Antengene Announces ATG-101 Granted Orphan Drug Designation by the U.S. FDA

September 19, 2022, Beijing Time — 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 hematology and oncology, today announced that **ATG-101, the company's in-house developed novel PD-L1/4-1BB bispecific antibody, has been granted an Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of pancreatic cancer**. This ODD will help Antengene facilitate regulatory communication with the FDA, accelerate the clinical development and the future registration of ATG-101.

At present, no PD-L1/4-1BB bispecific antibody has been approved for the treatment of pancreatic cancer worldwide.

Orphan Drugs, also known as Rare Disease Drugs, refers to pharmaceutical products developed for the prevention, diagnosis, and treatment of rare diseases or conditions. **Orphan Drug Designations by the U.S. FDA are meant to support the development of drug candidates that could potentially bring substantial therapeutic benefits to patients**

with rare diseases (a condition with a prevalence of less than 200,000 in the U.S.), and to provide incentives to the subsequent development, registration and commercialization to designated drugs. Those incentives include tax credit on expenditures incurred in clinical studies, a waiver of the New Drug Application (NDA) fee, and 7-year market exclusivity in the U.S. regardless of the patent status of the designated drug.

Pancreatic cancer is a highly malignant type of gastrointestinal cancer. According to the statistics by the World Health Organization (WHO), pancreatic cancer was ranked 13th and 7th globally by its incidence and mortality rates in 2012. In 2018, the U.S. reported over 55,000 newly-diagnosed pancreatic cancer cases and 44,330 related deaths. Whereas still defined as an orphan disease currently, it is projected that by 2030, pancreatic cancer will become the second most common cause of cancer-related deaths.

ATG-101 is a novel PD-L1/4-1BB bispecific antibody that was designed to block the binding of immunosuppressive PD-1/PD-L1 and conditionally induce 4-1BB stimulation, thus activating anti-tumor immune effectors, while delivering enhanced anti-tumor activity, with an improved safety profile. In preclinical studies, ATG-101

demonstrated significant anti-tumor activity in animal models of resistant tumors as well as those that had progressed on anti-PD-1/L1 treatment. Furthermore, ATG-101 has also shown an excellent safety profile in Good Laboratory Practice (GLP) toxicology studies. **ATG-101 is the first PD-L1/4-1BB bispecific antibody entering clinical development in Australia and is currently being evaluated in clinical studies in Australia, China, and the U.S.**

Dr. Bo Shan, Antengene's Chief Scientific Officer, said, "We are very encouraged by this Orphan Drug Designation from the U.S. FDA and are hopeful that ATG-101 will offer a novel therapeutic to patients with pancreatic cancer. As Antengene's first in-house developed asset with global rights, ATG-101 has already entered clinical development in Australia, China, and the U.S. We will strive to accelerate the global clinical development of ATG-101 in efforts to provide a new treatment option to patients around the world."

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".**

Since 2017, Antengene has built a broad and expanding pipeline of 15 clinical and preclinical assets, of which 10 are global rights assets, and 5 came with rights for Asia Pacific markets including the Greater China region. To date, Antengene has obtained 24 investigational new drug (IND) approvals in the U.S. and Asia, and submitted 6 new drug applications (NDAs) in multiple Asia Pacific markets, with the NDA for XPOVIO® (selinexor) already approved in mainland 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. 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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