Antengene Highlights Encouraging ATG-008 Efficacy Results From TORCH-2 Study in Combination with PD-1 Antibody in Relapsed/Metastatic Cervical Cancer

- ***An objective response rate (ORR) of 52.4%*** *was observed in* ***relapsed or metastatic cervical cancer*** *in Phase I/II* ***TORCH-2 Study*** *of ATG-008 (onatasertib) in combination with toripalimab, regardless of PD-L1 status*
- *Study builds on promising results of Phase II TORCH monotherapy study in HBV+ patients with unresectable hepatocellular carcinoma (HCC) which demonstrated an ORR of 16.7% in the 45 mg per day dosing cohort*
- *Activity also seen in patients with prior CPI treatment*
- *Antengene plans to meet with the Center for Drug Evaluation (CDE) of China and move forward to pivotal study in cervical cancer as soon as possible*

Shanghai and Hong Kong, PRC, November 15, 2022 — 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 therapeutics in hematology and oncology,

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

today highlighted **preliminary positive results from the TORCH-2 study of ATG-008 (onatasertib) used in combination with toripalimab (PD-1 antibody) in relapsed/metastatic cervical cancer patients (NCT04337463).** The combination therapy demonstrated an ORR of 52.4% (based on all treated patients) regardless of PD-L1 status. The results are based on early data from 21 patients, including 10 patients who reached partial response (PR) and 1 patient who achieved a complete response (CR). Five out of the ten responders are still responding, and two patients who are currently in stable disease (SD) still remain on treatment. The median progression free survival (PFS) for these patients is currently 5.5 months.

Notably, in the TORCH-2 study, the ORR for PD-L1 positive subjects was 77.8% (7/9). In addition, 1 out of 2 CPI-exposed patients also reached PR.

Antengene also highlighted data from the 45 milligram (mg) per day monotherapy dosing cohort of the open-label Phase II TORCH Trial in subjects with Hepatitis B positive (HBV+) unresectable HCC who have received at least one prior line of systemic therapy (NCT03591965). ATG-008 monotherapy demonstrated a 16.7% ORR based on 3

confirmed PRs out of 18 patients in this cohort. The median duration of response (DOR) for these patients is 4.3 months. In the TORCH study, 2 of the 3 patients with PRs were previously treated with a PD-1/PD-L1 antibody.

Treatment with ATG-008 monotherapy and in combination with toripalimab was associated with manageable side effects, similar to observations in previous global studies with ATG-008. ATG-008's pharmacokinetic profiles were comparable between ATG-008 monotherapy and the combination with PD-1 antibody and across Asia Pacific (including Greater China) and the U.S. populations.

" The 52.4% ORR from the TORCH-2 study with ATG-008 and toripalimab in patients with relapsed/metastatic cervical cancer, coupled with a manageable safety profile, is an exciting result that provides a potential guide to a registration program for ATG-008. Antengene intends to review the data with the Chinese CDE and move forward into pivotal studies as quickly as possible." said **Dr. Jay Mei, Antengene's Founder, Chairman and CEO.**

Dr. Mei continued, "Data from the TORCH and TORCH-2 studies have also demonstrated activity of ATG-008 in patients who have failed

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previous CPI treatments. This is an important signal that warrants further investigation in a group of patients where there is a desperate need. Importantly, observation of a 16.7% ORR as a monotherapy in the TORCH study is a strong validation of ATG-008's single agent activity."

The updated and detailed study results of the TORCH and TORCH-2 will be presented at international scientific conferences in 2023.

About the TORCH-2 Trial

The TORCH-2 trial (NCT04337463) was designed to evaluate the safety and efficacy of ATG-008 combined with toripalimab (PD-1 antibody) in subjects with advanced solid tumors. Promising signals in several tumor types were observed, especially in advanced cervical cancer. As of the Oct 21, 2022 efficacy evaluation, 21 cervical cancer patients had been dosed with the ATG-008/toripalimab combination including 9 patients (42.9%) who were PD-L1 positive. Initial results of the TORCH-2 study were presented at the 2022 American Society of Clinical Oncology (ASCO 2022) Annual Meeting.

About the TORCH Trial

The TORCH trial was designed as a multi-regional clinical trial to

evaluate the pharmacokinetics, safety, tolerability and efficacy of oral ATG-008 in hepatitis B positive (HBV+) hepatocellular carcinoma (HCC) who had failed at least one prior line of systemic therapy. ATG-008 was administered daily until radiological disease progression (according to RECIST 1.1 criteria) or intolerable toxicity. A total of 73 subjects from mainland China, Taiwan, and South Korea were enrolled in the trial in four dosing cohorts (15 mg per day, 30 mg per day, 20 mg twice a day and 45 mg per day).

In the 18 subjects of the 45 mg per day dosing cohort, ATG-008 demonstrated a 16.7% ORR, based on 3 confirmed partial responses (PRs), validating the single agent activity of ATG-008. Notably, 2 of the 3 confirmed PRs were previously treated with a PD-1/PD-L1 antibody.

About ATG-008

ATG-008 (onatasertib) is an orally available mTORC 1/2 inhibitor. ATG-008 inhibits the activity of mTOR, which may result in the induction of tumor cell apoptosis and a decrease in tumor cell proliferation. mTOR, a serine/threonine kinase that is upregulated in a variety of tumors, has an important role in the PI3K/AKT/mTOR signaling pathway, which is frequently dysregulated in human cancers. ATG-008 has

been studied in clinical trials to treat a broad range of tumor types including multiple myeloma (MM), glioblastoma (GBM), hepatocellular carcinoma (HCC), non-small cell lung cancer (NSCLC), diffuse large B-cell lymphoma (DLBCL), etc.

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, driven by its vision of **"Treating Patients Beyond Borders" .**

Since its founding in 2017, Antengene has built a broad and expanding pipeline of 15 clinical and preclinical assets, including 10 assets with global rights and 5 with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 26 investigational new drug (IND) approvals in Asia and the U.S., and submitted 6 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in mainland China, Taiwan, 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 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, see the section titled "Risk Factors" in our periodic reports filed with the Hong Kong Stock Exchange and the other risks and uncertainties described in the Company's Annual Report for year-end December 31, 2021, and subsequent filings with the Hong Kong Stock Exchange.

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