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## **Antengene Corporation Limited**

**德琪醫藥有限公司**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 6996)**

### **VOLUNTARY ANNOUNCEMENT**

#### **AN UPDATE ON LATEST DEVELOPMENTS**

Antengene Corporation Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) hereby informs the shareholders and potential investors of the Company of the attached press release that provides an update on the Group’s latest developments.

This is a voluntary announcement made by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board  
**Antengene Corporation Limited**  
**Dr. Jay Mei**  
*Chairman*

Hong Kong, June 18, 2021

*As at the date of this announcement, the board of directors of the Company comprises Dr. Jay Mei, Mr. John F. Chin, Dr. Kevin Patrick Lynch and Mr. Donald Andrew Lung as executive directors; Mr. Yanling Cao and Dr. Kan Chen as non-executive directors; and Mr. Mark J. Alles, Ms. Jing Qian and Mr. Sheng Tang as independent non-executive directors.*

## ANTENGENE PROVIDES AN UPDATE ON ITS LATEST DEVELOPMENTS

- Announces two new in-house discovered assets – ATG-031, a potential first-in-class anti-CD24 monoclonal antibody, and ATG-027, a potential first-in-class B7H3/PD-L1 bi-specific antibody
- Provides an update on commercial readiness across the Asia Pacific markets for selinexor, Antengene’s first asset expected to receive approval in multiple markets from 4Q2021 to 1Q2022
- Provides an update on pipeline progress across breadth of Antengene’s APAC and global rights assets

Shanghai and Hong Kong, PRC, June 18, 2021-Antengene Corporation Limited (“**Antengene**”, SEHK: 6996.HK), a leading innovative biopharmaceutical company dedicated to discovering, developing and commercializing global first-in-class and/or best-in-class therapeutics in hematology and oncology, would like to provide an update on the state of its business operations and other recent developments.

Significant progress has been made with respect to our pipeline and business operations since the company’s IPO on November 20, 2020. During this period, Antengene continued to execute its dual-engine growth strategy leveraging both external partnerships and in-house discovery and have **built a pipeline of thirteen assets, five with APAC rights and eight with global rights**. Antengene has advanced the clinical trials of our six in-licensed assets in APAC and have continued to expand its pipeline through internal discovery efforts with the announcement of two additional novel targets into our pipeline. In addition, Antengene is reaching an inflection point in its transition from a clinical stage to a commercial stage company, and has further built out its commercial infrastructure in multiple APAC markets in preparation for the commercial launch of selinexor towards the end of 2021.

### Corporate Updates

- As of June 18, 2021, Antengene has built a strong and dedicated team of over 200 full time employees, over a third of whom are in research and development.
- With the expected approvals for selinexor across multiple APAC markets towards the end of 2021, Antengene has continued to build up its experienced commercial team across China and the APAC region with plans to grow its commercial organization to up to 200 full time employees in functions including in-house marketing, field force, pricing and market access by the end of 2021.
- In May 2021, Antengene completed its manufacturing center in Shaoxing. To date, Antengene has finished the GMP renovation of plant buildings that will house the packaging line for solid dose formulation, installed supporting facilities, and set up a quality control laboratory for raw materials and finished products.
- In May 2021, Antengene has entered into a framework agreement with the Hangzhou Qiantang New Area Administrative Committee to build a drug discovery and manufacturing center for antibody biologics.

## AN UPDATE ON PIPELINE CANDIDATES

### Asia Pacific Rights Portfolio

#### *Selinexor*

*Selinexor is a first-in-class, only-in-class orally available XPO1 inhibitor being developed for the treatment of hematologic malignancies and solid tumors.*

- Data from the MARCH trial of selinexor published at ASCO annual meeting in June 2021 include an objective response rate (ORR) of 26.7% in all analyzed patients with relapsed or refractory multiple myeloma (RRMM) and an ORR of 33.3% in patients with triple-class-exposed RRMM. These data are consistent with that observed in the STORM trial, from which, data had supported the accelerated approval of selinexor by the U.S. Food and Drug Administration (FDA). In addition, the data also showed an ORR of 44.4% in patients who had received prior CAR-T therapies.
- Antengene has submitted a new drug application (NDA) for selinexor to the National Medical Products Administration (NMPA) in January 2021 with priority review granted to the NDA in February 2021.
- Multiple combination regimens of selinexor have already been included in the 2021 Chinese Society of Clinical Oncology (CSCO) Guidelines.
- Antengene submitted NDAs for selinexor in Australia, Korea, Singapore and Hong Kong, and plans to submit an NDA for three indications in hematologic malignancies in Taiwan in 3Q2021.
- Antengene is exploring additional indications of selinexor through two global Phase III registrational trials for the treatment of relapsed or refractory diffuse large B-cell lymphoma (RRDLBCL, the XPORT-DLBCL-030 trial) and endometrial cancer (the SIENDO trial); two registrational trials for the treatment of RRDLBCL (the SEARCH trial) and RRMM (the BENCH trial) in China; and China-only trials including for the treatment of relapsed or refractory T-cell and NK/T-cell lymphoma (the TOUCH trial).

