



Antengene Announces Interim Financial Results for 2023 with New Clinical Data Highlighting the Growing Value of Its Pipeline

Shanghai and Hong Kong, PRC, August 25, 2023 — Antengene Corporation Limited (“**Antengene**” SEHK: 6996.HK), today announced **its interim results for the six-months ended June 30, 2023, and provided updates on multiple milestones achieved since the beginning of 2023.**

Dr. Jay Mei, Antengene’s Founder, Chairman and CEO, said, “In the first half of this year, Antengene has **achieved significant progress across its clinical programs**. We are very encouraged that the **mTORC1/2 inhibitor ATG-008**, a drug candidate in late-stage clinical development, continues to show impressive and robust therapeutic potential in patients with cervical cancer with expanded patient enrollment. Meanwhile, we have made **big strides with our global rights assets**, particularly **ATG-022 (Claudin 18.2 antibody-drug conjugate)** and **ATG-101 (PD-L1/4-1BB bispecific antibody)**, two clinical stage global rights programs in dose escalation studies that have **already reported partial responses (PRs) at clinical centers at low dose levels**. Furthermore, ATG-031, one of our in-

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house developed programs, has been cleared by the US FDA to enter a clinical study, thus becoming **the world's first CD24 monoclonal antibody entering clinical development in oncology**. We look forward to releasing more clinical data as we progress into the next few months. While making rapid advances in clinical development, **we entered into a landmark partnership with Hansoh Pharma**, one of the largest pharmaceutical companies in China. We are confident that this partnership will further expand the commercial reach of XPOVIO® in China and boost the opportunities for the drug upon additional NRDL listings and indication expansions. During the same period, we delivered on **multiple commercial milestones for XPOVIO® in our APAC markets**, namely the recent regulatory approval for the drug in **Hong Kong China**, NDA submission in **Indonesia**, expanded insurance coverage by **the Australian Pharmaceutical Benefits Scheme (PBS)** for the two XPOVIO® regimens, and inclusion into the **Cancer Drug List in Singapore**.” **Dr. Mei continued**, “With the rapid progress in our differentiated clinical portfolio, positive early results from multiple trials, momentous growth trajectory for XPOVIO®, and a solid cash position, we are well positioned to maintain steady progress in our global R&D pipeline and deliver on our

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mission of bringing more transformative medicines to cancer patients around the world.”

1. Excellent progress in first/best-in-class global rights clinical programs with clinical readouts beginning this fall

Antengene has built an expansive pipeline of oncology drugs at various stages going from clinical to commercial. This pipeline comprises 6 global rights assets and 3 assets with rights for the APAC region.

- **ATG-022 (Claudin 18.2 antibody-drug conjugate)**, with activity across a range of Claudin 18.2 expression levels, advanced to Phase I in Australia and the Mainland of China, and granted two Orphan Drug Designations (ODD) consecutively by the U.S. Food and Drug Administration (FDA) for treatment of gastric and pancreatic cancers. The drug is currently enrolling patients in the dose escalation phase, and a PR has already been reported by the clinical center earlier than the projected efficacious dose range.
- **ATG-031 (anti-CD24 monoclonal antibody)**, a potential first-in-class program to target the “don’t eat me” pathways, has successfully achieved US IND clearance for its Phase I trial. Our preclinical data suggest that CD24 is a target not expressed on

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human red blood cells, meaning that it will unlikely cause anemia issues commonly seen in molecules targeting CD47. Moreover, CD24 has higher tumor expression compared to CD47, making it a differentiated, high-potential approach to this exciting macrophage-regulating pathway. Antengene has selected multiple centers across the US for this clinical trial, with the MD Anderson Cancer Center in Houston, TX as the leading clinical site which is currently in active preparation for initiation. As part of the site initiation process, the Scientific Review Committee of MD Anderson Cancer Center has granted approval, putting us on a solid track to initiate enrollment in the fourth quarter of this year.

- **ATG-101 (PD-L1/4-1BB bispecific antibody)** has been designed to target PD-1/PD-L1 resistant cancers, supported by conditional 4-1BB activation of an enhanced T-cell response. The program is currently in dose escalation cohorts in its study spanning the Mainland of China, Australia, and the United States. The study is approaching the biologically active dose with good tolerability, and has already reported PR and durable stable diseases (SDs) in patients treated at low doses levels. Notably, from low dose level,

SD has been observed in the longest-treated patient who had been on the drug for over a year.

