



## **Antengene Announces Full Year 2023 Financial Results, Highlights Clinical Progress Across First-in-Class, Best-in- Class Pipeline**

- Promising clinical activities and efficacies during dose escalations for four lead global rights programs targeting CD24, Claudin 18.2, CD73, and PD-L1/4-1BB
- Positive, differentiated cervical cancer data advancing mTORC1/2 inhibitor on registrational track for APAC markets
- RMB1.188 billion cash expected to support planned operations

Shanghai and Hong Kong, PRC, March 22, 2024 — Antengene Corporation Limited ( **“Antengene”** , SEHK: 6996.HK), a leading innovative, commercial-stage global biopharmaceutical company dedicated to discovering, developing and commercializing first-in-class and/or best-in-class medicines for cancer, today announced its **full year results for the period ended December 31, 2023, and provided an update on the impressive progress of its clinical development pipeline over the last several months.**

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“2023 has been a breakout year for Antengene, with excellent pipeline momentum across multiple first/best-in-class programs marked by **encouraging clinical activities and efficacies during dose escalations for our four lead global-rights programs, namely ATG-031, ATG-022, ATG-037, and ATG-101** which are designed to target CD24, Claudin 18.2, CD73, and PD-L1/4-1BB. With respect to our APAC-rights programs, our **second generation mTORC1/2 inhibitor ATG-008** has made steady progress towards registrational path for the indication of cervical cancer, complemented by the inclusion of XPOVIO® in **the 2023 China National Reimbursement Drug List**. Furthermore, we have entered into a partnership with Hansoh Pharma, a leading Chinese pharmaceutical company, for the commercialization of XPOVIO® in the Mainland of China,” said **Dr. Jay Mei, Antengene’s Founder, Chairman and CEO**. “Looking into 2024 and beyond, we are confident that our four lead global rights programs will continue to deliver encouraging results and emerge as category leaders. Our current cash balance totaling RMB1.188 billion is expected to fund planned operations and product development. We look forward to report on our progress throughout the year, starting with **the presentation of several abstracts at the American Association for Cancer Research Annual Meeting (AACR 2024).**”

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## 1. Momentous clinical development across four lead global-rights programs

- **ATG-031 (anti-CD24 monoclonal antibody): Promising Activity at Starting Doses:** ATG-031 is the first-in-class humanized anti-CD24 monoclonal antibody to enter the clinic for cancer in the U.S. ATG-031 acts by inhibiting the “don’t eat me” signal while stimulating the “eat me” signal and enhances macrophage-mediated phagocytosis of cancer cells.
  - **Phase I “PERFORM” study:** To date, a total of 5 late-stage cancer patients have been treated with ATG-031 in the Phase I dose escalation study. To date, no dose-limiting toxicities (DLTs) have been observed among the 5 patients. Tumor shrinkage based on CT scan was observed in one heavily pre-treated patient (7 prior lines of therapy). Key study sites include four major U.S. cancer centers: The University of Texas MD Anderson Cancer Center, the University of California San Francisco, the University of Colorado, and Yale University Cancer Center.
  - **Next ATG-031 Milestone:** Completion of the dose escalation portion of the Phase I “PERFORM” Study in H1 2025.

- **ATG-022 (Claudin 18.2 antibody-drug conjugate, “ADC” ):**

**Potential to Target Claudin 18.2 Low Expressors:** ATG-022 is differentiated by its potential ability to be active across a range of Claudin 18.2 expression levels, including in low expressors. Antengene has also developed a companion diagnostic assay to support the clinical program. The ADC has been awarded two Orphan Drug Designations (ODD) by the U.S. Food and Drug Administration (FDA) for treatment of gastric and pancreatic cancers.

  - **Phase I “CLINCH” study:** To date, 7 gastric cancer patients (without pre-screening patients’ Claudin 18.2 expression levels) have been treated with ATG-022. Antengene has observed one complete response (CR) and one partial response (PR) in 2 patients with metastatic gastric cancer. In the 2.4 mg/kg dose cohort, one patient with extremely low expression of Claudin 18.2 achieved CR, while one patient from the 1.8 mg/kg dose cohort achieved PR. The study has already completed the dose escalation portion and initiated the dose expansion portion.

