targeting Gastric Cancer with both High and Ultra-low Claudin 18.2 (CLDN18.2) Expression**

- ATG-022 is a highly differentiated asset demonstrating activity across a wide range of CLDN18.2 expression levels, including both high and low/ultra-low expression level. ATG-022 has received two Orphan Drug Designations (ODD) from the U.S. Food and Drug Administration (FDA) for the treatment of gastric cancer and pancreatic cancer.
- The Phase I CLINCH dose escalation study was completed earlier this year, 2.4 mg/kg was selected as the recommended Phase II dose (RP2D). ATG-022 has now progressed to the Phase II monotherapy dose expansion stage.
- As of Aug 21<sup>st</sup> 2024, Data from the on-going Phase II CLINCH dose expansion study, shows that 21 CLDN18.2 positive gastric cancer patients have been treated with ATG-022. Among the 12 patients who at least underwent their first tumor assessment after study treatment, 5 achieved partial response (PR), resulting in an overall response rate (ORR) of 41.7% (including one patient with ultra-low CLDN18.2

expression), and a disease control rate (DCR) of 100%. The Phase II CLINCH study is currently progressing smoothly in China and Australia.

### **ATG-037 (CD73 Small Molecule Inhibitor): Demonstrated Potential in Reversing Resistance to anti-PD-1 Therapies during Dose Escalation**

- Inhibiting CD73 is intended to stop the production of adenosine, a key immunosuppressive molecule in the tumor microenvironment. As a small molecule inhibitor of CD73, ATG-037 has demonstrated pre-clinically the ability to overcome the “hook effect” that can limit efficacy and is commonly seen in anti-CD73 antibodies. Antengene entered into a global clinical collaboration with MSD and is currently evaluating this molecule in combination with the anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with locally advanced or metastatic solid tumors.
- ATG-037 demonstrated an excellent safety profile during the dose escalation stage. Notably, four partial responses in patients previously treated with a checkpoint inhibitor were observed — two in melanoma patients and two in non-small cell lung cancer patients. With the Phase I dose escalation now complete, the company plans

to initiate the Phase II dose-expansion of the STAMINA study in China and Australia in the third quarter of 2024.

**ATG-101 (PD-L1/4-1BB Bispecific Antibody): Durable Responses and Preliminary Efficacy in “Cold Tumors” Observed at Low Doses Without Off-target Liver Toxicity**

- ATG-101’s differentiated approach to targeting PD-L1 resistant cancers incorporates the conditional activation of the T-cell co-stimulatory receptor 4-1BB. The bispecific antibody utilizes high PD-L1 affinity and conditional 4-1BB activation, to reduce the risk of hepatotoxicity.
- ATG-101 is currently undergoing dose-escalation studies in the US, the Mainland of China, and Australia. The treatment has demonstrated excellent tolerability, with no significant liver toxicity observed to date. Encouragingly, durable stable disease has been observed even at low dose levels, as along with a partial response in a patient with microsatellite stable (MSS) colorectal cancer. The Phase I dose escalation phase is on track for completion by the first half of 2025.



## **ATG-031 (Anti-CD24 Monoclonal Antibody): First-in-Class Macrophage**

### **Activator Targeting CD24**

- ATG-031 is the first-in-class humanized anti-CD24 monoclonal antibody to enter clinical trials for cancer in the U.S. ATG-031 works by blocking CD24-Siglec10 and enhancing macrophage-mediated phagocytosis of cancer cells. Key study sites of ATG-031 include four renowned cancer centers in the United States: MD Anderson Cancer Center at the University of Texas, University of California, San Francisco (UCSF), University of Colorado, and Yale Cancer Center.
- In the Phase I PERFORM study, 19 late-stage cancer patients have been treated with early low doses in the dose escalation segment, with no dose-limiting toxicities (DLTs) observed. Observations include stable disease (SD), objective tumor shrinkage, and clinical improvements among enrolled patients. The company targets a Phase I data readout in the first half of 2025.

### **Promising Pre-clinical Programs:**

- Antengene is committed to advancing its proprietary "2+1" T-cell engager platform, AnTenGager™. T cell engagers developed from this platform are designed to induce disease-associated antigen

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(DAA)-dependent T-cell binding and activation, delivering strong therapeutic activity while minimizing the risk of cytokine release syndrome (CRS).

- The development of preclinical candidates, including ATG-042, a selective PRMT5 inhibitor targeting MTAP-null tumors, and ATG-201, a CD19 x CD3 T-cell engager, is ongoing.

## **2、 Expanding APAC Presence with Inclusion in Multiple National Health Insurance Programs**

- In June 2024, South Korea's National Health Insurance Service (NHIS) has approved the reimbursement of XPOVIO<sup>®</sup>, effective from July 1, 2024. This marks the fourth Asia-Pacific market, following the Mainland of China, Australia, and Singapore, where the company has secured reimbursement/insurance coverage for XPOVIO<sup>®</sup>. The company is actively working to secure health insurance inclusion for XPOVIO<sup>®</sup> in more Asia-Pacific markets.
- In July 2024, XPOVIO<sup>®</sup> received approval for a new indication in the Mainland of China, offering a new treatment option for patients with DLBCL. This is the second indication approved for XPOVIO<sup>®</sup> in the



Mainland of China, following its approval for relapsed/refractory multiple myeloma (R/R MM).

- In August 2024, XPOVIO® was officially approved for marketing in Malaysia. To date, XPOVIO® has received multiple new drug approvals across eight countries and regions in the Asia-Pacific market (the Mainland of China, Taiwan, Hong Kong, Macau, Australia, South Korea, Malaysia, and Singapore). The company has also submitted NDA for XPOVIO® in other ASEAN markets such as Thailand and Indonesia, with approvals expected later this year.
- Since being included in the National Reimbursement Drug List (NRDL) in December 2023, XPOVIO® has shown impressive revenue performance in the first half of 2024. As of June 30, 2024, XPOVIO® sales revenue has reached RMB 60.8 million.

### **3、Strong Cash and Bank Balance to Support Strategic Objectives**

As of June 30, 2024, the company held RMB 1.024 billion in cash and bank balance. The steady growth in revenue, strong cash and bank balance coupled with careful spending, will provide strong support to the continuous growth, development, and operations of Antengene.

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For more details on the 2024 interim financial results, please refer to the full announcement available in the "Investor Relations" section of the company's official website.

## **About Antengene**

Antengene Corporation Limited ( “Antengene” , SEHK: 6996.HK) is a leading commercial-stage R&D-driven global biopharmaceutical company focused on the discovery, development, manufacturing and commercialization of innovative first-in-class/best-in-class therapeutics for the treatment of hematologic malignancies and solid tumors, in realizing its vision of “Treating Patients Beyond Borders” .

Since 2017, Antengene has built a pipeline of 9 oncology assets at various stages going from clinical to commercial, including 6 with global rights, and 3 with rights for the APAC region. To date, Antengene has obtained 29 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 10 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in Mainland of China, Taiwan China, Hong Kong China, Macau China, South Korea, Singapore, Malaysia and Australia.

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## **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, 2023, and the documents subsequently submitted to the Hong Kong Stock Exchange.