Akeso, Inc.
康方生物科技(開曼)有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 9926)

VOLUNTARY ANNOUNCEMENT

PFS HR 0.51, MPFS 11.14 MONTHS IVONESCIMAB MONOTHERAPY VS PEMBROLIZUMAB AS 1L TREATMENT OF PD-L1 POSITIVE NSCLC (AK112-303/HARMORNI-2) PHASE III RESULTS PUBLISHED AT 2024 WCLC

This announcement is made by Akeso, Inc. (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**") is pleased to announce that the results of AK112-303/HARMONi-2 (CTR20222137) were published at the Presidential Symposium of IASLC 2024 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer (IASLC). The results of this trial were presented in an oral presentation by the principal investigator of this trial, Professor ZHOU Caicun, Chief Physician and Director of the Department of Medical Oncology at Shanghai Pulmonary Hospital, Tongji University School of Medicine, and President-Elect of IASLC.

AK112-303/HARMONi-2 (CTR20222137) is a China-based randomized, double-blind, registrational Phase III clinical trial to evaluate 依達方® (ivonescimab, PD-1/VEGF) versus pembrolizumab as first-line monotherapy for locally advanced or metastatic NSCLC patients with PD-L1 positive (PD-L1 TPS≥1%) with primary endpoint of PFS by blind IRRC per RECIST v1.1, and secondary endpoints of OS, ORR, DoR, safety and etc. 398 participants were enrolled in this trial. The results of this interim analysis showed:

Ivonescimab demonstrated statistically significant improvement and clinically meaningful benefit.

- Among ITT population, ivonescimab demonstrated a statistically significant improvement in PFS when compared to pembrolizumab, achieving HR of 0.51 (95% CI: 0.38, 0.69; p<0.0001). The mPFS of ivonescimab group was 11.14 months, and the mPFS of pembrolizumab group was 5.82 months. Ivonescimab showed clinically meaningful benefits over pembrolizumab by 5.3 months improvement in mPFS.

Ivonescimab demonstrated clinically meaningful PFS benefit across clinical subgroups, consistent with the ITT population.

- PD-L1 TPS≥50% PFS HR 0.46 (95% CI: 0.28, 0.75)
- PD-L1 TPS 1–49% PFS HR 0.54 (95% CI: 0.37, 0.79)
- Squamous histology PFS HR 0.48 (95% CI: 0.31, 0.74)
- Non-squamous histology PFS HR 0.54 (95% CI: 0.36, 0.82)
- Liver metastases presence/absence PFS HR 0.47/0.53
- Brain metastases presence/absence PFS HR 0.55/0.53

Ivonescimab group demonstrated higher ORR and DCR.

- Ivonescimab ORR 50.0% versus pembrolizumab ORR 38.5%
- Ivonescimab DCR 89.9% versus pembrolizumab DCR 70.5%

OS data was not yet mature at the time of the data cut-off and will be evaluated in the future.

Ivonescimab demonstrated acceptable and manageable safety profile, which was consistent with previous studies.

- Ivonescimab exhibited similar immune-related AEs (irAEs) to that of pembrolizumab.
- All VEGF-related AEs were grade 1–3 in both arms, ivonescimab did not significantly increase bleeding compared to control group.
- HRQoL with ivonescimab was comparable to that with pembrolizumab.

Based on the results of HARMONi-2, our partner SUMMIT announced its intention to initiate HARMONi-7, which is currently planned as a multi-regional Phase III clinical trial that will compare ivonescimab monotherapy to pembrolizumab monotherapy in metastatic NSCLC patients whose tumors have high PD-L1 expression (PD-L1 TPS > 50%).

Ivonescimab is the world's first and only drug to show superior efficacy compared with pembrolizumab as monotherapy in a Phase III head-to-head setting. In August 2024, the National Medical Products Administration ("**NMPA**") of China has accepted the supplemental New Drug Application of ivonescimab for this indication. Ivonescimab is expected to bring a better first-line "chemo-free" treatment therapy to PD-L1 positive advanced NSCLC patients, and potentially become a new standard of care in the treatment of NSCLC.

DEFINITIONS

ITT	Intent-to-treat
NSCLC	Non-small cell lung cancer
IRRC	Independent radiologic review committee
RECIST	Response evaluation criteria in solid tumors
PFS	Progression-free-survival
mPFS	Median progression-free-survival
HR	Hazard ratio
CI	Confidence interval
ORR	Objective response rate
DoR	Duration of response
DCR	Disease control rate
OS	Overall survival
irAE	Immune-related adverse events
AE	Adverse events
HRQoL	Health-related quality of life
SUMMIT	Summit Therapeutics Inc., a company incorporated under the law of the State of Delaware, the United States, and whose shares are listed on Nasdaq (NASDAQ: SMMT)

ABOUT依達方® (IVONESCIMAB, PD-1/VEGF)

依達方® (ivonescimab) is a novel global first-in-class PD-1/VEGF bi-specific immuno-therapy drug independently developed by the Company. On May 24, 2024, 依達方® was granted marketing approval by NMPA for the treatment of EGFR mutated locally advanced or metastatic non-squamous NSCLC patients who have progressed after EGFR TKI treatment. Currently, ivonescimab's first indication has been approved in China, and the Company is conducting 8 Phase III trials including 2 global MRCTs and 6 Phase III trials versus PD-(L)1. The Company is also conducting more than 25 clinical trials of ivonescimab covering 17 indications including gastrointestinal cancer, hepatocellular carcinoma and colorectal cancer.

By order of the Board
Akeso, Inc.
Dr. XIA Yu
Chairwoman and executive director

Hong Kong, September 9, 2024

As at the date of this announcement, the Board comprises Dr. XIA Yu as chairwoman and executive director, Dr. LI Baiyong, Dr. WANG Zhongmin Maxwell and Dr. ZHANG Peng as executive directors, Mr. XIE Ronggang as non-executive director, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.