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康宁杰瑞

ALPHAMAB ONCOLOGY

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康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

INSIDE INFORMATION ANNOUNCEMENT

PRELIMINARY RESULTS OF A PHASE I CLINICAL TRIAL OF JSKN003 IN AUSTRALIA FOR THE TREATMENT OF HER2- EXPRESSING ADVANCED SOLID TUMORS

This inside information announcement is made by Alphamab Oncology (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

JSKN003-101 is an open-label, multi-center, dose-escalation phase I clinical trial in Australia designated to evaluate the safety, tolerability, and preliminary efficacy of JSKN003 as well as to determine the RP2D of JSKN003 in the treatment of advanced solid tumors, which was divided into two stages, being the dose-escalation stage and the dose-expansion stage. This clinical trial has completed the first patient dosed successfully in September 2022 and the dose-escalation stage in October 2023, and enrolled 32 subjects in total.

The Board is pleased to announce that the preliminary efficacy and promising tolerability of JSKN003 have been demonstrated in JSKN003-101, the details of which are presented as follows:

Among the 32 enrolled patients in the dose-escalation stage, who have received multi-line treatment of HER2-expressing solid tumors, the median number of lines of therapy for the enrolled patients was 3 (from 1 to 9 line(s)), of which 7 patients (21.9%) were treated with trastuzumab and 5 patients (15.6%) with HER2-high expressing BC were treated with T-DM1. The median age was 65 years old (aged from 30 to 79) and the median dosing cycle was 5 cycles (from 1 to 18 cycle(s)) with the longest dosing cycle having exceeded 1 year. 15 patients (46.9%) had an ECOG PS of 0 and 17 patients (53.1%) had an ECOG PS of 1. There were 9 patients (28.1%) with HER2 IHC 1+, 16 patients (50.0%) with IHC 2+, and 7 patients (21.9%) with IHC 3+. Among all the patients, 46.9% are BC patients, including 10 patients with HER2-low expressing BC and 5 patients with HER2-high expressing BC, 15.6% are patients with ovarian cancer, and 12.5% are patients with bladder cancer, involving 8 different tumor types.

- *Efficacy:* As of October 26, 2023, with a median follow-up of 4.2 months (95% CI: 2.3 to 5.8), 20 patients (62.5%) are still on treatment, PFS and DoR are not yet mature, and the ORR is subject to further observation. Among the 30 patients who have undergone at least one tumor evaluation, the ORR was 46.7% (95% CI: 28.3% to 65.7%) and the DCR was 90.0% (95% CI: 73.5% to 97.7%). The ORR was 40.0% (95% CI: 12.2% to 73.8%) in patients with HER2-low expression BC and 75.0% (95% CI: 19.4% to 99.4%) in patients with HER2-high expressing BC.
- *Safety:* Among the 32 enrolled patients, TRAEs at grade 3 or higher levels occurred in 2 patients (6.3%) and drug-related hematologic toxicity occurred in 1 patient without interstitial lung disease (ILD). No patients experienced drug-related serious adverse events. The dose was escalated to a dose of 8.4 mg/kg, without the occurrence of dose-limiting toxicities, and the trial did not reach the maximum tolerated dose (the “**MTD**”).

Conclusions: JSKN003 has shown initial efficacy in HER2-expressing solid tumors, and has been well tolerated by the treated patients, without dose-limiting toxicity or reaching the MTD. A phase I/II clinical trial of JSKN003 is currently undergoing in China, with 56 subjects enrolled as of October 26, 2023, the safety profile of which was consistent with that of JSKN003-101, and no additional safety signal was identified.

ABOUT JSKN003

JSKN003 is a biparatopic HER2-targeting antibody-drug conjugate, of which a topoisomerase I inhibitor is linked to the N glycosylation site of the antibody KN026 (a recombinant humanized anti-HER2 bispecific antibody) via the glycosite-specific conjugation. The click reaction-based conjugation confers better serum stability than maleimide-Michael reaction-based conjugation. The biparatopic HER2 targeting enables JSKN003 to have stronger internalization induction and bystander killing effect leading to potent anti-tumor activity in HER2 expression tumors with the mild toxicity drug payload. A phase I clinical trial JSKN003 in Australia and phase I/II and phase III clinical trials of JSKN003 in China are currently undergoing.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in China with a fully integrated proprietary biologics platform in bispecific and protein engineering. Differentiated in-house clinical pipeline of the Company includes the oncology drug candidates with one approved for marketing by the National Medical Products Administration of China (國家藥品監督管理局), three in late clinical stage and two in phase I clinical trial stage. The Company has developed various technologies and platforms of antibody-based therapies for oncology treatment and expertise in this regard. Benefitting from the proprietary protein engineering platforms and structure-guided molecular modeling expertise, the Company is able to create a new generation of multi-functional biological new drug candidates that could potentially benefit patients globally.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“95% CI”	95% confidence interval, a commonly used concept in biostatistics, meaning in approximately 95 out of 100 times, the interval will contain the true mean value
“BC”	breast cancer
“Board”	the board of Directors of our Company
“China”	the People’s Republic of China
“DCR”	disease control rate
“Director(s)”	the directors of our Company
“DoR”	duration of response
“ECOG PS”	ECOG Scale of Performance Status, one standard criteria describing a patient’s level of functioning in terms of their ability to care for themselves, daily activity and physical ability (walking, working, etc.). ECOG PS 0 means the patient is fully active, able to carry on all pre-disease performance without restriction. ECOG PS 1 means the patient is restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work

“HER2”	human epidermal growth factor receptor 2
“IHC”	Immunohistochemistry, which tests whether or not the cancer cells have HER2 receptors and/or hormone receptors on their surface
“ORR”	objective response rate
“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“RP2D”	recommended phase II dose
“T-DM1”	an antibody–drug conjugate incorporating HER2-targeted antitumor properties of trastuzumab with the cytotoxic activity of the microtubule-inhibitory agent DM1
“TRAE(s)”	treatment-related adverse event(s)
“%”	per cent

Cautionary Statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that it will be able to develop, or ultimately market, JSKN003 and KN026 successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
Alphamab Oncology
Dr. XU Ting
Chairman and Executive Director

Hong Kong, November 16, 2023

As of the date of this announcement, the Board comprises Dr. XU Ting as the chairman and executive Director and Ms. LIU Yang as executive Director, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.