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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)

**VOLUNTARY ANNOUNCEMENT
ABSTRACTS ON PRELIMINARY RESULTS FROM CLINICAL TRIALS OF
KN035 ACCEPTED FOR POSTER PRESENTATION AT
2020 ASCO ANNUAL MEETING**

This announcement is made by Alphamab Oncology (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

The board of directors of the Company (the “**Board**”) announces that abstracts on clinical trial results of (i) KN035, a recombinant humanized single domain antibody against PD-L1, in patients with advanced tumors with mismatch-repair deficiency and (ii) a combination therapy with KN035 plus chemotherapy for advanced GC/GEJ cancer have been accepted for poster presentation at the upcoming 2020 American Society of Clinical Oncology (the “**ASCO**”) Annual Meeting. The poster presentation material will be available on the Company’s website at www.alphamabonc.com on May 29, 2020.

**PRELIMINARY RESULTS OF KN035 IN ADVANCED TUMORS WITH
MISMATCH-REPAIR DEFICIENCY**

- As of December 17, 2019, 103 patients with MSI-H/dMMR advanced cancers were enrolled at 25 centers in China. The PEPi included 39 patients with CRC and 11 patients with GC, with a median follow-up of 7.5 months. The overall population included 65 patients with CRC (24 patients had prior therapy with fluoropyrimidine (F) and oxaliplatin (O) or irinotecan (I)), 18 patients with GC, and 20 patients with other tumors, with a median follow-up of 6.7 months.
- The confirmed objective response rate was 30% (95% CI: 17.9%, 44.6%) in the PEPi, 54.2% (95% CI: 32.8%, 74.4%) in the CRC patients who had prior therapy with F and O or I, and 34.0% (95% CI: 24.9%, 44.0%) in the overall population.

- Amongst the patients who had an objective response at the interim analysis, 80% of those in the PEPi, 84.6% of CRC patients who had prior therapy with F and O or I, and 85.7% of those in the overall population were still responding at the time of data cutoff.
- Median PFS was 6.6 months in both the PEPi and the overall population. Median overall survival was not reached in either population. 14 patients (13.6%) had grade 3-4 TRAEs. No grade 5 TRAEs, pneumonitis, or colitis were reported. Local injection-site reactions, all grade 1 or 2, were reported in 9 patients.

Conclusions: KN035 demonstrated durable anti-tumor activity with a manageable safety profile in patients with previously treated advanced MSI-H/dMMR cancer.

PRELIMINARY RESULTS OF KN035 PLUS CHEMOTHERAPY IN ADVANCED GC/GEJ CANCER

- A total of 15 subjects were treated and evaluable for response. ECOG performance status was 1 in 80% of subjects. Majority had GC (86.7%). At the time of data cutoff, the minimum follow-up was 6 months.
- The TEAE occurrence was 100% for all grades and 73.3% for grades 3-4. The most frequent grades 3-4 TEAE included neutrophil count decrease (46.7%), anemia (20.0%), and platelet disorder (20.0%).
- Confirmed ORR was 60% (unconfirmed ORR: 73.3%).
- Median DOR was not reached. Median PFS was 6.8 months.

Conclusion: KN035 plus FOLFOX demonstrated a manageable safety profile with promising clinical efficacy as a first line therapy for advanced GC/GEJ cancer.

ABOUT KN035

KN035 is a recombinant single domain antibody against PD-L1 fused with human Fc, a drug independently invented by the Company and co-developed with 3D Medicines (Beijing) Co., Ltd. (思路迪(北京)医药科技有限公司) since 2016. It is likely to become the first PD-1/PD-L1 antibody with subcutaneous injection to be marketed globally. KN035 has undergone clinical trials for multiple tumor indications in China, the United States and Japan, with a total of more than 900 patients enrolled. Currently, phase II pivotal clinical trial for advanced solid tumors with MSI-H/dMMR and phase III pivotal clinical trial for advanced biliary tract cancer (BTC) are being conducted in China. On January 18, 2020, the U.S. Food and Drug Administration (FDA) rewarded KN035 with orphan drug designation in treating advanced BTC. TRACON Pharmaceuticals, Inc. (the shares of which are listed on the Nasdaq Global Select Market (Ticker Symbol: TCON)) was granted the exclusive and nontransferable license in the United States, Canada, Mexico and each of their dependent territories for KN035 in the field of human therapeutic applications for sarcoma.

ABOUT THE COMPANY

The Company is a leading clinical-stage biopharmaceutical company in China with a fully-integrated proprietary biologics platform in bispecific and protein engineering. Differentiated in-house pipeline of the Company consists of eight oncology drug candidates, including four in the phase I-III clinical trial development 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 bio-macromolecule 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
“CRC”	colorectal cancer, a cancer of the colon or rectum, located at the digestive tract’s lower end
“dMMR”	deficient mismatch repair, the ability of a cell in correcting mistakes made when DNA is copied in a cell. Mismatch repair deficient cells usually have many DNA mutations, which may lead to cancer
“DOR”	duration of response, the length of time between the initial response to therapy and subsequent disease progression or relapse
“ECOG”	Eastern Cooperative Oncology Group
“FOLFOX”	a combination of chemotherapy drugs used to treat bowel cancer and GC, consisting of oxaliplatin, leucovorin and 5-FU (Fluorouracil)
“GC”	gastric cancer
“GC/GEJ”	gastric/gastroesophageal junction
“MSI-H”	microsatellite instability-high, a feature of cancer’s genetic coding with a high amount of instability in a tumor
“ORR”	objective response rate, which is equal to the sum of complete response and partial response

“PD-L1”	programmed death ligand 1, a protein on the surface of a normal cell or a cancer cell that can attach to programmed cell death protein 1 (PD-1) on the surface of the T-cell that causes the T-cell to turn off its ability to kill the cancer cell
“PEP”	primary efficacy population including patients with CRC who failed fluoropyrimidine (F), oxaliplatin (O), and irinotecan (I) plus those with advanced GC who had failed at least one prior systemic treatment
“PEPi”	primary efficacy population for interim analysis, patients in the PEP who had at least two post-baseline tumor assessments
“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“TEAE”	treatment emergent adverse events, adverse events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment. The association between TEAE and the therapeutic agent or intervention received may not be necessary
“TRAEs”	treatment-related adverse events

Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that it will be able to develop, or ultimately market, KN035 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, May 15, 2020

As at the date of this announcement, the Board comprises Dr. XU Ting as the Chairman and Executive Director and Ms. LIU Yang as Executive Director, Mr. XU Zhan Kevin and Mr. QIU Yu Min as Non-executive Directors, and Dr. JIANG Hualiang, Mr. WEI Kevin Cheng and Mr. WU Dong as Independent Non-executive Directors.