Antengene to Present Latest Clinical Results from Two Studies in CPI-resistant Solid Tumors at ASCO 2025

- ATG-037, an oral small molecule CD73 inhibitor, in combination with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), achieved an overall response rate (ORR) of 36.4% and disease control rate (DCR) of 100% in checkpoint inhibitor (CPI)-resistant melanoma patients in the ongoing STAMINA-01 trial, with one patient maintaining a partial response (PR) and remained on treatment for over 2 years without any safety concerns.

- In CPI-resistant non-small cell lung cancer (NSCLC), the combination of ATG-037 and pembrolizumab achieved an ORR of 22% and DCR of 67% in the same study.

- ATG-008, an oral dual mTORC1/2 inhibitor, in combination with toripalimab, achieved an ORR of 22.2% and DCR of 85.2% in CPI-resistant cervical cancer patients in the ongoing TORCH-2 trial.

Shanghai and Hong Kong, PRC, May 23, 2025 — 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 hematologic malignancies and solid tumors,

today announced that **it will present the latest clinical data of its CD73 oral small molecule inhibitor ATG-037 and oral dual mTORC1/2 inhibitor ATG-008 in Poster Presentations at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from May 30th to June 3rd in Chicago, IL, the United States.**

Details of the Poster Presentations:

ATG-037 (CD73 Small Molecule Inhibitor)

Title: A First-In-Human Phase I/Ib study of ATG-037 Monotherapy and Combination Therapy with Pembrolizumab in Patients with Advanced Solid Tumors - STAMINA-01

Abstract: 3123

Session: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology

Date: June 2, 2025

Time: 1:30 PM - 4:30 PM (Central Time)

2:30 AM - 5:30 AM, June 3, 2025 (Beijing Time)

- **Robust clinical benefit observed in CPI-resistant patients:** As of April 27, 2025, the study has already completed the dose escalation part in which 43 patients were enrolled and received monotherapy. Among them, 28 CPI-resistant patients also received the combination therapy. Among patients treated with the combination therapy, 6 patients (4

melanoma and 2 NSCLC patients) achieved a confirmed PR with an ORR of 21.4%, and 16 patients achieved stable disease (SD) with a DCR of 78.6%. **The combination regimen delivered particularly encouraging efficacy in melanoma, with all 11 CPI-resistant patients achieving disease control (DCR 100%) and an ORR of 36.4% (4 PRs), including 1 patient having maintained PR and remained in the study for over 2 years without any safety concerns. In CPI-resistant NSCLC, the combination regimen achieved an ORR of 22% (PRs) and a DCR of 67%.** These results highlight the potential of ATG-037 to deliver meaningful clinical benefit across multiple tumor types, reinforcing its promise as a novel treatment option in CPI-resistant cancers.

- **Manageable safety profile:** Treatment-related adverse events were reported in 56% (24/43) of patients receiving monotherapy and 61% (17/28) of patients receiving the combination therapy. The majority of these TRAEs were grade 1-2. Only one serious TRAE (grade 3 immune mediated hepatitis) was observed in the study.
- **Two key differentiators:** ATG-037 is an oral small molecule CD73 inhibitor offering greater convenience over intravenous (IV) injectable agents and is uniquely designed to overcome the 'hook effect' commonly seen in anti-CD73 antibodies, enabling complete and more effective CD73 inhibition.
- **The STAMINA-01 trial:** STAMINA-01 is a Phase I/Ib study jointly

conducted by Antengene and MSD (Merck & Co., Inc., Rahway, NJ, USA). The study was designed to evaluate the safety, pharmacokinetics, and optimal dosing of ATG-037 as a monotherapy and in combination with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with refractory/relapsed solid tumors. At present, dose optimization and dose expansion parts of the study are being carried out as planned in China and Australia.

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

ATG-008 (mTORC1/2 Small Molecule Inhibitor)

Title: A TORC1/2 inhibitor onatasertib combined with toripalimab in patients with advanced cervical cancers with prior anti-PD-(L)1 therapy

Abstract: 5540

Session: Gynecologic Cancer

Date: June 1, 2025

Time: 9:00 AM - 12:00 PM (Central Time)

10:00 PM, June 1, 2025 - 1:00 AM, June 2, 2025 (Beijing Time)

- **The TORCH-2 trial:** ATG-008 is an oral dual mTOR1/2 inhibitor. The TORCH-2 trial is a Phase I/II dose escalation and dose expansion study of ATG-008 in combination with the anti-PD-1 monoclonal antibody

toripalimab in patients with advanced solid tumors. **This abstract reports data from patients with advanced cervical cancer who had previously received at least prior 1 line of anti-PD-(L)1 therapy and 1 line of platinum chemotherapy, regardless of the PD-L1 expression.** As of November 25, 2024, 30 qualified patients were enrolled and received ATG-008 15 mg orally once a day (QD) in combination with toripalimab 240 mg, once every 21 days (Q3W). Among them, 14 and 16 patients had received 1 and at least 2 prior lines of systemic therapy, respectively. The median time since initial diagnosis was 37 months.

- **Encouraging efficacy in patients with CPI-resistant cervical cancer:** Among 27 efficacy-evaluable patients, the combination regimen achieved an ORR of 22.2% and a DCR of 85.2%. The ORRs of PD-L1 positive and PD-L1 negative populations were 30% (3/10) and 33.3% (2/6), respectively. The median time to response was 1.7 months (1.4, 4.2) and the median duration of response (DOR) was 5.7 months (95% CI: 2.7, NE). The median progression-free survival (PFS) was 4.2 months (95% CI: 3.3, 5.8) and the median overall survival (OS) was 21.4 months (95% CI: 15.5, NE). These results underscore the potential of ATG-008 in combination with toripalimab in providing meaningful clinical benefit for CPI-resistant cervical cancer patients, reinforcing its promise as a novel treatment option for this difficult-to-treat patient population.
- **Manageable safety profile:** All 30 patients experienced at least one

TEAE, and 22 patients (73.3%) reported grade ≥3 TRAEs. The most common all-grade TRAEs were hyperglycaemia (56.7%), rash (43.3%) and white blood cell decreased (43.3%). Most TRAEs were grade 1-2, and no TEAE led to death.

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"**.

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 31 investigational new drug (IND) approvals in the U.S. and Asia, and submitted new drug applications (NDAs) in 11 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, 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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