BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Alphamab starts phase I clinical trial in Australia

October 11, 2018 | News

Alphamab has developed in house the next-generation immune-oncology program KN046, a bi-specific antibody targeting both PD-L1 and CTLA-4. KN046 is engineered to target the tumor micro-environment with reduced side effects on human peripheral systems.



Alphamab Oncology has announced that its proprietary humanized PD-L1 - CTLA-4 bispecific antibody program, the first of its class, has recently started phase I clinical trial in Australia. The antibody has also obtained the IND approval from the National Medical Products Administration (NMPA) in China and will enter clinical trials in the country as well.

The successful development of antibody drugs against immune checkpoints marked a major breakthrough in the history of anti-cancer research. The 2018 Nobel Prize in Physiology/Medicine was awarded to two scientists who have made outstanding contributions to the research in CTLA-4 and PD-(L)1, as of now, the only two clinically-validated immune-oncology checkpoint targets. However, only a small portion of patients benefit from approved products. The combination of CTLA-4 and PD-(L)1 antibodies has enhanced the efficacy, but the regimen has been limited by increased side effects.

Alphamab has developed in house the next-generation immune-oncology program KN046, a bispecific antibody targeting both PD-L1 and CTLA-4. KN046 is engineered to target the tumor microenvironment with reduced side effects on human peripheral systems. In preclinical studies, KN046 has demonstrated excellent anti-tumor efficacy, and its toxicity is significantly reduced compared with the existing CTLA-4 antibody Yervoy (ipilimumab). The ongoing clinical trial has also shown its good tolerability in humans.

"KN046, the world's first PD-L1 - CTLA-4 bispecific therapeutics, is positioned as the backbone of the second generation of tumor immunotherapy," said Dr. Ting Xu, Chairman of the Board and CEO of Alphamab Oncology. "We are pleased to see that the phase I clinical trial of KN046 in Australia is progressing well and has achieved the anticipated therapeutic dose. We expect the overall clinical profile of KN046 to be superior to monotherapy with the PD-(L)1 or CTLA-4 antibody, as well as to the combination of the two antibody drugs."

"Based on KN046's unique mechanism of action, excellent preclinical and CMC profile, the Drug Evaluation Center at NMPA approved the IND application for KN046 within 3 months," added Xu. "We are very grateful to the NMPA for its recognition and support. We have been in discussion with leading international oncologists about global development plan for KN046. We plan to kick off its clinical development for multiple indications simultaneously in the near future, and rapidly advance the

KN046 program, with the aim of benefiting cancer patients around the world."