#### *ATG-016 (Eltanexor)*

*Eltanexor is a next-generation XPO1 inhibitor being developed for the treatment of patients with myelodysplastic syndromes (MDS) or solid tumors.*

- Data with eltanexor published at ASCO annual meeting in June 2021 showed a bone marrow complete response (mCR) in 7 patients (47%) and a total disease control rate (DCR) of 80%, of the 15 efficacy-evaluable patients with MDS refractory to hypomethylating agents.
- In May 2021, Antengene has treated the first patient in a Phase I/II trial of eltanexor in patients with MDS (the HATCH trial).
- A Phase Ib/II trial of eltanexor in patients with advanced solid tumors (the REACH trial) is currently on-going in Mainland China.

### ***ATG-008 (Onatasertib)***

*Onatasertib is a next-generation dual mTORC1/2 inhibitor being developed for the treatment of advanced solid tumors.*

- In April 2021, a Phase II trial of ATG-008 (the BUNCH trial) in patients with advanced solid tumors harboring NFE2L2, STK11, RICTOR or other specific genetic alterations has enrolled and treated its first patient in Mainland China.
- The TORCH trial, as the first trial of ATG-008 for the treatment of Asian patients, is now enrolling at the 45mg cohort in this dose-optimization trial in late-stage HBV+ HCC patients.
- The TORCH-2 trial, a combination trial of ATG-008 with a PD-1 antibody (Toripalimab) in advanced solid tumors and HCC, is now enrolling patients at its third dose cohort.
- Preclinical data demonstrating the synergistic effect of the combination of selinexor and ATG-008 for the treatment of triple-hit diffuse large B-cell lymphoma were presented at the 2021 American Association for Cancer Research (AACR) Annual Meeting.

### ***ATG-019 (PAK4/NAMPT inhibitor)***

*ATG-019 is an orally bioavailable dual PAK4/NAMPT inhibitor with first-in-class potential in the treatment of non-Hodgkin lymphoma (NHL) and advanced solid tumors.*

- A Phase I clinical trial (TEACH) of ATG-019 in patients with advanced solid tumors or NHL has been initiated in Mainland China following the initial dose-escalation phase in Taiwan.

### **Global Rights Portfolio**

#### ***ATG-017 (ERK 1/2 inhibitor)***

*ATG-017 is a potent and selective small molecule extracellular signal-regulated kinases 1 and 2 (ERK1/2) inhibitor in clinical development for advanced solid tumors and hematologic malignancies.*

- The on-going dose-escalation study of ATG-017 for the treatment of advanced solid tumors and hematologic malignancies in Australia (the ERASER trial) has completed the first 3 cohorts in solid tumors (5 mg QD, 5 mg BID and 10 mg BID), and has started treating patients in the fourth cohort (20 mg BID).
- Preliminary data from the ERASER trial will be announced in 4Q2021.

### ***ATG-101 (PD-L1/4-1BB bi-specific antibody)***

*ATG-101 is a novel PD-L1/4-1BB bi-specific antibody being developed for the treatment of cancer. ATG-101 can activate anti-tumor immune effectors by simultaneously blocking PD-L1/PD-1 binding and inducing 4-1BB stimulation. In the presence of PD-L1 over-expressed cancer cells, ATG-101 showed a significant and PD-L1 crosslinking-dependent 4-1BB agonist activity, thus enhancing therapeutic efficacy, and mitigating hepatotoxicity simultaneously.*

- Antengene will initiate a first-in-human Phase I trial of ATG-101 in patients with metastatic/advanced solid tumors or non-Hodgkin's B-cell lymphoma (B-NHL).
- Antengene has submitted clinical trial applications to the Human Research Ethics Committee (HREC) in Australia for the first-in-human trial of ATG-101 in patients with metastatic/advanced solid tumors or non-Hodgkin's B-cell lymphoma (B-NHL).
- In addition, Antengene plans to submit Investigational New Drug (IND) applications for ATG-101 in the US and China in 4Q2021.
- ATG-101 demonstrated potent activity in preclinical animal models, including strong tumor-suppressing effect in models of PD-1/PD-L1 inhibitor-resistant or -relapsed tumors. Meanwhile, the GLP toxicology study of ATG-101 has produced results highlighting a favorable safety profile.

