

Antengene Announces Phase I Study of Anti-CD24 Monoclonal Antibody ATG-031

- The Phase I "PERFORM" study will evaluate the safety and tolerability, pharmacology, immunogenicity, and preliminary efficacy of ATG-031 in patients with advanced solid tumors or B-cell non-Hodgkin's lymphoma (B-NHL).
- ATG-031, discovered and developed in-house by Antengene, is

 the world's first anti-CD24 antibody to advance to the clinic

 in oncology and Antengene's third drug candidate to enter

 clinical studies in the U.S.

Shanghai and Hong Kong, PRC, September 21, 2023 — Antengene Corporation Limited ("Antengene" SEHK: 6996.HK), a leading commercial-stage innovative, global biopharmaceutical company dedicated to discovering, developing, and commercializing first-in-class and/or best-in-class medicines for hematology and oncology, today announced that a Phase I study of the best-in-class anti-CD24 antibody, ATG-031, has been approved by the Institutional Review Board (IRB) of The University of Texas MD

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Anderson Cancer Center in Houston, Texas, the United States.

This clinical study, codenamed the PERFORM trial and led by MD

Anderson, will be conducted in patients with advanced solid

tumors or B-NHL.

The PERFORM trial is a first-in-human, multi-center, open-label,

Phase I dose-finding study of ATG-031 in patients with advanced

solid tumors or B-NHL. The study's primary objective is to

evaluate the safety and tolerability of ATG-031 as a

monotherapy, and determine the appropriate dose for Phase II

studies. The secondary objective is to characterize the

pharmacology, evaluate the immunogenicity, and assess the

preliminary efficacy of ATG-031.

Dr. Amily Zhang, Antengene's Chief Medical Officer said, "We are

excited about the progress being made with ATG-031. We look

forward to further characterizing the safety, tolerability, and

preliminary efficacy of ATG-031. We will begin enrolling patients

for the study as soon as possible and plan to release the first batch

of preliminary data from the study in 2024."

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"Through committed work and unrelenting innovation, our R&D

organization successfully advanced the ATG-031 program to the

clinical stage in just three years, an achievement that has truly

made us proud," said Dr. Jay Mei, Antengene's Founder,

Chairman and CEO. "Based on the robust preclinical data of ATG-

031, we are confident that the drug will continue to demonstrate

its therapeutic potential in clinical studies. Moving forward,

Antengene will press ahead the clinical development of its global

rights programs with the aim of serving a broader population of

patients."

About ATG-031

ATG-031 is a first-in-class humanized CD24 monoclonal antibody

which inhibits the "don't eat me" signal and enhances

macrophage-mediated phagocytosis of cancer cells. Tumor cells

evade the surveillance of the human immune system by over-

expressing "don't eat me" surface proteins that signal

macrophages to prevent the detection and phagocytosis of cancer

cells. CD24 (cluster of differentiation 24) is a prominent "don't eat

me" signal that plays a significant role in tumor immune evasion

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by suppressing macrophage-mediated phagocytosis. Compared to

CD47, another well-known "don't eat me" target, CD24 has a

more restricted distribution in normal tissue and higher expression

in cancerous tissue. In addition, unlike CD47, CD24 is not expressed

on human red blood cells, allowing for a wider therapeutic window

and minimal on-target-off-tumor toxicity as a CD24-targeted

therapy.

As a novel innate immune checkpoint, CD24 orchestrates immune

evasion through its interaction with the inhibitory receptor Siglec-

10 (sialic-acid-binding Ig-like lectin 10) expresses on tumor-

associated macrophages (TAMs). Preclinical data presented in

2023 at the American Association for Cancer Research Annual

Meeting (AACR 2023) demonstrated that ATG-031 can specifically

bind to CD24 with nM affinity and block the interaction of CD24 and

Siglec-10. Furthermore, ATG-31 induces efficient phagocytosis

with a picomolar EC50 and stimulates the pro-inflammatory

cytokines production by macrophages.

About Antengene

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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.

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

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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.

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