- **ATG-037 (CD73 inhibitor)**, which shows preclinical activity in the CD73 pathway without a hook effect, is advancing through a dose escalation study. Patients are being enrolled at both Australian and Chinese sites. The trial was designed to include a dose escalation study of ATG-037 monotherapy and in combination with pembrolizumab, to assess the potential for additional clinical benefits. At present, a total of 13 patients have started the combination treatment.
- **ATG-017 (ERK1/2 inhibitor)**, a small molecular kinase inhibitor, has reached RP2D for monotherapy and successfully progressed to a combination dose expansion study, in conjunction with nivolumab, in the US and Australia.
- **ATG-018 (ATR inhibitor)**, a unique small molecule inhibitor, is making smooth progress through its dose escalation phase. 7 patients are with stable disease out of 12 efficacy evaluable patients at low dose levels.
- **AACR posters** highlighted preclinical proof-of-concept data for three clinical programs: ATG-031 (anti-CD24 monoclonal antibody),



ATG-017 (ERK1/2 inhibitor), ATG-037 (CD73 inhibitor) and a new research program: an LILRB4 antagonist antibody, ATG-034.

2. Encouraging clinical results for mid-to-late-stage APAC programs

- **ATG-008 (mTORC1/2 inhibitor) unique, differentiated results in cervical cancer** - The Phase II "TORCH-2" study is currently enrolling both checkpoint inhibitor (CPI)-naïve and CPI-pre-treated cervical cancer patients. Based on the latest data review as of August 23rd, 2023, out of the 31 CPI-naïve patients who received treatment (and 28 who had at least one tumor assessment), the objective response rate (ORR) was observed to be 46.4%. Among the 17 patients with prior CPI treatment (and 15 patients who had at least one tumor assessment), the ORR was observed to be 26.7%. Updated clinical data will be presented in the Antengene Annual R&D Day in November.
- **Selinexor (XPO1 inhibitor) expansion opportunities in Myelofibrosis and endometrial cancer** - These clinical data demonstrate the deep and broad expansion potential of selinexor beyond the initial indications of multiple myeloma and diffuse large B-cell lymphoma.

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- **Myelofibrosis:** Results from the “XPORT-MF-034” study evaluating selinexor in combination with ruxolitinib in treating treatment-naïve myelofibrosis patients show that 91.7% of efficacy evaluable patients and 78.6% of intent-to-treat (ITT) patients achieved a 35% or greater spleen volume reduction (SVR35) at week 24. Moreover, 77.8% of efficacy evaluable patients and 58.3% ITT patients achieved a 50% or greater reduction of their total symptom score (TSS50) at week 24. As a co-sponsor of the global registrational Phase III trial, Antengene will participate in the planning and conduction of the trial in the Mainland of China.
- **Endometrial Cancer:** Updated exploratory subgroup analyses from the Phase III “SIENDO” study of selinexor as a maintenance therapy in patients with advanced or recurrent endometrial cancer showed a median progression free survival (PFS) of 27.4 months among TP53 wild-type endometrial cancer patients who were treated with selinexor as a maintenance therapy, compared to 5.2 months in the placebo cohort. Karyopharm is currently conducting the “XPORT-EC-042” study, a registrational Phase III trial in the US for indication

expansion into the maintenance setting for endometrial cancer.

Topline data are expected in late 2024-2025. A U.S. approval could open the door to registration in Antengene's territories.

3. Fast-Growing Pan-APAC commercialization of XPOVIO® spotlighting the new partnership with Chinese pharmaceutical company Hansoh Pharma for the commercialization of XPOVIO® in the Mainland of China

- In the first six months of 2023, XPOVIO® obtained a New Drug Application (NDA) approval in **Hong Kong China**, achieved expansion in the insurance coverage by the **Australian Pharmaceutical Benefits Scheme (PBS)** to the XVd regimen, beyond the initially included Xd regimen, and was included into **the Cancer Drug List in Singapore**. Moreover, Antengene has completed an NDA submission for XPOVIO® in **Indonesia**. Antengene plans to submit a supplementary NDA (sNDA) for XPOVIO® for the treatment of relapsed/refractory diffuse large B-cell lymphoma in China in 2H 2023.
- The exclusive partnership with Hansoh Pharma for the commercialization of XPOVIO® in the Mainland of China positions

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Antengene to achieve greater national coverage across a larger number of cities, hospitals, prescribers, and maximizes the opportunity for future National Reimbursement Drug List (NRDL) inclusions.

- Deal terms include upfront payment of up to RMB200 million and future milestone payments of up to RMB535 million. Antengene will continue to record revenues from sales of XPOVIO® in the Mainland of China and Hansoh Pharma will charge a service fee to Antengene.

4. A Strong Cash and Bank Balance to Provide Runway Beyond 2025

- As of June 30th, 2023, the company has a cash and bank balance of RMB1.32 billion. This strong cash and bank balance together with careful spending enables the continuous growth, development, and operation of Antengene beyond 2025.

Antengene plans to release the updated data across its clinical portfolio at the annual R&D Day in November 2023.

To learn more about the interim financial results of 2023, please see the full announcement at:

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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, South Korea, Singapore 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, 2022, and the documents subsequently submitted to the Hong Kong Stock Exchange.