- **Next ATG-022 Milestone:** Clinical data readout of Phase I “CLINCH trial” , including preliminary efficacy and safety in H2 2024.
  
- **ATG-037 (CD73 small molecule inhibitor): Early Combination Activity Shown Potential in Reversing Prior PD-1 Resistance:**

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.
  
- **Phase I “STAMINA” study:** In the dose escalation segment of ATG-037 combined with pembrolizumab, Antengene has observed PRs in two patients with melanoma and one patient with non-small cell lung cancer (NSCLC), all of whom were refractory to prior treatment with checkpoint inhibitors (CPIs). To

date, 23 patients have been enrolled and received a first tumor assessment.

- **Next ATG-037 Milestone:** Completion of Phase I dose escalation and proceed to dose expansion in H1 2024.
  
- **ATG-101 (PD-L1/4-1BB bispecific antibody): Durable Responses at Low Doses with No Off-Target Hepatotoxicity Observed and Efficacy in Cold Tumors:** ATG-101's differentiated approach to targeting PD-L1 resistant cancers incorporates 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.
  - **Phase I "PROBE" study:** Antengene has observed a PR in a patient with metastatic colon adenocarcinoma (microsatellite stability biomarker [MSS], liver metastasis, and three prior lines of therapy). In addition, SD has been observed in two patients for longer than 1 year.
  - **Next ATG-101 Milestone:** Completion of Phase I dose escalation and proceed to dose expansion in H1 2025.

- **Progressing Early programs:** Antengene continues to advance IND candidate, **ATG-042 (MTAP<sup>null</sup>-selective PRMT5 Inhibitor)**, and the proprietary **AnTenGager™ “2+1”** T cell engager platform.

## 2. Steadily progressing mid/late-stage clinical programs continue to demonstrate clinical potentials

- **ATG-008 (mTORC1/2 small molecule inhibitor): Positive, Robust Cervical Cancer Data** -The mTOR complex regulates different cellular processes and is upregulated in multiple tumors. mTORC1 and mTORC2 have to be inhibited simultaneously to maximize efficacy and minimize the development of resistance. ATG-008 was designed to inhibit both.
  - **Phase II “TORCH-2” study:** ATG-008 has demonstrated positive Phase II results in cervical cancer that position the program to have a competitive profile compared to other agents approved across different global markets. The Phase II "TORCH-2" study is currently enrolling both checkpoint inhibitor (CPI)-naïve and CPI-pre-treated patients. Based on the latest data review as of March 14<sup>th</sup>, 2024, out of the 31 CPI-naïve patients who received treatment (30 had at least one tumor assessment),

the objective response rate (ORR) was observed to be 53.3%, the disease control rate (DCR) was 86.7%. Among the 30 patients with prior CPI treatment (26 patients had at least one tumor assessment), the ORR was 23.1%, with a DCR of 84.6%.

- **Next ATG-008 Milestone:** Confirm registrational pathway in cervical cancer with health authorities.

### **3. Solidifying presence in APAC markets through accelerating commercialization**

- Antengene and Hansoh Pharma entered into a collaboration for the commercialization of XPOVIO® in the Mainland of China in August 2023.
- XPOVIO® has been added to the NRDL (2023 Version) as announced on December 14<sup>th</sup>, 2023. The updated NRDL, taking effect on January 1<sup>st</sup>, 2024, will significantly improve the accessibility of XPOVIO® in Mainland of China.
- As of December 2023, Antengene has successfully secured XPOVIO® regulatory approvals in seven markets: Mainland of China, Taiwan China, Hong Kong China, Macau China, Australia, South Korea, and Singapore. National reimbursement has been secured in 3 markets:

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Mainland of China (NRDL), Australia (Pharmaceutical Benefits Scheme), and Singapore (Cancer Drug List). In June 2023, the coverage of XPOVIO® by the Australian Pharmaceutical Benefits Scheme (PBS) was extended from Xd to include both XVd and Xd regimens.

#### **4. Strong cash and bank balance enabling continuous growth**

As of December 31, 2023, the company's cash resources of about RMB1.188 billion, coupled with careful spending, will provide strong support to the continuous growth, development, and operations of Antengene.

To learn more about the annual financial results of 2023, please see the full announcement on the “Investor Relations” section of the 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

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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 11 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 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

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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.

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