

## Antengene To Present Latest Results from TORCH-2 Study of ATG-008 in Advanced Solid Tumors in Poster Discussion at ASCO 2023

- The TORCH-2 study is a Phase I/II trial of the mTORC1/2 inhibitor

  ATG-008 plus the Anti-PD-1 monoclonal antibody toripalimab for

  the treatment of patients with advanced solid tumors.
- The combination treatment produced an objective response rate

  (ORR) of 52.4% in the advanced cervical cancer cohort (including

  75% in PD-L1 positive and 41.7% in PD-L1 negative patients), a

  disease control rate (DCR) of 90.5% and a median progression-free survival (mPFS) of 7.2 months.

Shanghai and Hong Kong, PRC, May 26, 2023 — 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 that the latest results from the Phase I/II TORCH-2 study will be presented as a poster at the 2023 American Society for Clinical Oncology Annual Meeting (ASCO)

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2023) taking place from June 2<sup>nd</sup> to 6<sup>th</sup>, 2023 at the McCormick Place Convention Center in Chicago, IL. Being among the 22 China studies selected for Poster Discussions this year, the abstract will also be presented in a Poster Discussion session on June 3<sup>rd</sup>.

"It is our pleasure to have the latest results from the TORCH-2 study selected for Poster Discussion at ASCO 2023," said **Dr. Amily Zhang, Antengene's Chief Medical Officer**. "Going forward, we will maintain close collaboration with the investigator team of the TORCH-2 study and liaise with regulatory authorities in China and other APAC markets to align on a registration path in cervical cancer and to continue evaluating the combination in additional ongoing studies in other solid tumors."

The TORCH-2 study is a Phase I/II trial of the mTORC1/2 inhibitor ATG-008 plus the Anti-PD-1 monoclonal antibody toripalimab for the treatment of patients with advanced solid tumors. The study enrolled 46 patients, including 21 patients with cervical cancer, to evaluate ATG-008 at three doses (15, 20 and 30 mg) in combination with the standard dose of toripalimab. Study patients had advanced solid tumors with a baseline Eastern Cooperative Oncology Group (ECOG) score of 0-1 (the

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majority scored 1 on the ECOG scale) and a median of 2 lines of therapy

(range:0-7). Median patient age was 53 years. Patients with prior

PI3K/AKT/mTOR therapy were excluded. Pharmacokinetics and

exploratory biomarkers of drug activity were also evaluated. The data are

presented as of the cut-off date of October 21st, 2022.

**Poster Details** 

**Title:** A phase I/II study of the TORC1/2 inhibitor onatasertib combined

with toripalimab in patients with advanced solid tumors

Abstract: 2526

**Session:** Developmental Therapeutics - Immunotherapy

Poster: 368

Poster Discussion Session Date and Time: 3:00 PM - 4:30 PM, June 3, 2023

(Central Time) / 4:00 AM - 5:30 AM, June 4, 2023 (Beijing Time)

**52.4% ORR in the Cervical Cancer Cohort:** Among the 21 patients in

the cervical cancer cohort, 1 patient with negative PD-L1 expression

experienced a CR and 9 patients experienced a partial response (PR).

Note that the patient who achieved a CR in this cohort remained on

treatment for more than 883 days and is on treatment with single

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agent ATG-008 as of the cut-off date. The mPFS for the cohort was 7.2 months.

- Additional Responses in Patients with Nasopharyngeal Carcinoma
   (NPC): The study reported one additional PR in a patient with NPC;
   this patient remained on study for over two years.
- Recommended Phase II Dose (RP2D) was Defined: The RP2D for ATG-008 was determined to be 15 mg in combination with toripalimab.
- or Maximum Tolerated Dose (MTD) from the Dose Escalation Phase:

  The study did not identify any DLT or reach the MTD; 97.8% of patients had more than one treatment emergent adverse event (TEAE) and 69.6% of patients had TEAEs > grade 3, most common of which were decreased lymphocytes (23.9%), rash (10.6%) and hyperglycemia (10.9%). Pharmacokinetic profiles of ATG-008 in combination with toripalimab were similar to ATG-008 monotherapy across APAC and US patients. No new safety signals were reported.

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, in realizing its vision of "Treating Patients Beyond Borders".

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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 China, Taiwan 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 the understanding that our actual future results or

performance may be materially different from what we expect.

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