### ***ATG-037 (Small molecule inhibitor of CD73)***

*ATG-037 is a highly potent, selective, orally-bioavailable small molecule inhibitor of CD73 that has best-in-class potential as either a monotherapy or in combination against a range of tumor types. It overcomes the 'hook-effect' of clinical anti-CD73 antibodies and could completely block CD73 activity in vitro.*

- On May 17, 2021, Antengene and Calithera Biosciences entered into an exclusive, worldwide license agreement for the development and commercialization of ATG-037, a small molecule inhibitor of CD73.
- Antengene plans to submit IND application for ATG-037 in Australia, United States and China by the end of 2021.

### ***ATG-018 (ATR inhibitor)***

*ATG-018 is a small molecule inhibitor targeting ataxia telangiectasia and Rad3 related (ATR) kinase being developed for the treatment of hematological malignancies and solid tumors.*

- ATG-018, an in-house discovered ATR inhibitor, is at the IND-enabling stage, targeting IND submissions in Australia, United States and China by the end of 2021, or the beginning of 2022.

### ***ATG-022 (ADC Targeting Claudin 18.2)***

- ATG-022, an antibody drug conjugate targeting Claudin 18.2, is in the late pre-clinical research and GMP CMC stage. IND submissions are expected in 2022.

## ***ATG-012 (KRAS inhibitor)***

- ATG-012, a KRAS inhibitor, and a potential combination agent with ATG-017 and ATG-101, is in late pre-clinical research stage, with IND submissions expected in 2022.

## **New Targets**

**ATG-031** is a potential first-in-class anti-CD24 monoclonal antibody being developed for the treatment of hematologic malignancies and solid tumors. ATG-031 potently stimulates macrophage-mediated phagocytosis and induces the destruction of cancer cells by blocking the ‘Don’t eat me’ signals characterizing the growth of many cancers. In pre-clinical research, ATG-031 demonstrated single agent anti-tumor activity in animal models and showed synergy with chemotherapies, checkpoint inhibitors, and other therapeutic agents. ATG-031 is at IND enabling stage.

**ATG-027** is a potential first-in-class bispecific antibody being developed for the treatment of hematologic malignancies and solid tumors. ATG-027 blocks the PD-1/PD-L1 interaction and the B7H3 interaction with its ligand to stimulate the activation of immune cells and mediates anti-tumor effect. ATG-027 also leads to the elimination of B7H3-positive tumor cells through ADCC/CDC effect. ATG-027 showed potent in vivo anti-tumor activity in mouse tumor models. ATG-027 is at preclinical research stage.

“I am excited to announce Antengene’s discovery of two proprietary assets targeting two novel mechanistic pathways, namely ATG-031, a first-in-class CD24 antibody, and ATG-027, a first-in-class B7H3/PD-L1 bispecific antibody. These discoveries are yet another testament to our dual-engine drug development strategy. This year, we aim to advance ATG-101 into clinical development, as our internal development efforts continue to yield results. Moreover, we have recently obtained the global rights to ATG-037, an oral small molecule inhibitor of CD73 with best-in-class potential, and we are poised to advance the drug candidate into global clinical development in the near future,” said Dr. Jay Mei, Founder, Chairman and CEO of Antengene.

“While in commercialization, we have built a world-class commercial organization in the APAC region, led by industry veterans with strong track record in successfully launching innovative oncology therapies in APAC markets, and deep expertise in the areas of multiple myeloma and lymphoma.”

**“In just half of a year, we further strengthened our pipeline through the addition of three assets that have enormous combinatory potential with other agents,** broadening the therapeutic potential of our pipeline. Like many patients around the world, we have high expectations for these first-in-class therapies in the APAC region and we are committed to advancing the global development of these assets, and fulfilling our mission of ‘Treating Patients Beyond Borders’.”

## **ABOUT ANTENGENE**

Antengene Corporation Limited (“**Antengene**”, SEHK: 6996.HK) is a leading clinical-stage R&D driven biopharmaceutical company focused on innovative medicines for oncology and other life-threatening diseases. Antengene aims to provide the most advanced anti-cancer drugs to patients in the Asia Pacific Region and around the world. Since its establishment in 2017, Antengene has built a broad and expanding pipeline of clinical and pre-clinical stage assets through partnerships as well as in-house drug discovery, and obtained 15 investigational new drug (IND) approvals and submitted 5 new drug applications (NDA) in multiple markets in Asia Pacific. Antengene’s vision is to “Treat Patients Beyond Borders”. Antengene is focused on and committed to addressing significant unmet medical needs by discovering, developing and commercializing first-in-class/best-in-class therapeutics.

## **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.